# 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.

#### 4] Paradigm Issues –

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

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

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

# 2

#### 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.

# 3

#### Text – States ought to individually domestically establish single-payer national health insurance.

#### Solves evergreening and drug prices while avoiding our innovation turns.

Narayanan 19 Srivats Narayanan 8-15-2019 "Medicare for All and Evergreening" <https://medium.com/@srivats.narayanan/medicare-for-all-and-evergreening-cb84c930e0ea> (UMKC School of Medicine)//Elmer

Drug companies rake in massive profits. The pharmaceutical industry has some of the largest profit margins among American industries. Unfortunately, pharmaceutical giants don’t always have patients’ best interests in mind — they make a big portion of their money by exploiting the patent process instead of making breakthrough drugs that would meaningfully improve patients’ lives. Pharmaceutical corporations aren’t as innovative as one might expect. Although the Food and Drug Administration (FDA) has been consistently approving new (and expensive) drugs every year, most of these drugs aren’t impacting healthcare much. Many studies have revealed that a whopping 85–90% of new drugs since the mid-1990s “provide few or no clinical advantages.” This is because pharmaceutical firms are spending their time and money on a technique known as “evergreening.” Evergreening is when drug companies produce redundant drugs that are nothing but minor modifications of old drugs. By making slight alterations to their medicines, biotech companies continue to hold patents for drugs with minimal spending on research and development (R&D). Pharmaceutical companies then use those patents to prevent competitors from selling generic versions of their drugs. Without any competition, these corporations get away with ridiculously high drug pricing and can thus make big profits on their drugs. The companies simultaneously justify their absurd drug prices by pointing to the inflated R&D costs of producing new drugs. This excuse has been used time and again by the profit-hungry pharmaceutical industry, and it’s coming at the expense of patients who struggle to afford their medicines. A well-known example of evergreening pertains to the anticonvulsant medication gabapentin, which was first sold by Pfizer under the brand name Neurontin. When the drug became available as a generic medication over a decade ago, Pfizer created a very similar medicine, pregabalin (Lyrica), that didn’t have any significant benefits over the original drug. As a result, Pfizer has kept a control over the market for anticonvulsant drugs with negligible innovation. The drug industry’s reliance on evergreening is undoubtedly stifling innovation. This is where **Medicare for All**, **which would impose the government as the only health insurer**, **would be useful**. **In our current system**, **there are many insurers** **and they each have** **little market power** **and** consequently **little negotiating power** **to reduce** treatment **prices**. **Since the government would have** **consolidated control over healthcare financing** under Medicare for All, **its stronger bargaining power would force drug companies to charge lower prices for their products**. In addition, prescription drugs would be paid for by the government and not by patients under Medicare for All. **Medicare for All would prevent evergreening**. **National healthcare financing** **would align** **how much the government pays a drug company with how much patients benefit** from the company’s drugs. **If a new drug had more clinical benefits** than an older version, **the government would pay more** for it. If a new drug produced the same results as an older version, the government wouldn’t pay more for the new drug. So, Medicare for All would **encourage** pharmaceutical **companies to pursue truly innovative drugs because such drugs would be more profitable**. The policy would incentivize companies to invest in R&D for more useful drugs, instead of just producing redundant and expensive medications. A national healthcare plan would prioritize “patient and community needs” and match up pharmaceutical companies’ interests with actually improving public health. Evergreening has become the name of the game for the pharmaceutical industry. A major solution to the evergreening problem is Medicare for All. **A single-payer system** like Medicare for All **would sharply curtail evergreening**, since drug companies wouldn’t be able to profit from it. Medicare for All would **usher** in **a new era of medical innovation**.

# 4

#### Counterplan Text – Member states of the World Trade Organization ought to consult the World Health Organization on whether or not to [do the Plan]. The World Health Organization ought to publicly declare that their decision on [the Plan] will represent their future decisions on all intellectual property protections on medicines.

#### The Plan’s unilateral action by the WTO on medical IP undermines WHO legitimacy – forcing a perception of WHO action against Patents is key to re-assert it – they say yes.

Rimmer 4, Matthew. "The race to patent the SARS virus: the TRIPS agreement and access to essential medicines." Melbourne Journal of International Law 5.2 (2004): 335-374.

<https://law.unimelb.edu.au/__data/assets/pdf_file/0007/1681117/Rimmer.pdf> (BA (Hons), LLB (Hons) (Australian National University), PhD (New South Wales); Lecturer at ACIPA, the Faculty of Law, The Australian National University)//SidK + Elmer

