# 1NC

## 1

#### 1] Interpretation – Affs must defend a reduction in intellectual property protections that protect the medicines.

#### Medicines are physical substances.

American Heritage Dictionary of Medicine 18 The American Heritage Dictionary of Medicine 2018 by Houghton Mifflin Harcourt Publishing Company <https://www.yourdictionary.com/medicine> //Elmer

"A **substance**, **especially a drug**, **used to treat** the signs and symptoms of a **disease**, condition, or injury."

#### For means “intended to” – the object of the IP Protection must be Medicines.

Cambridge Dictionary No Date "For" <https://dictionary.cambridge.org/us/dictionary/english/for> //Elmer

**intended to be given to:**

#### 2] Violation - Data exclusivity protects clinical trial data, NOT MEDICINE. The plan doesn’t affect the actual production of Medical Substances, just the structural factors that influence it.

Thrasher 5-25 Rachel Thrasher 5-25-2021 "Chart of the Week: How Data Exclusivity Laws Impact Drug Prices" <https://www.bu.edu/gdp/2021/05/25/chart-of-the-week-how-data-exclusivity-laws-impact-drug-prices/> //sid

Data exclusivity is a form of intellectual property protection that appliesspecifically to data from pharmaceutical clinical trials. While innovator firms run their own clinical trials to gain marketing approval, generic manufacturers typically rely on the innovator’s clinical trials for the same approval. Data exclusivity rules keep generic firms from relying on that data for 5 to 12 years, depending on the specific law. Data exclusivity operates independently of patent protection and can block generic manufacturers from gaining marketing approval even if the patent has expired or the original pharmaceutical product does not qualify for patent protection. Although data exclusivity laws are matters of domestic legislation, the United States, the EU and others increasingly demand in their free trade agreement (FTA) negotiations that their trading partners protect clinical trial data in this way. Data exclusivity is just one of a host of “TRIPS-plus” treaty provisions designed to raise the overall level of intellectual property protection for innovator firms. Although the WTO’s Agreement on Trade-Related Intellectual Property Rights (TRIPS) does require Member states to protect clinical trial and other data from “unfair commercial use,” it does not require exclusivity rules that block the registration of generic products.

#### The Aff is both Effects and Extra-T because they effect things unrelated to Medical IP like Data – both of which are voters for Limits and Ground.

#### 3] The Standard is Limits – allowing Affs that relate to the factors and structures surrounding Medicines allows treatments, drug discovery techniques, computer programs, and production techniques that all have IP protections to be topical which eviscerate a stable locus of predictability.

#### Fairness and education are voters – its how judges evaluate rounds and why schools fund debate

#### Neg theory is DTD - 1ARs control the direction of the debate because it determines what the 2NR has to go for – DTD allows us some leeway in the round by having some control in the direction

#### Competing interps – Reasonability invites arbitrary judge intervention and a race to the bottom of questionable argumentation – it also collapses since brightlines operate on an offense-defense paradigm

#### No RVIs – A – Going all in on theory kills substance education which outweighs on timeframe B - Discourages checking real abuse which outweighs on norm-setting C – Encourages theory baiting – outweighs because if the shell is frivolous, they can beat it quickly D – its illogical for you to win for proving you were fair – outweighs since logic is a litmus test for other arguments E - Kills norm setting since debaters can never admit they’re wrong – outweighs since norm setting is the constitutive purpose of theory F – They are the logic of criminalization that over-punish people-of-color for trying to create productive discourse

## 2

#### A. Interpretation: If the affirmative defends anything other than whole res then they must provide a counter-solvency advocate for their specific advocacy in the 1AC. *(To clarify, you must have an author that states we should not do your aff, insofar as the aff is not a whole res phil aff)*

#### B. Violation:

#### C. Standards:

#### 1. Fairness – This is a litmus test to determining whether your aff is fair –

#### a) Limits – there are infinite things you could defend outside the exact text of the resolution which pushes you to the limits of contestable arguments, even if your interp of the topic is better, the only way to verify if it’s substantively fair is proof of counter-arguments. Nobody knows your aff better than you, so if you can’t find an answer, I can’t be expected to. Our interp narrows out trivially true advocacies since counter-solvency advocates ensure equal division of ground for both sides.

#### b) Shiftiness-Having a counter-solvency advocate helps us conceptualize what their advocacy is and how it’s implemented. Intentionally ambiguous affirmatives we don’t know much about can’t spike out of DA’s and CP’s if they have an advocate that delineates these things.

#### 2. Research – Forces the aff to go to the other side of the library and contest their own view points, as well as encouraging in depth-research about their own position. Having one also encourages more in-depth answers since I can find responses. Key to education since we definitionally learn more about positions when we contest our own.

## 3

#### Reconciliation passes now – the delay gives Biden time to work magic in the wings, but PC and focus are key

Herb et al. 10-1 (Jeremy Herb, CNN Politics Reporter, Kevin Liptak, Reporter, Phil Mattingly, Senior White House Correspondent, Lauren Fox, CNN Congressional Correspondent, Melanie Zanona, Capitol Hill Reporter, “'It doesn't matter when': How Biden gave feuding House Democrats an off-ramp”, CNN Politics, 10-1-21, <https://www.cnn.com/2021/10/01/politics/dems-biden-infrastructure-delay/index.html)//babcii>

(CNN)President Joe Biden didn't [travel to Capitol Hill on Friday](https://www.cnn.com/2021/10/01/politics/house-vote-infrastructure-democrats/index.html) to close the deal, or to rally the troops through a final legislative gantlet. There was nothing cinematic -- or dramatic -- about the trip down Pennsylvania Avenue for the 36-year Senate veteran, who has more than once informed aides of [his unparalleled ability](http://www.cnn.com/2021/09/27/politics/biden-agenda-congress-deal-maker/index.html) to read, speak to and corral lawmakers. Instead, in remarks that lasted less than 30 minutes, Biden served a singular purpose: a presidential pressure relief valve. In a week deemed an "inflection point" by top aides, where the President was rarely seen in public as his entire domestic agenda hung in the balance, it marked a seemingly low bar to clear for success. There would be no miraculous deal to unlock the formula to move forward on the two key components Democrats are attempting to pass. The promised vote on the [$1.2 trillion infrastructure bill](https://www.cnn.com/politics/live-news/congress-infrastructure-bill-vote-10-01-21/index.html) would not materialize. But after days of intraparty warfare and feverish late-night negotiations, a reset was desperately needed -- and the best Biden could offer. In delivering an unscripted and at times unwieldy message that the infrastructure vote wasn't likely to happen -- and the top-line cost of the economic and climate package was going to have to come down -- the President made the bet that he can keep both sides of the intraparty feud on board in the critical days and weeks to follow. **White House and Democratic leaders will now launch an all-out effort to win** over the two Senate Democratic holdouts, Sens. [Joe Manchin of West Virginia](https://www.cnn.com/2021/09/30/politics/joe-manchin-budget-bill-1-5-trillion-schumer/index.html) and [Kyrsten Sinema of Arizona](https://www.cnn.com/2021/09/30/politics/kyrsten-sinema-arizona-reaction/index.html), as they shape what the multitrillion-dollar economic and social package looks like -- and how high its price tag will be. Congressional Democrats and White House officials say progress was made this week getting all sides closer to an agreement on the massive economic, climate and health care spending package that Democratic leaders intend to pair with the bipartisan $1.2 trillion infrastructure bill that's passed the Senate already. But in the House, moderate and progressive Democrats were engaged in a **slow-motion game of chicken** over the infrastructure vote, with moderates demanding a vote on the infrastructure bill this week that had been pledged by House Speaker Nancy Pelosi -- and [progressives standing firm that they would vote it down](https://www.cnn.com/2021/09/30/politics/house-infrastructure-negotiations-vote/index.html) without an agreement on the framework for the larger economic package. On Friday, Biden sought the off-ramp. It marked his most direct effort to date to cajole the House Democratic caucus at a moment when its members have grown increasingly frustrated about the amount of attention the President and his team have paid to their side of the Capitol. Though well received with several ovations, the appearance didn't serve to salve those wounds entirely -- with some saying afterward that his pep talk had actually exacerbated them. But it did deliver a critical message and a consequential moment, multiple members said: Compromise now -- or end up with nothing. It's likely too soon to say whether the debate this week is just a preamble to Democrats' enacting their historic agenda or if it's a feud that leads to legislative defeat, hobbling the President's party ahead of a tough midterm election cycle with little to show for controlling both chambers of Congress and the White House. 'Who knows what label I get' After the roughly half hour meeting with the President, Democrats described a leader who was in his element and not working to change minds as much as remind members of their shared and unified goals as a caucus. Throughout the infrastructure push, Biden has made clear to Democrats that party unity -- or, in some participants' interpretation, loyalty -- is of utmost importance with only the slimmest of majorities in the House and Senate. He tried to break down the stalemate and the tensions that have hung over the party for weeks, reminding them that he's not on one side or the other. At one point, he made a reference to his own political ideology, saying, "Who knows what label I get." To which Pelosi replied: "President," prompting loud laughter from the room. Biden also talked about how he had redone his office to have paintings hung of Lincoln and FDR -- "A deeply divided country and the biggest economic transformation," said Rep. David Cicilline of Rhode Island, "which is kind of the moment we're in." White House officials think the President accomplished what he went to do on Capitol Hill: Remind Democrats of what is at stake while relieving some of the pressure that had built up over the last several days and reiterating his commitment to passing both pieces of legislation. With that done, officials believe, negotiators have a better environment to be able to push toward a deal. "We're going to get this done," Biden told reporters as he left the meeting. "It doesn't matter when. It doesn't, whether it's in six minutes, six days or six weeks -- we're going to get it done." 'As long as we're still alive' Even before Friday, Biden had alluded in recent days to negotiations slipping beyond the week's end. With the stakes simply too high -- on both the political and policy fronts -- there are no plans to walk away. "It may not be by the end of the week," the President had responded when asked Monday how he would define success at the end of this week. "I hope it's by the end of the week." "But as long as we're still alive ...," Biden said before shifting course in his thought.