The WHO has been instrumental in coordinating the international network of research on the SARS virus. It has emphasised the need for collaboration between the network participants. The WHO presented the containment of the SARS virus as ‘one of the biggest success stories in public health in recent years’.206 However, it **was less active in the debate over patent law** and public health epidemics. The 56th World Health Assembly considered the relationship between intellectual property, innovation and public health. It stressed that in order to tackle new public health problems with international impact, such as the emergence of severe acute respiratory syndrome (SARS), access to new medicines with potential therapeutic effect, and health innovations and discoveries should be universally available without discrimination.207 However, there was much disagreement amongst the member states as to what measures would be appropriate. The WHO has made a number of aspirational statements about patent law and access to essential medicines. Arguably, though, the organisation could be a much more informed and vocal advocate. Initially, the WHO did not view the patent issues related to SARS as being within its field of activities. The agency didnoteven seem aware of the patent proceedings, leaving individual research institutions without guidance. Spokesman Dick Thompson said: ‘What we care about is [that] the international collaboration continues to function. Patents, they don’t really concern us’.208 The director of WHO’s Global Influenza project, Klaus Stöhr, expressed his opinion that the patent filings would not interfere with the international cooperation on the SARS research: ‘I don’t think this will undermine the collaborative spirit of the network of labs’.209 However, he believed that, after the international network of researchers had identified the coronavirus, it was necessary to rely upon companies to commercialise such research. Klaus Stöhr conceded: ‘At a certain point of time you have to give way for competitive pharmaceutical companies’.210 On a policy front, the WHO remained deferential to the WTO over the debate over patent law and access to essential medicines, observing: Owing to the inconclusive nature of the studies conducted to date, and because of the effect that potentially significant price increases could have on access to drugs in poor countries, WHO is currently monitoring and evaluating the effects of TRIPS on the prices of medicines. It is also monitoring the TRIPS impact on other important issues such as transfer of technology, levels of research and development for drugs for neglected diseases, and the evolution of generic drug markets.211 In such a statement, the WHO appears diffident, unwilling to take on more than a spectator role. Such a position is arguably too timid, given the gravity of national emergencies, such as the SARS virus. The organisation could take a much stronger stance on the impact of the **TRIPS** Agreement on public health concerns. The WHO has since enunciated a position statement on the patenting of the SARS virus. A number of high ranking officials from the organisation have commented on the need to ensure that international research into the SARS virus is not impeded by competition over patents. Arguably though, the WHO **should not be limited to a mere spectator role in such policy discussions. It** needstoplay an active advocacy role in the debate over patent law and access to essential medicines. The WHO released a position statement on ‘Patent Applications for the SARS Virus and Genes’ on 29 May 2003.212 The organisation stressed that it had no per se objection to the patenting of the SARS virus: Some people have objected to the SARS patent applications on the ground that the virus and its genes should not be patentable because they are mere discoveries, not inventions. This distinction no longer prevents the granting of patents; the novel claim rests not with the virus itself but with its isolation, and likewise with the identification of the genetic sequence not its mere occurrence. Many patents have been issued on viruses and genetic sequences, though the appropriate policies to follow in such cases — particularly as genomic sequencing becomes more routine and less ‘inventive’ — remain matters of dispute.213 Furthermore, it recognised that public institutions could legitimately use patents as a defensive means to prevent undue commercial exploitation of the research: The “defensive” use of patents can be a legitimate part of researchers’ efforts to make their discoveries (and further discoveries derived therefrom) widely available to other researchers, in the best collaborative traditions of biomedical science.214 The WHO affirmed the need for further cooperation between research organisations in respect of the SARS virus: ‘For continued progress against SARS, it is essential that we nurture the spirit of the unprecedented, global collaboration that rapidly discovered the novel virus and sequenced its genome’.215 The WHO announced its intention to monitor the effects of patents (and patent applications) on the speed with which SARS diagnostic tests, treatments, and vaccines are developed and made available for use, and on the manner in which prices are set for these technologies. It observed: In the longer term, the manner in which SARS patent rights are pursued could have a profound effect on the willingness of researchers and public health officials to collaborate regarding future outbreaks of new infectious diseases. WHO will therefore examine whether the terms of reference for such collaborations need to be modified to ensure that the credit for any intellectual property developed is appropriately attributed, that revenues derived from licensing such property are devoted to suitable uses, and that legitimate rewards for innovative efforts do not impose undue burdens on efforts to make tests, therapies, and preventive measure available to all.216 It maintained that in order to tackle new public health problems with international impact, such as the emergence of severe acute respiratory syndrome (SARS), access to new medicines with potential therapeutic effect, and health innovations and discoveries should be universally available without discrimination.219 The Assembly requested that the Director-General continue to support Member States in the exchange and transfer of technology and research findings, according high priority to access to antiretroviral drugs to combat HIV/AIDS and medicines to control tuberculosis, malaria and other major health problems, in the context of paragraph 7 of the Doha Declaration which promotes and encourages technology transfer.220 The WHO also considered a report on the emergence of the SARS virus and the international response to the infectious disease.221 It was ‘deeply concerned that SARS ... poses a serious threat to global health security, the livelihood of populations, the functioning of health systems, and the stability and growth of economies’.222 The Committee on Infectious Diseases requested that the Director-General ‘mobilize global scientific research to improve understanding of the disease and to develop control tools such as diagnostic tests, drugs and vaccines that are accessible to and affordable by Member States’.223 The Director-General of the WHO, Dr Gro Harlem Brundtland, **told the World Health** Assembly that there was a need to build trust and forge solidarity in the face of public health epidemics: ‘**Ensuring that patent regimes stimulate research and do not hinder international scientific cooperation** is a critical challenge — whether the target is SARS or any other threat