#### Attacks on Pharmaceutical Profits triggers Mod Dem Backlash – it disrupts unity.

Cohen 9-6 Joshua Cohen 9-6-2021 "Democrats’ Plans To Introduce Prescription Drug Pricing Reform Face Formidable Obstacles" <https://www.forbes.com/sites/joshuacohen/2021/09/06/democrats-plans-to-introduce-prescription-drug-pricing-reform-face-obstacles/?sh=37a269917395> (independent healthcare analyst with over 22 years of experience analyzing healthcare and pharmaceuticals.)//Elmer

There’s considerable uncertainty regarding passage with a simple majority of the 2021 massive budget reconciliation bill. Last week, Senator Joe Manchin called on Democrats to pause pushing forward the budget reconciliation bill. If Manchin winds up saying no to the bill, this would scuttle it as the Democrats can’t afford to lose a single Senator. And, there’s speculation that provisions to reduce prescription drug prices may be watered down and not incorporate international price referencing. Additionally, reduced prices derived through Medicare negotiation may not be able to be applied to those with employer-based coverage. While the progressive wing of the Democratic Party supports drug pricing reform, **several key centrist Democrats** in both the House and Senate appear to be **uncomfortable** **with** particular aspects of the budget reconciliation bill, including a potential deal-breaker, namely the potential **negative impact of drug price controls on the domestic pharmaceutical industry**, as well as long-term patient access to new drugs. A paper released in 2019 by the nonpartisan Congressional Budget Office found that the proposed legislation, H.R. 3, would reduce global revenue for new drugs by 19%, leading to 8 fewer drugs approved in the U.S. between 2020 and 2029, and 30 fewer drugs over the next decade. And, a new report from the CBO reinforces the message that drug pricing legislation under consideration in Congress could lead to fewer new drugs being developed and launched. **Intense lobbying efforts from biopharmaceutical industry groups** **are underway**, **warning of** what they deem are **harms from price controls in** the form of diminished patient **access to new innovations**. The argument, based in part on assumptions and modeling included in the CBO reports, asserts that price controls would dampen investment critical to the biopharmaceutical industry’s pipeline of drugs and biologics. **This** won’t sway most Democrats, but has been a traditional talking point in the Republican Party for decades, and **may convince some centrist Democrats to withdraw backing** of provisions **that** in their eyes **stymie pharmaceutical innovation.** If the budget reconciliation bill would fail to garner a majority, a pared down version of H.R. 3, or perhaps a new bill altogether, with Senator Wyden spearheading the effort, could eventually land in the Senate. But, a similar set of provisos would apply, as majority support in both chambers would be far from a sure thing. In brief, Democrats’ plans at both the executive and legislative branch levels to introduce prescription **drug pricing reform** **encounter challenges** which may prevent impactful modifications from taking place.

#### Sinema specifically jumps Ship.

Hancock and Lucas 20 Jay Hancock and Elizabeth Lucas 5-29-2020 "A Senator From Arizona Emerges As A Pharma Favorite" <https://khn.org/news/a-senator-from-arizona-emerges-as-a-pharma-favorite/> (Senior Correspondent, joined KHN in 2012 from The Baltimore Sun, where he wrote a column on business and finance. Previously he covered the State Department and the economics beat for The Sun and health care for The Virginian-Pilot of Norfolk and the Daily Press of Newport News. He has a bachelor’s degree from Colgate University and a master’s in journalism from Northwestern University.)//Elmer

Sen. Kyrsten **Sinema formed** a **congressional caucus to raise** “**awareness of the benefits of personalized medicine**” in February. Soon after that, employees of **pharmaceutical companies** **donated** $35,000 to her campaign committee. Amgen gave $5,000. So did Genentech and Merck. Sanofi, Pfizer and Eli Lilly all gave $2,500. Each of those companies has invested heavily in personalized medicine, which promises individually tailored drugs that can cost a patient hundreds of thousands of dollars. **Sinema** is a first-term Democrat from Arizona but has nonetheless **emerged as a pharma favorite in Congress** as the industry steers through a new political and economic landscape formed by the coronavirus. She is a **leading recipient of pharma campaign cash** even though she’s not up for reelection until 2024 and lacks major committee or subcommittee leadership posts. For the 2019-20 election cycle through March, political action committees run by employees of drug companies and their trade groups gave her $98,500 in campaign funds, Kaiser Health News’ Pharma Cash to Congress database shows. That stands out in a Congress in which a third of the members got no pharma cash for the period and half of those who did got $10,000 or less. The contributions give companies a chance to cultivate Sinema as she restocks from a brutal 2018 election victory that cost nearly $25 million. Altogether, pharma PACs have so far given $9.2 million to congressional campaign chests in this cycle, compared with $9.4 million at this point in the 2017-18 period, a sustained surge as the industry has responded to complaints about soaring prices. Sinema’s pharma haul was twice that of Sen. Susan Collins of Maine, considered one of the most vulnerable Republicans in November, and approached that of fellow Democrat Steny Hoyer, the powerful House majority leader from Maryland. It all adds up to **a bet by drug companies that** the 43-year-old **Sinema**, first elected to the Senate in 2018, **will** gain influence in coming years and **serve as an industry ally** in a party that also includes many lawmakers harshly critical of high drug prices and the companies that set them.

#### Pharma backlash independently turns Case.

Huetteman 19 Emmarie Huetteman 2-26-2019 “Senators Who Led Pharma-Friendly Patent Reform Also Prime Targets For Pharma Cash” <https://khn.org/news/senators-who-led-pharma-friendly-patent-reform-also-prime-targets-for-pharma-cash/> (former NYT Congressional correspondent with an MA in public affairs reporting from Northwestern University’s Medill School)//Elmer

Early last year, as lawmakers vowed to curb rising drug prices, Sen. Thom Tillis was named chairman of the Senate Judiciary Committee’s subcommittee on intellectual property rights, a committee that had not met since 2007. As the new gatekeeper for laws and oversight of the nation’s patent system, the North Carolina Republican signaled he was determined to make it easier for American businesses to benefit from it — a welcome message to the drugmakers who already leverage patents to block competitors and keep prices high. Less than three weeks after introducing a bill that would make it harder for generic drugmakers to compete with patent-holding drugmakers, Tillis opened the subcommittee’s first meeting on Feb. 26, 2019, with his own vow. “From the United States Patent and Trademark Office to the State Department’s Office of Intellectual Property Enforcement, no department or bureau is too big or too small for this subcommittee to take interest,” he said. “And we will.” In the months that followed, tens of thousands of dollars flowed from pharmaceutical companies toward his campaign, as well as to the campaigns of other subcommittee members — including some who promised to stop drugmakers from playing money-making games with the patent system, like Sen. John Cornyn (R-Texas). Tillis received more than $156,000 from political action committees tied to drug manufacturers in 2019, more than any other member of Congress, a new analysis of KHN’s Pharma Cash to Congress database shows. Sen. Chris Coons (D-Del.), the top Democrat on the subcommittee who worked side by side with Tillis, received more than $124,000 in drugmaker contributions last year, making him the No. 3 recipient in Congress. No. 2 was Sen. Mitch McConnell (R-Ky.), who took in about $139,000. As the Senate majority leader, he controls what legislation gets voted on by the Senate. Neither Tillis nor Coons sits on the Senate committees that introduced legislation last year to lower drug prices through methods like capping price increases to the rate of inflation. Of the four senators who drafted those bills, none received more than $76,000 from drug manufacturers in 2019. Tillis and Coons spent much of last year working on significant legislation that would expand the range of items eligible to be patented — a change that some experts say would make it easier for companies developing medical tests and treatments to own things that aren’t traditionally inventions, like genetic code. They have not yet officially introduced a bill. As obscure as patents might seem in an era of public **outrage** **over** drug prices, the fact that **drugmakers** gave most **to** the **lawmakers working to change the patent system** belies how important securing **the exclusive right to market a drug, and keep competitors at bay, is to their bottom line**. “**Pharma will fight to the death to preserve patent rights**,” said Robin Feldman, a professor at the UC Hastings College of the Law in San Francisco who is an expert in intellectual property rights and drug pricing. “Strong patent rights are central to the games drug companies play to extend their monopolies and keep prices high.” Campaign contributions, closely tracked by the Federal Election Commission, are among the few windows into how much money flows from the political groups of drugmakers and other companies to the lawmakers and their campaigns. Private companies generally give money to members of Congress to encourage them to listen to the companies, typically through lobbyists, whose activities are difficult to track. They may also communicate through so-called dark money groups, which are not required to report who gives them money. Over the past 10 years, the **pharmaceutical industry** has **spent** about $**233 million per year on lobbying**, according to a new study published in JAMA Internal Medicine. That is more than any other industry, including the oil and gas industry. Why Patents Matter Developing and testing a new drug, and gaining approval from the Food and Drug Administration, can take years and cost hundreds of millions of dollars. Drugmakers are generally granted a six- or seven-year exclusivity period to recoup their investments. But drugmakers have found ways to extend that period of exclusivity, sometimes accumulating hundreds of patents on the same drug and blocking competition for decades. One method is to patent many inventions beyond a drug’s active ingredient, such as patenting the injection device that administers the drug. Keeping that arrangement intact, or expanding what can be patented, is where lawmakers come in. Lawmakers Dig In Tillis’ home state of North Carolina is also home to three major research universities and, not coincidentally, multiple drugmakers’ headquarters, factories and other facilities. From his swearing-in in 2015 to the end of 2018, Tillis received about $160,000 from drugmakers based there or beyond. He almost matched that four-year total in 2019 alone, in the midst of a difficult reelection campaign to be decided this fall. He has raised nearly $10 million for his campaign, with lobbyists among his biggest contributors, according to OpenSecrets. Daniel Keylin, a spokesperson for Tillis, said Tillis and Coons, the subcommittee’s top Democrat, are working to overhaul the country’s “antiquated intellectual property laws.” Keylin said the bipartisan effort protects the development and access to affordable, lifesaving medication for patients,” adding: “No contribution has any impact on how [Tillis] votes or legislates.” Tillis signaled his openness to the drug industry early on. The day before being named chairman, he reintroduced a bill that would limit the options generic drugmakers have to challenge allegedly invalid patents, effectively helping brand-name drugmakers protect their monopolies. Former Sen. Orrin Hatch (R-Utah), whose warm relationship with the drug industry was well-known, had