to human health’.224 Similarly, Dr Marie-Paule Kieny, Director of the WHO Initiative for Vaccine Research, said: If we are to develop a SARS vaccine more quickly than usual, we have to continue to work together on many fronts at once, on scientific research, intellectual property and patents issues, and accessibility. It is a very complicated process, involving an unprecedented level of international cooperation, which is changing the way we work.225 She emphasised that patents and intellectual property issues and their safeguards can help rather than hinder the rapid development of SARS vaccines and ensure that, once developed, they are available in both industrialised and developing countries.226 C Summary The WHO should play a much more active role in the policy debate over patent law and access to essential medicines. James Love, the director of the Consumer Project on Technology, run by Ralph Nader, is critical of the WHO statement on ‘Intellectual Property Rights, Innovation, and Public Health’.227 He maintains that the Assembly could have addressed ‘practical examples, like SARS’ and cites the report in The Washington Post that notes that a number of commercial companies are investing in SARS research.228 The non-government organisation Médecins Sans Frontières has been critical in the past of the passive role played by the WHO in the debate over access to essential medicines: ‘As the world’s leading health agency, and armed with the clear mandate of recent World Health Assembly resolutions, the WHO can and should **do much more’**.229 The WHO should become a vocal advocate for public health concerns at the WTO and its TRIPS Council — especially in relation to patent law and the SARS virus. It must staunchly defend the rights of member states to incorporate measures in their legislation that protect access to medicines — such as compulsory licensing, parallel imports, and measures to accelerate the introduction of generic pharmaceutical drugs. It needs to develop a clearer vision on global equity pricing for essential medicines. The race to patent the SARS virus seems to be an inefficient means of allocating resources. A number of public research organisations — including the BCCA, the CDC and HKU — were compelled to file patents in respect of the genetic coding of the SARS virus. Such measures were promoted as ‘defensive patenting’ — a means to ensure that public research and communication were not jeopardised by commercial parties seeking exclusive private control. However, there are important drawbacks to such a strategy. The filing of patents by public research organisations may be prohibitively expensive. It will also be difficult to resolve the competing claims between the various parties — especially given that they were involved in an international research network together. Seth Shulman argues that there is a need for international cooperation and communication in dealing with public health emergencies such as the SARS virus: The success of a global research network in identifying the pathogen is an example of the huge payoff that can result when researchers put aside visions of patents and glory for their individual laboratories and let their work behave more like, well, a virus. After all, the hallmark of an opportunistic virus like the one that causes SARS is its ability to spread quickly. Those mounting a response need to disseminate their information and innovation just as rapidly.230 There is a danger that such competition for patent rights may undermine trust and cooperation within the research network. Hopefully, however, such concerns could be resolved through patent pooling or joint ownership of patents. Furthermore, a number of commercial companies have filed patent applications in respect of research and development into the SARS virus. There will be a need for cooperation between the public and private sectors in developing genetic tests, vaccines, and pharmaceutical drugs that deal with the SARS virus. There is also a need to reform the patent system to deal with international collaborative research networks — such as that created to combat the SARS virus. Several proposals have been put forward. There has been a renewed debate over whether patents should be granted in respect of genes and gene sequences. Some commentators have maintained that the SARS virus should fall within the scope of patentable subject matter — to promote research and development in the field. However, a number of critics of genetic technology have argued that the SARS virus should not be patentable because it is a discovery of nature, and a commercialisation of life. There has been a discussion over the lack of harmonisation over the criteria of novelty and inventive step between patent regimes. As Peter Yu comments, ‘[w]hile [the] US system awards patents to those who are the first to invent, the European system awards patents to those who are the first to file an application’.231 There have been calls for the requirement of utility to be raised. There have also been concerns about prior art, secret use and public disclosure. Representative Lamar Smith of Texas has put forward the CREATE Act, which recognises the collaborative nature of research across multiple institutions. Such reforms are intended to ensure that the patent system is better adapted to deal with the global nature of scientific inquiry. The race to patent the SARS virus also raises important questions about international treaties dealing with access to essential medicines. The public health epidemic raises similar issues to other infectious diseases — such as AIDS, malaria, tuberculosis, influenza, and so forth. The WHO made a public statement about its position on the patenting of the SARS virus. It has stated that it will continue to monitor developments in this field. Arguably, there is a need for the WHO to play a larger role in the debate over patent law and access to essential medicines. Not only could it mediate legal disputes over patents in respect of essential medicines, it could be a vocal advocate in policy discussions. The WTO has also played an important role in the debate over patent law and access to essential medicines. A number of public interest measures could be utilised to secure access to patents relating to the SARS virus including compulsory licensing, parallel importation and research exceptions. The appearance of the SARS virus shows that there should be an open-ended interpretation of the scope of diseases covered by the Doha Declaration on the TRIPS Agreement and Public Health. Important lessons should be learned from the emergence of the SARS virus, and the threat posed to global health. As the World Health Report 2003 notes: SARS will not be the last new disease to take advantage of modern global conditions. In the last two decades of the 20th century, new diseases emerged at the rate of one per year, and this trend is certain to continue. Not all of these emerging infections will transmit easily from person to person as does SARS. Some will emerge, cause illness in humans and then disappear, perhaps to recur at some time in the future. Others will emerge, cause human illness and transmit for a few generations, become attenuated, and likewise disappear. And still others will emerge, become endemic, and remain important parts of our human infectious disease ecology.232 Already, in 2004, there have been worries that pharmaceutical drug companies and patent rights are impeding efforts to prevent an outbreak of bird flu — avian influenza.233 There is a need to ensure that the patent system is sufficiently flexible and adaptable to cope with the appearance of new infectious diseases.234