introduced the legislation, the Hatch-Waxman Integrity Act, just days before his retirement in 2018. At his subcommittee’s first hearing, Tillis said the members would rely on testimony from private businesses to guide them. He promised to hold hearings on patent eligibility standards and “reforms to the Patent Trial and Appeal Board.” In practice, the Hatch-Waxman Integrity Act would require generics makers challenging another drugmaker’s patent to either take their claim to the Patent Trial and Appeal Board, which acts as a sort of cheaper, faster quality check to catch bad patents, or file a lawsuit. A study released last year found that, since Congress created the Patent Trial and Appeal Board in 2011, it has narrowed or overturned about 51% of the drugmaker patents that generics makers have challenged. Feldman said the drug industry “went berserk” over the number of patents the board changed and has been eager to limit use of the board as much as possible. Patent reviewers are often stretched thin and sometimes make mistakes, said Aaron Kesselheim, a Harvard Medical School professor who is an expert in intellectual property rights and drug development. Limiting the ways to challenge patents, as Tillis’ bill would, does not strengthen the patent system, he said. “You want overlapping oversight for a system that is as important and fundamental as this system is,” he said. As promised, Tillis and Coons also spent much of the year working on so-called Section 101 reform regarding what is eligible to be patented — “a very major change” that “would overturn more than a century of Supreme Court law,” Feldman said. Sean Coit, Coons’ spokesperson, said lowering drug prices is one of the senator’s top priorities and pointed to Coon’s support for legislation the pharmaceutical industry opposes. “One of the reasons Senator Coons is leading efforts in Congress to fix our broken patent system is so that life-saving medicines can actually be developed and produced at affordable prices for every American,” Coit wrote in an email, adding that “his work on Section 101 reform has brought together advocates from across the spectrum, including academics and health experts.” In August, when much of Capitol Hill had emptied for summer recess, Tillis and Coons held closed-door meetings to preview their legislation to stakeholders, including the Pharmaceutical Research and Manufacturers of America, or PhRMA, the brand-name drug industry’s lobbying group. “We regularly engage with members of Congress in both parties to advance practical policy solutions that will lower medicine costs for patients,” said Holly Campbell, a PhRMA spokesperson. Neither proposal has received a public hearing. In the 30 days before Tillis and Coons were named leaders of the revived subcommittee, drug manufacturers gave them $21,000 from their political action committees. In the 30 days following that first hearing, Tillis and Coons received $60,000. Among their donors were PhRMA; the Biotechnology Innovation Organization, the biotech lobbying group; and five of the seven drugmakers whose executives — as Tillis laid out a pharma-friendly agenda for his new subcommittee — were getting chewed out by senators in a different hearing room over patent abuse. Cornyn Goes After Patent Abuse Richard Gonzalez, chief executive of AbbVie Inc., the company known for its top-selling drug, Humira, had spent the morning sitting stone-faced before the Senate Finance Committee as, one after another, senators excoriated him and six other executives of brand-name drug manufacturers over how they price their products. Cornyn brought up AbbVie’s more than 130 patents on Humira. Hadn’t the company blocked its competition? Cornyn asked Gonzalez, who carefully explained how AbbVie’s lawsuit against a generics competitor and subsequent licensing deal was not what he would describe as anti-competitive behavior. “I realize it may not be popular,” Gonzalez said. “But I think it is a reasonable balance.” A minute later, Cornyn turned to Sen. Chuck Grassley (R-Iowa), who, like Cornyn, was also a member of the revived intellectual property subcommittee. This is worth looking into with “our Judiciary Committee authorities as well,” Cornyn said, effectively threatening legislation on patent abuse. The next day, Mylan, one of the largest producers of generic drugs, gave Cornyn $5,000, FEC records show. The company had not donated to Cornyn in years. By midsummer, every drug company that sent an executive to that hearing had given money to Cornyn, including AbbVie. Cornyn, who faces perhaps the most difficult reelection fight of his career this fall, ranks No. 6 among members of Congress in drugmaker PAC contributions last year, KHN’s analysis shows. He received about $104,000. Cornyn has received about $708,500 from drugmakers since 2007, KHN’s database shows. According to OpenSecrets, he has raised more than $17 million for this year’s reelection campaign. Cornyn’s office declined to comment. On May 9, Cornyn and Sen. Richard Blumenthal (D-Conn.) introduced the **Affordable Prescriptions for Patients Act,** which proposed to define two tactics used by drug companies to make it easier for the Federal Trade Commission to **prosecute** them: “**product-hopping**,” when drugmakers withdraw older versions of their drugs from the market to push patients toward newer, more expensive ones, and “**patent-thicketing**,” when drugmakers amass a series of patents to drag out their exclusivity and slow rival generics makers, who must challenge those patents to enter the market once the initial exclusivity ends. **PhRMA opposed the bill.** **The next day, it gave Cornyn $1,000**. Cornyn and Blumenthal’s bill would have been “very tough on the techniques that pharmaceutical companies use to extend patent protections and to keep prices high,” Feldman said. “The **pharmaceutical industry lobbied tooth and nail against it**,” she said. “And **when the bill finally came** out of committee, the strongest provisions — the **patent-thicketing provisions — had been stripped**.” In the months after the bill cleared committee and waited to be taken up by the Senate, Cornyn blamed Senate Democrats for blocking the bill while trying to secure votes on legislation with more direct controls on drug prices. The Senate has not voted on the bill.

#### Infrastructure reform solves Existential Climate Change – it results in spill-over.

USA Today 7-20 7-20-2021 "Climate change is at 'code red' status for the planet, and inaction is no longer an option" <https://www.usatoday.com/story/opinion/todaysdebate/2021/07/20/climate-change-biden-infrastructure-bill-good-start/7877118002/> //Elmer

**Not long ago**, **climate change** for many Americans **was** like **a distant bell**. News of starving polar bears or melting glaciers was tragic and disturbing, but other worldly. Not any more. **Top climate scientists** from around the world **warned of a "code red for humanity**" in a report issued Monday that says severe, human-caused global warming is become unassailable. Proof of the findings by the United Nations' Intergovernmental Panel on Climate Change is a now a factor of daily life. Due to **intense heat waves and drought**, 107 wildfires – including the largest ever in California – are now raging across the West, consuming 2.3 million acres. Earlier this summer, hundreds of people died in unprecedented triple-digit heat in Oregon, Washington and western Canada, when a "heat dome" of enormous proportions settled over the region for days. Some victims brought by stretcher into crowded hospital wards had body temperatures so high, their nervous systems had shut down. People collapsed trying to make their way to cooling shelters. Heat-trapping greenhouse gases Scientists say the event was almost **certainly made worse and more intransigent by human-caused climate change**. They attribute it to a combination of warming Arctic temperatures and a growing accumulation of heat-trapping greenhouse gases caused by the burning of fossil fuels. The **consequences of** what mankind has done to the atmo**sphere are now inescapable**. Periods of **extreme heat** are projected to **double** in the lower 48 states by 2100. **Heat deaths** are far **outpacing every other form of weather killer** in a 30-year average. A **persistent megadrought** in America's West continues to create tinder-dry conditions that augur another devastating wildfire season. And scientists say **warming oceans** are **fueling** ever **more powerful storms**, evidenced by Elsa and the early arrival of hurricane season this year. Increasingly severe weather is causing an estimated $100 billion in damage to the United States every year. "It is honestly surreal to see your projections manifesting themselves in real time, with all the suffering that accompanies them. It is heartbreaking," said climate scientist Katharine Hayhoe. **Rising seas** from global warming Investigators are still trying to determine what led to the collapse of a Miami-area condominium that left more than 100 dead or missing. But one concerning factor is the corrosive effect on reinforced steel structures of encroaching saltwater, made worse in Florida by a foot of rising seas from global warming since the 1900s. The clock is ticking for planet Earth. While the U.N. report concludes some level of severe climate change is now unavoidable, there is still a window of time when far more catastrophic events can be mitigated. But mankind must act soon to curb the release of heat-trapping gases. Global **temperature** has **risen** nearly **2 degrees** Fahrenheit since the pre-industrial era of the late 19th century. Scientists warn that in a decade, it could surpass a **2.7**-degree increase. That's **enough** warming **to cause catastrophic climate changes**. After a brief decline in global greenhouse gas emissions during the pandemic, pollution is on the rise. Years that could have been devoted to addressing the crisis were wasted during a feckless period of inaction by the Trump administration. Congress must act Joe Biden won the presidency promising broad new policies to cut America's greenhouse gas emissions. But Congress needs to act on those ideas this year. Democrats cannot risk losing narrow control of one or both chambers of Congress in the 2022 elections to a Republican Party too long resistant to meaningful action on the climate. So what's at issue? A trillion dollar **infrastructure bill** negotiated between Biden and a group of centrist senators (including 10 Republicans) is a start. In addition to repairing bridges, roads and rails, it would **improve access** by the nation's power infrastructure **to renewable energy sources,** **cap millions of abandoned oil and gas wells spewing greenhouse gases**, **and harden structures against climate change**. It also **offers tax credits for** the **purchase of electric vehicles** and funds the construction of charging stations. (**The nation's largest source of climate pollution are gas-powered vehicles**.) Senate approval could come very soon. Much **more is needed** if the nation is going to reach Biden's necessary goal of cutting U.S. climate pollution in half from 2005 levels by 2030. His ideas worth considering include a federal clean electricity standard for utilities, federal investments and tax credits to promote renewable energy, and tens of billions of dollars in clean energy research and development, including into ways of extracting greenhouse gases from the skies. Another idea worth considering is a fully refundable carbon tax. **The vehicle** for these additional proposals **would be a second infrastructure bill**. And if Republicans balk at the cost of such vital investment, Biden is rightly proposing to pass this package through a process known as budget reconciliation, which allows bills to clear the Senate with a simple majority vote. These are drastic legislative steps. But drastic times call for them. And when Biden attends a U.N. climate conference in November, he can use American progress on climate change as a mean of persuading others to follow our lead. Further delay is not an option.

## 4

### Framework

#### The meta-ethic is procedural moral realism.

#### This entails that moral facts stem from procedures while substantive realism holds that moral truths exist independently of that in the empirical world. Prefer procedural realism –

#### [1] Collapses – the only way to verify whether something is a moral fact is by using procedures to warrant it.

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

#### [3] Is/Ought Gap – we can only perceive what is, not what ought to be. It’s impossible to derive an ought statement from descriptive facts about the world, necessitating a priori premises.

#### Regress – I can keep asking “why should I follow this” which results in skep since obligations are predicated on ignorantly accepting rules. Only reason solves since asking “why reason?” requires reason which is self-justified.

#### That means we must universally will maxims— any non-universalizable norm justifies someone’s ability to impede on your ends.

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

#### Prefer –

#### [1] Performativity—freedom is the key to the process of justification of arguments. Willing that we should abide by their ethical theory presupposes that we own ourselves in the first place.

#### [2] All other frameworks collapse—non-Kantian theories source obligations in extrinsically good objects, but that presupposes the goodness of the rational will.