#### WHO Cred key to Global Right to Health – medicine access is critical.

* Note the Bottom Paragraph is at the bottom of the PDF – I put a paragraph break to indicate it as such – no words are missing.

Bluestone 3, Ken. "Strengthening WHO's position should be a priority for the new Director-General." The Lancet 361.9351 (2003): 2. (Senior Policy Adviser, Voluntary Service Overseas (VSO))//Elmer

To meet these challenges, WHO must strengthen its resolve to maintain its **independence and lead its member states**, **even at the risk of causing controversy**. A meaningful example is the role that WHO can have in **ensuring access to medicines** for the world’s poorest people. WHO is the only global institution that has the **remit to drive this agenda forward**, yet has failed to do so convincingly. The new Director-General must support and reinvigorate the advocacy efforts of the organisation and provide a proper counterbalance to the interests of the pharmaceutical industry and wealthy member states. As the new Director-General takes office, they will face the dual challenge of **seeing that** the broadest possible public health interpretation of the World Trade Organization’s Doha Agreement on Trade Related Aspects on Intellectual Property Rights (TRIPS) **is not lost, and** of seizing an opportunity to bring about an international framework for sustainable and predictable tiered pricing of medicines. Without the active intervention of a public health advocate at the level of WHO, there is a risk that both of these initiatives **could founder.** Some people in positions of power still do not have high expectations of WHO or its new Director-General. But for the world’s poorest people, the overwhelming majority of whom live in developing countries, this person’s legacy could literally make the difference between life and death. Ken Bluestone Senior Policy Adviser, Voluntary Service Overseas (VSO)

New leader should re-establish WHO’s credibility The credibility of WHO’s advocacy of the right to health for all has been eroded in recent years. A large reason is WHO’s **failure to challenge the pharmaceutical** industry on access to medicines for people with HIV/AIDS and other diseases. WHO’s collaboration with the industry in the “Accelerated Access” programme on antiretroviral medicines sounds good. In fact, the programme has served as a cover for the organisation’s frequent acceptance of industry arguments for restricting treatment access. To re-establish WHO’s credibility, the new Director-General must lead the organisation to stand consistently with those most deprived of health services. Kenneth Roth, Executive Director, Human Rights Watch.

#### Right to Health solves Nationalist Populism.

Friedman 17 Eric Friedman March 2017 “New WHO Leader Will Need Human Rights to Counter Nationalistic Populism” <https://www.hhrjournal.org/2017/03/new-who-leader-will-need-human-rights-to-counter-populism/> (JD, Project Leader of the Platform for a Framework Convention on Global Health at the O’Neill Institute for National and Global Health Law at the Georgetown University Law Center in Washington, DC)//Elmer

The need for WHO leadership on human rights—and for global leadership on health and human rights beyond WHO—has always been present, yet has become ever more pressing. A reactionary, nationalist populism has been gaining momentum, particularly in the United States and parts of Europe, and some of its most disturbing features, such as xenophobia and disregard for international law and institutions, are surfacing elsewhere. Persisting health challenges—such as immense national and global health inequities, with universal health coverage and the Sustainable Development Goals offering some hope of lessening them—and growing threats such as outbreaks of infectious disease, worsening antimicrobial resistance, and climate change demand the type of leadership that the right to health entails. In this immensely challenging environment, WHO needs to become a 21st century institution that has the gravitas and credibility to carve a path through these obstacles towards global health justice. The next WHO Director-General, to be elected in May, must lead the organization there. The right to health can light the way ahead, with reforms to, and driven by, WHO. These reforms must develop an internal governance that is far more welcoming of civil society, with WHO member states significantly increasing contributions so work on the social determinants of health can expand, and with enhanced transparency and accountability. Furthermore, reforms are needed so that WHO leads on global health equity and human rights, including through national health equity strategies and, above all, the Framework Convention on Global Health (FCGH). The FCGH could help bring the right to health to the next level by capturing core aspects of the right to health, such as: 1) participation and accountability, setting clear standards for people’s participation in health policy-making at all levels, and establishing multi-layered health accountability frameworks with standards to which all nations would be held; 2) equity, including by catalyzing national health equity strategies—which must be developed through broad participation, itself a potentially empowering process—and advancing data disaggregation and more equitable financing; 3) financial resources, with global norms on national and international health financing responsibilities; and 4) respecting and promoting the right to health in all policies, from setting standards on health impact assessments—including participatory processes in developing them, human rights standards, an equity focus, and follow-up processes—to firmly ensuring the primacy of the right to health in other legal regimes that may undermine. From an earlier WHO treaty, the Framework Convention on Tobacco Control, we know the power of international law to significantly advance health, with the transformative power of legally binding global health norms. As a treaty, the FCGH would increase political accountability and accountability through the courts, while helping protect health other treaty-based international regimes, such as trade. It would also be a bold assertion of global solidarity for global justice, as so urgently needed, “demonstrating that the community of nations are indeed stronger together.” One candidate for the WHO Director-General election, David Nabarro, has recognized the value and civil society support that FCGH has already received, and the need to further explore the treaty (mentioned at 1:46:38 mark). A good first step would be establishing a WHO working group on the FCGH, with broad participation, particularly from states, civil society, and representatives of communities most affected by health inequities, along with relevant international agencies. We see signs of resistance of the dangerous nationalist populism, from protests that persist and judicial checks on one of the administration’s vilest acts (an immigration and refugee travel ban, with its effects falling heaviest on Muslims) in the United States to the rejection of the far-right candidate in the elections in the Netherland. Such resistance can prevent some of the worst impacts on the right to health, from discrimination against migrants to cuts to programs vital for health. Meanwhile, let’s construct an edifice for the future of health and human rights, even as we stand against its destruction. WHO, right to health, and FCGH leadership ought to be a core part of that endeavor.