#### [3] Necessity—my framework is inherent to the way we set ends. Ethics must be necessary and not contingent since otherwise its claims could be escapable. Necessary truths outweigh on probability—if a necessary truth is possible that means it’s true in a possible world, but that implies it’s true in all worlds since that’s what necessity is, so they have to prove there’s 0 risk of my framework.

### Offense

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

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

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

## 5

#### NC theory first - 1] They started the chain of abuse and forced me down this strategy 2] We have more speeches to norm over it 3] It was introduced first so it comes lexically prior.

#### Neg abuse outweighs Aff abuse – 1] Infinite prep time before round to frontline 2] 2AR judge psychology 3] 1st and last speech 4] Infinite perms and uplayering in the 1AR.

#### Reasonability on 1AR shells – 1AR theory is very aff-biased because the 2AR gets to line-by-line every 2NR standard with new answers that never get responded to

#### DTA on 1AR shells - They can blow up blippy 20 second shells in the 2AR but I have to split my time and can’t preempt 2AR spin which necessitates judge intervention

#### RVIs on 1AR theory – 1AR being able to spend 20 seconds on a shell and still win forces the 2N to allocate at least 2:30 on the shell which means RVIs check back time skew

#### No new 1ar theory paradigm issues- A] New 1ar paradigms moot any 1NC theoretical offense B] introducing them in the aff allows for them to be more rigorously tested

## Case

### Framework

#### Consequentialism is incoherent:

#### 1. Induction fails. Induction assumes that things will always happen the same way in the future as they have in the past. But this begs the question of how we know what happened in the past will happen in the future. Thus, induction is logically fallacious.

#### On AOD

#### 1. Doesn't justify util. Simply means you have to account for tradeoffs when making a decision which is not unique to util i.e deont can weigh between imperfect and perfect duties, Aristotle weighs between virtues.

#### 2. Impact justified, doesn’t warrant why the state legitimacy is necessary for obligations, rather just says state would be illegitimate if it didn't account for tradeoffs.

#### On Bostrom

#### Begs the question of uncertainty- I’ll destroy you on the framework debate so there don’t be uncertainty

#### Definitionally the fallacy of origin—just because life is a prerequisite for anything doesn’t mean that it comes first.

### Advantage

#### Data exclusivity is key to prevent freerider production of new biologics which is necessary for innovation.

Gangil, J, et al 10. “Do Intellectual Property Rights and Data Exclusivity Encourage Innovation in the Pharmaceutical World?” Systematic Reviews in Pharmacy, vol. 1, no. 2, 22 Dec. 2010, p. 190., doi:10.4103/0975-8453.75088. //sid

The purpose of data exclusivity is to ensure that the initial registrants of a new drug can recover the costs of testing the drug for efficacy and safety. Extensive testing directly translates into considerable costs for generating the data necessary to obtain approval of each new active ingredient. Drug developers challenge that they cannot afford to bring drugs to market without data exclusivity because later registrants, who did not have to invest in the high cost of obtaining marketing approval, can free-ride on the initial registrant’s approval and sell the same or similar drug at a lower price.[7] Experts argue that data exclusivity offers benefits to domestic innovators in developing countries and, in particular, that it provides incentives for research to identify new uses for the existing unpatented product. Data exclusivity is likely to have the largest effect in countries where for historical or other reasons there are many products with no current patent protection that may gain rights to exclusivity. Today in many developing countries, there are numerous medicines that are not patented. This is often the case in developing countries where TRIPS-based laws have only recently been introduced. In addition, even where there are patent laws, companies may not have considered the market sufficiently valuable to justify the expense and administrative cost of securing patents. In that case, the introduction of data exclusivity laws may bring into exclusivity drugs that would otherwise be open to generic competition. The perceived absence of strong patent protection in India, even after the law was revised in 2005, and the presence of a large number of products without patent protection due to the absence of product patent protection before 2005, is a major reason why the international pharmaceutical industry lobbied very hard for a strong data exclusivity regime in India. In contrast, Indian companies focusing principally on generics argued for a weaker data protection regime.[8] In certain cases it is observed that “data exclusivity” helps innovator companies to recover investments made on discovering and developing a new drug; for example, according to a published article, Aventis’s innovative drug Leflunomide for rheumatoid arthritis took 17 years from discovery to commercialization.[9] Data Exclusivity Plays a Key Role for Biologics New Economics Research supports 13–16 years of data exclusivity for biologics. A new working paper by Duke University economist Dr. Henry Grabowski, “Data Exclusivity for New Biological Entities,” identifies 12.9–16.2 years or about 13–16 years of data exclusivity as necessary to sustain investment in the research and development (R and D) of new biologics in any approach to creating an abbreviated pathway for follow-on biologics (FOBs). The Duke University working paper states that without sufficient data exclusivity, there would be little incentive to develop and market new biologics with uncertain or few remaining years of patent protection. Under this scenario, innovators would be less likely to pursue the development of a molecule if there were uncertainty regarding the possibility of recouping their investments and achieving a positive return.[10]

#### Data exclusivity ­does not prevent competitive products.

GaBi Online 11 “Data Exclusivity Is Not the Same as Market Exclusivity.” GaBi Online, 26 Jan. 2011, www.gabionline.net/policies-legislation/Data-exclusivity-is-not-the-same-as-market-exclusivity. //sid

Furthermore, Mr Quinn states that it is fiction that 12 years of data exclusivity would extend innovators’ monopoly power. “Data exclusivity does not give it any sort of monopoly”, he writes. “You would be hard pressed to find a term that is used more and understood less than the term ‘monopoly’. “Patents don’t give monopolies, and neither would data exclusivity. If patents gave monopolies then how is it possible that anyone other than Apple could sell a portable MP3 player? Apple has the iPod and iPhone locked up tight, but not so tight that other companies are prohibited from selling similar products. Look at all the iPhone wanna-bes that are on the market now. Seriously! You have to stop thinking that patents grant monopolies. What they do is make it difficult for others to copy an innovation, but if you can make something that does the same thing that isn’t a copy, then patent law does not prevent that”. He explains that similarly, products that compete with innovative biologicals can still be introduced during the period of data exclusivity. A period of data exclusivity merely means that those who do not innovate cannot piggyback off the hard work of innovators and rely on the research conducted by the innovator company. They must conduct their own safety and efficacy research and testing to obtain FDA approval and, obviously, not infringe the patents owned by the innovator. “So can we please stop using the world ‘monopoly’? No matter how many times it is used it will never accurately describe the protections provided. If you doubt that do a patent search and you will see in every industry numerous patents that all purport to cover similar things. How else, for example, could Microsoft and Apple both have patent portfolios? How else could Motorola and Nokia have patent portfolios? How else could AMD and IBM have patent portfolios? And so on” Mr Quinn states. (see also [Minimal 12 years of biologicals data exclusivity required](http://www.gabionline.net/Biosimilars/News/Minimal-12-years-of-biologicals-data-exclusivity-required), [12 years exclusivity workable for patients; not anticompetitive](http://www.gabionline.net/Generics/General/12-years-exclusivity-workable-for-patients-not-anticompetitive) and [Innovative biologicals development must be preserved](http://www.gabionline.net/Pharma-News/Innovative-biologicals-development-must-be-preserved))

#### Alt Causes to lack of generics thump Aff solvency to zero – pay-for-delay, citizen petitions, authorized generics, and testing sample access – this is terminal since they’d just shift tactics to non-patent strategies.

Fox 17, Erin. "How pharma companies game the system to keep drugs expensive." Harvard Business Review (April 6, 2017), https://hbr. org/2017/04/how-pharma-companies-game-the-system-to-keep-drugs-expensive (last visited on November 22, 2019) (2017). (director of Drug Information at University of Utah Health)//Elmer

The ways companies stop generics One of the ways branded drug manufacturers prevent competition is simple: cash. In so-called “pay for delay” agreements, a brand drug company simply pays a generic company not to launch a version of a drug. The Federal Trade Commission estimates these pacts cost U.S. consumers and taxpayers $3.5 billion in higher drug costs each year. “Citizen petitions” offer drug companies another way to delay generics from being approved. These ask the Food and Drug Administration to delay action on a pending generic drug application. By law, the FDA is required to prioritize these petitions. However, the citizens filing concerns are not individuals, they’re corporations. The FDA recently said branded drug manufacturers submitted 92% of all citizen petitions. Many of these petitions are filed near the date of patent expiration, effectively limiting potential competition for another 150 days. “Authorized generics” are another tactic to limit competition. These aren’t really generic products at all; they are the same product sold under a generic name by the company that sells the branded drug. Why? By law, the first generic company to market a drug gets an exclusivity period of 180 days. During this time, no other companies can market a generic product. But the company with the expiring patent is not barred from launching an “authorized generic.” By selling a drug they’re already making under a different name, pharmaceutical firms are effectively extending their monopoly for another six months. Another way pharmaceutical firms are thwarting generics is by restricting access to samples for testing. Generic drug makers need to be able to purchase a sample of a brand-name product to conduct bioequivalence testing. That’s because they have to prove they can make a bioequivalent product following the current good manufacturing practices (CGMP) standard. These manufacturers don’t need to conduct clinical trials like the original drug company did. But the original drug developer often declines to sell drug samples to generics manufacturers by citing “FDA requirements,” by which they mean the agency’s Risk Evaluation and Mitigation Strategies program. The idea behind this program is a good one: give access to patients who will benefit from these personalized medicines, and bar access for patients who won’t benefit and could be seriously harmed. However, brand drug makers are citing these requirements for the sole purpose of keeping generics from coming to market.

#### Petitions to the FDA swamp and deter generics.

Feldman 17 Robin Feldman 6-16-2017 "Pharma companies fight behind-the-scenes wars over generic drugs" <https://www.statnews.com/2017/06/16/generic-drugs-biosimilars-pharma/> (Arthur J. Goldberg Distinguished Professor of Law and Director of the Center for Innovation.)//Elmer

One tactic that my colleague Evan Frondorf and I describe in our book, “Drug Wars: How Big Pharma Raises Prices and Keeps Generics Off the Market,” involves petitions to the Food and Drug Administration asking that the agency not give the green light to generic versions of a drug. Our research on 12 years of FDA data shows that in some years nearly 1 out of every 5 petitions filed on any topic — including food, tobacco, dietary supplements, and devices — was related to delaying generic entry. The FDA denies 80 percent of these petitions, but the process takes time, even for silly petitions, such as one asking the FDA to declare that a generic must provide information that the regulations already require. The time it takes to respond to these petitions delays the entry of the generic.