#### Populism is an existential threat.

de Waal 16 Alex de Waal 12-5-2016 “Garrison America and the Threat of Global War” <http://bostonreview.net/war-security-politics-global-justice/alex-de-waal-garrison-america-and-threat-global-war> (Executive Director of the World Peace Foundation at the Fletcher School at Tufts University)//Elmer

Polanyi recounts how economic and financial crisis led to global calamity. Something similar could happen today. In fact we are already in a steady unpicking of the liberal peace that glowed at the turn of the millennium. Since approximately 2008, the historic decline in the number and lethality of wars appears to have been reversed. Today’s wars are not like World War I, with formal declarations of war, clear war zones, rules of engagement, and definite endings. But they are wars nonetheless. What does a world in global, generalized war look like? We have an unwinnable “war on terror” that is metastasizing with every escalation, and which has blurred the boundaries between war and everything else. We have deep states—built on a new oligarchy of generals, spies, and private-sector suppliers—that are strangling liberalism. We have emboldened middle powers (such as Saudi Arabia) and revanchist powers (such as Russia) rearming and taking unilateral military action across borders (Ukraine and Syria). We have massive profiteering from conflicts by the arms industry, as well as through the corruption and organized crime that follow in their wake (Afghanistan). We have impoverishment and starvation through economic warfare, the worst case being Yemen. We have “peacekeeping” forces fighting wars (Somalia). We have regional rivals threatening one another, some with nuclear weapons (India and Pakistan) and others with possibilities of acquiring them (Saudi Arabia and Iran). Above all, today’s generalized war is a conflict of destabilization, with big powers intervening in the domestic politics of others, buying influence in their security establishments, bribing their way to big commercial contracts and thereby corroding respect for government, and manipulating public opinion through the media. Washington, D.C., and Moscow each does this in its own way. Put the pieces together and a global political market of rival plutocracies comes into view. Add virulent reactionary populism to the mix and it resembles a war on democracy. What more might we see? Economic liberalism is a creed of optimism and abundance; reactionary protectionism feeds on pessimistic scarcity. If we see punitive trade wars and national leaders taking preemptive action to secure strategic resources within the walls of their garrison states, then old-fashioned territorial disputes along with accelerated state-commercial grabbing of land and minerals are in prospect. We could see mobilization against immigrants and minorities as a way of enflaming and rewarding a constituency that can police borders, enforce the new political rightness, and even become electoral vigilantes. Liberal multilateralism is a system of seeking common wins through peaceful negotiation; case-by-case power dealing is a zero-sum calculus. We may see regional arms races, nuclear proliferation, and opportunistic power coalitions to exploit the weak. In such a global political marketplace, we would see middle-ranking and junior states rewarded for the toughness of their bargaining, and foreign policy and security strategy delegated to the CEOs of oil companies, defense contractors, bankers, and real estate magnates. The United Nations system appeals to leaders to live up to the highest standards. The fact that they so often conceal their transgressions is the tribute that vice pays to virtue. A cabal of plutocratic populists would revel in the opposite: applauding one another’s readiness to tear up cosmopolitan liberalism and pursue a latter-day mercantilist naked self-interest. Garrison America could opportunistically collude with similarly constituted political-military business regimes in Russia, China, Turkey, and elsewhere for a new realpolitik global concert, redolent of the early nineteenth-century era of the Congress of Vienna, bringing a façade of stability for as long as they collude—and war when they fall out. And there is a danger that, in response to a terrorist outrage or an international political crisis, President Trump will do something stupid, just as Europe’s leaders so unthinkingly strolled into World War I. The multilateral security system is in poor health and may not be able to cope. Underpinning this is a simple truth: the plutocratic populist order is a future that does not work. If illustration were needed of the logic of hiding under the blanket rather than facing difficult realities, look no further than Trump’s readiness to deny climate change. We have been here before, more or less, and from history we can gather important lessons about what we must do now. The importance of defending civility with democratic deliberation, respecting human rights and values, and maintaining a commitment to public goods and the global commons—including the future of the planet—remain evergreen. We need to find our way to a new 1945—and the global political settlement for a tamed and humane capitalism—without having to suffer the catastrophic traumas of trying everything else first.

# Case

#### 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.

#### Generic companies are just incompetent – means even without patents, they wouldn’t be able to produce.

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

Problems with generic drug makers Although makers of a branded drug are using a variety of tactics to create barriers to healthy competition, generic drug companies are often not helping their own case. In 2015, there were 267 recalls of generic drug products—more than one every other day. These recalls are for quality issues such as products not dissolving properly, becoming contaminated, or even being outright counterfeits. A few high-profile recalls have shaken the belief that generic drugs are truly the same. In 2014, the FDA withdrew approval of Budeprion XL 300 — Teva’s generic version of GlaxoSmithKline’s Wellbutrin XL. Testing showed the drug did not properly release its key ingredient, substantiating consumers’ claims that the generic was not equivalent. In addition, concerns about contaminated generic Lipitor caused the FDA to launch a $20 million initiative to test generic products to ensure they are truly therapeutically equivalent. In some cases, patent law also collides with the FDA’s manufacturing rules. For example, the Novartis patent for Diovan expired in 2012. Ranbaxy received exclusivity for 180 days for the first generic product. However, due to poor quality manufacturing, Ranbaxy couldn’t obtain final FDA approval for its generic version. The FDA banned shipments of Ranbaxy products to the United States. Ranbaxy ended up paying a $500 million fine, the largest penalty paid by a generic firm for violations. Due to these protracted problems with the company that had won exclusivity, a generic product did not become available until 2014. The two-year delay cost Medicare and Medicaid at least $900 million. Ranbaxy’s poor-quality manufacturing also delayed other key generic products like Valcyte and Nexium. Ironically, it was Mylan—involved in its own drug pricing scandal over its EpiPen allergy-reaction injector—that filed the first lawsuit to have the FDA strip Ranbaxy of its exclusivity. Mylan made multiple attempts to produce generic products but was overruled in the courts.

#### Otherwise, authorized Generics decimate competition.

Sipkoff 4 Martin Sipkoff 8-4-2004 "Big Pharma uses effective strategies to battle generic competitors" <https://www.drugtopics.com/view/big-pharma-uses-effective-strategies-battle-generic-competitors> (Healthcare Writer)//Elmer

But, according to Cutting Edge, brand-name pharmaceutical companies have begun flanking generics in an inventive way: They enter into manufacturing and distribution agreements with a generic company before a patent is about to expire, attempting to preempt market share. "A typical agreement specifies that the generic company will serve as a distributor of the nonbranded, generic form of the drug, which will continue to be produced in the branded drug company's manufacturing facilities," said Hess. "It's an increasingly popular strategy, often stemming from out-of-court patent lawsuit settlements." A successful flanking strategy can be beneficial to a generic manufacturer because it saves on capital outlay by not having to build or modify manufacturing facilities. "The brand-name pharmaceutical company benefits because the partnership enables it to continue to operate its manufacturing lines and turn a profit, thereby recouping more of its R&D investment in the drug and more of its capital investment in the manufacturing plant," said Hess. Here's an example of effective flanking: Generic drugmaker Apotex launched a version of GlaxoSmithKline's blockbuster drug Paxil in September 2003, threatening to significantly dent GSK's $3.2 billion-a-year bestseller. In response to Apotex's entry into the market, GSK struck a licensing agreement with another generic drugmaker, Par Pharmaceutical, in April 2003. The agreement specifies that GSK will supply Par with generic Paxil, in immediate-release form. The tablets are made by a GSK subsidiary, and Parwhich pays a royalty to GSK on salesdistributes them in the United States. "The royalty payments help GSK capture a small segment of the generic Paxil market, which offsets the losses of its branded Paxil sales following the drug's patent expiration," said Hess. Flanking is very controversial because it virtually derails competition. In fact, some generic manufacturers say it's illegal. It's very similar to what the Generic Pharmaceutical Association and others regard as the illegitimate strategy of "authorized generics." "It's an easy concept to describe," said Robert Reznick, a partner with the national law firm Hughes Hubbard & Reed. He chairs the firm's Pharmaceutical and Healthcare Practice Group and has written about the legality of authorized generics. "An authorized generic is like any other generic in that it is deemed equivalent to a brand-name drug," he said. "But rather than being made by an independent generic drug manufacturer pursuant to an Abbreviated New Drug Application, it is either made by or under a license from the New Drug Application holder itself. It may be marketed by an affiliate of the brand-name manufacturer or by a third party." In a white paper titled "Are Authorized Generics Lawful?" Reznick and his colleagues recently concluded that agreements between brand and generic manufacturers to create authorized generics may be legal under antitrust law, but the issue has yet to be fully settled.

#### The impact—

#### 1] Be extremely skeptical of the brink or uniqueness for this – COVID has happened for nearly two years and we have yet to see a great power conflict.

#### 2] No disease can cause extinction

Adalja 16 [Amesh Adalja is an infectious-disease physician at the University of Pittsburgh. Why Hasn't Disease Wiped out the Human Race? June 17, 2016. https://www.theatlantic.com/health/archive/2016/06/infectious-diseases-extinction/487514/]

But when people ask me if I’m worried about infectious diseases, they’re often not asking about the threat to human lives; they’re asking about the threat to human life. With each outbreak of a headline-grabbing emerging infectious disease comes a fear of extinction itself. The fear envisions a large proportion of humans succumbing to infection, leaving no survivors or so few that the species can’t be sustained.

I’m not afraid of this apocalyptic scenario, but I do understand the impulse. Worry about the end is a quintessentially human trait. Thankfully, so is our resilience.

For most of mankind’s history, infectious diseases were the existential threat to humanity—and for good reason. They were quite successful at killing people: The 6th century’s Plague of Justinian knocked out an estimated 17 percent of the world’s population; the 14th century Black Death decimated a third of Europe; the 1918 influenza pandemic killed 5 percent of the world; malaria is estimated to have killed half of all humans who have ever lived.

Any yet, of course, humanity continued to flourish. Our species’ recent explosion in lifespan is almost exclusively the result of the control of infectious diseases through sanitation, vaccination, and antimicrobial therapies. Only in the modern era, in which many infectious diseases have been tamed in the industrial world, do people have the luxury of death from cancer, heart disease, or stroke in the 8th decade of life. Childhoods are free from watching siblings and friends die from outbreaks of typhoid, scarlet fever, smallpox, measles, and the like.

So what would it take for a disease to wipe out humanity now?

In Michael Crichton’s The Andromeda Strain, the canonical book in the disease-outbreak genre, an alien microbe threatens the human race with extinction, and humanity’s best minds are marshaled to combat the enemy organism. Fortunately, outside of fiction, there’s no reason to expect alien pathogens to wage war on the human race any time soon, and my analysis suggests that any real-life domestic microbe reaching an extinction level of threat probably is just as unlikely.

Any apocalyptic pathogen would need to possess a very special combination of two attributes. First, it would have to be so unfamiliar that no existing therapy or vaccine could be applied to it. Second, it would need to have a high and surreptitious transmissibility before symptoms occur. The first is essential because any microbe from a known class of pathogens would, by definition, have family members that could serve as models for containment and countermeasures. The second would allow the hypothetical disease to spread without being detected by even the most astute clinicians.

The three infectious diseases most likely to be considered extinction-level threats in the world today—influenza, HIV, and Ebola—don’t meet these two requirements. Influenza, for instance, despite its well-established ability to kill on a large scale, its contagiousness, and its unrivaled ability to shift and drift away from our vaccines, is still what I would call a “known unknown.” While there are many mysteries about how new flu strains emerge, from at least the time of Hippocrates, humans have been attuned to its risk. And in the modern era, a full-fledged industry of influenza preparedness exists, with effective vaccine strategies and antiviral therapies.

HIV, which has killed 39 million people over several decades, is similarly limited due to several factors. Most importantly, HIV’s dependency on blood and body fluid for transmission (similar to Ebola) requires intimate human-to-human contact, which limits contagion. Highly potent antiviral therapy allows most people to live normally with the disease, and a substantial group of the population has genetic mutations that render them impervious to infection in the first place. Lastly, simple prevention strategies such as needle exchange for injection drug users and barrier contraceptives—when available—can curtail transmission risk.

Ebola, for many of the same reasons as HIV as well as several others, also falls short of the mark. This is especially due to the fact that it spreads almost exclusively through people with easily recognizable symptoms, plus the taming of its once unfathomable 90 percent mortality rate by simple supportive care.

Beyond those three, every other known disease falls short of what seems required to wipe out humans—which is, of course, why we’re still here. And it’s not that diseases are ineffective. On the contrary, diseases’ failure to knock us out is a testament to just how resilient humans are. Part of our evolutionary heritage is our immune system, one of the most complex on the planet, even without the benefit of vaccines or the helping hand of antimicrobial drugs. This system, when viewed at a species level, can adapt to almost any enemy imaginable. Coupled to genetic variations amongst humans—which open up the possibility for a range of advantages, from imperviousness to infection to a tendency for mild symptoms—this adaptability ensures that almost any infectious disease onslaught will leave a large proportion of the population alive to rebuild, in contrast to the fictional Hollywood versions.

#### Data exclusivity is uniquely key to innovation. Lybecker ‘14

Kristina Lybecker {Dr. Kristina M. Lybecker is an Associate Professor of Economics at Colorado College in Colorado Springs, where she is also the Associate Chair of the Department of Economics and Business and the Gerald L. Schlessman Professor of Economics. Dr. Lybecker earned a B.A. in Economics and Latin American Studies from Macalester College and received her Ph.D. in Economics in 2000 from the University of California, Berkeley. Her Dissertation was on “Counterfeit Pharmaceuticals: Product Piracy and the Transition to Stronger Intellectual Property Rights in Developing Countries.”}, 14 - ("When Patents Aren’t Enough: The Case for Data Exclusivity for Biologic Medicines," IPWatchdog, 7-9-2014, https://www.ipwatchdog.com/2014/07/09/patents-arent-enough-data-exclusivity-for-biologic-medicines/id=50318/)//marlborough-wr/

Biologic medicines are fundamentally different from traditional “small molecule” therapies, presenting a host of new challenges in the design and enforcement of the intellectual property (IP) architecture that will protect them.[2] Protecting the intellectual property of biologics is complicated, difficult, and essential to the future of medicine. This new frontier is also one of the remaining hurdles in the Trans-Pacific Partnership (TPP) Trade Agreement negotiations. The debate over protecting biologics focuses on a proposed twelve years of data exclusivity and the consequences this will have for international trade, global public health, and access to medicines. The nuances of producing biologics greatly complicate the logistics of protecting their intellectual property, making patents alone inadequate for safeguarding their IP. Data exclusivity protection allows for a period of time following marketing approval during which competing firms may not use the innovative firm’s safety and efficacy data, from proprietary preclinical and clinical trial results, to obtain marketing authorization for a generic version of the drug. From the moment when the compound first shows medicinal promise, data is generated and compiled, a process that is both expensive and time consuming. Data exclusivity provides the innovative firm with a period of protection for their investment in clinical trials and data collection, regardless of the length of time required to bring the drug to market. Although complementary, patents and data exclusivity protection incentivize innovation in different ways and serve distinct purposes. Patents provide protection for innovations that meet the standards of patentability and are novel, nonobvious, and useful. In the context of biopharmaceuticals, patents protect both breakthrough discoveries as well as incremental improvements. Due to the length of the drug-development and patent-approval processes, effective patent terms rarely correspond to FDA approval. Accordingly, in some cases innovative therapies may experience patent expiry shortly after making it to market. In contrast, data exclusivity protects the tremendous investments of time, talent, and financial resources required to establish a new therapy as safe and effective. This is accomplished by requiring competing firms seeking regulatory approval of the same or a similar product to independently generate the comprehensive preclinical and clinical trial data rather than rely on or use the innovator’s data to establish safety and efficacy of their competing product. Alternatively, the competing firm may wait a set period of time after which they are able to utilize the innovator’s prior approval in an abbreviated regulatory approval, eliminating the need for independently generated data. Data exclusivity is not an extension of patent rights, and it does not preclude a third party from introducing a generic version of the innovator’s therapy during the data exclusivity period, provided that the innovator’s data is not used to secure marketing approval. Fundamentally, data exclusivity protection incentivizes biopharmaceutical firms to invest the necessary time and financial resources in establishing the safety and efficacy of their product and prevents competitors from free riding on these efforts for a limited period of time. [Kristina] The Hatch-Waxman Act of 1984 provided innovative drug firms with a period of patent extension as well as a period of data exclusivity, in the hopes of providing a return on their investment and an incentive for future innovation.[3] These protections have been crucial to the development of the innovative drugs and therapies that currently enhance and extend life. They are even more critical to the future of the biopharmaceutical industry and the development of biologic medicines that are more targeted and more complex. In an analysis of the appropriate length of data exclusivity, a financial model was utilized to determine how long the exclusivity period must be to provide a typical pioneer biologic a positive return on investment. Drawing on a representative portfolio of pioneer biologics, the break-even period ranges from thirteen to sixteen years.[4] An appropriate period of protection is essential if the promise of biologics is to come to fruition. Beyond the importance of biologics to public health and longevity, innovation is crucial to trade and economic prosperity. As evidence of the importance of these sectors, in 2011 IP-intensive industries exported more than $1 trillion in goods and services, which accounts for approximately seventy-four percent of total 2011 U.S. exports.[5] Moreover, the biopharmaceutical industry is a significant contributor. The biopharmaceutical industry of the United States is the fourth-largest U.S. exporter among IP-intensive industries, with exports valued at $49.4 billion in 2010.[6] Accordingly, the TPP Trade Agreement should include the proposed twelve years of data exclusivity and provide innovative firms with the incentives needed to continue to invest in the breakthrough therapies that will extend and enhance life for years to come. Technology inevitably evolves faster than the legal architecture that surrounds it. The provision of data exclusivity protections is a straightforward legal step to catch up to the science that brings us biologic medicines. Biologic medicines are critical to the healthcare advances of the future, and data exclusivity is vital to innovative biologics. The period of data exclusivity provides innovators with an incentive to invest in the testing data necessary to prove a drug’s safety and efficacy by granting them a measure of certainty that they will enjoy a fixed amount of time during which they maintain proprietary control of the test data that resulted in the approval of its drug before requiring that data be made available to generic imitators. As technology changes to enable the development of new biologic vaccines and therapies, intellectual property protection must also evolve to ensure protection for these products. If we believe in the importance of biologic medicines for the future of healthcare, we must protect them.

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