# c1

**CP: The member nations of the World Trade Organization ought to reduce intellectual property protections for all medicines except for medicines created by indigenous folks, for which all ownership ought to be transferred to the indigenous communities that originally developed the medicine.**

Ngoc **Tang**, 3-24-**2020**, *Finance Major, CSULB 2021,* "The Importance of Native American Intellectual Property," California State University, Long Beach, <https://www.csulb.edu/college-of-business/legal-resource-center/article/the-importance-of-native-american-intellectual> //SR \*brackets in text\*

Native Americans are known for their distinctive cultures and special symbols. Protecting these cultures from being abused is difficult. In the article "Intellectual Property, Traditional Knowledge, and Traditional Cultural Expressions in Native American Tribal Codes,” author Dalindyebo Bafana Shabalala explains what is considered as Native American intellectual property and why it needs protection. According to Shabalala, Native American intellectual property includes traditional knowledge, traditional cultural expressions, and genetic resources (Shabalala par. 4). Traditional knowledge is skills, practices, and innovation concerning biodiversity, agriculture or health (par. 8). Various forms of art such as symbols, designs, painting, dance, music, literature, and performance are considered as cultural expressions (par. 10). Genetic resources include plants, seeds, and medicine formulas. There have been many cases where the Native American intellectual property has been used without first obtaining permission and authorization from the Native Americans. As mentioned in Shabalala’s article, Allergan, a pharmaceutical company, was using the Saint Regis Mohawk tribe’s formula to make their eye drop drug. However, that is not their original formula, so “on Friday, September 8, 2017, the pharmaceutical company” had to “[transfer] ownership of all federal U.S. patents for its Restasis drug to the Saint Regis Mohawk tribe; the tribe then licensed them back to the company” (par. 1). Another interesting case mentioned in the article is about the series Twilight ​​by author Stephanie Myers. The author of this book used the Quileute tribe’s origin story and incorporated it with the fictitious werewolf story without the permission of the tribe. Shabalala says that although the book or the movie “may have a valid copyright in the realm of federal property, the unauthorized use of the Quileute origin story may cause harm when outsiders begin viewing the unauthorized use of the cultural property as a true reflection of the source culture” (par. 11). These actions not only abuse the use of Native American intellectual property, but they also affect the images, the stories, and the cultures of the native people. With these cases of the property being misused, Shabalala raises a question of how the Native Americans protect their cultural properties and how the current federal law acts in protecting these properties. Each Native American tribe has its own laws and rules; these laws and rules are called tribal codes. In his study of a hundred tribal codes, Shabalala shows that there are only nine codes mentioned about intellectual property or something related to intellectual property. This study demonstrates that the native people are unaware in protecting their cultural property. The native people are unaware because they do not know or think that other people would use these properties for their own purposes. However, the current federal laws are not providing enough protection for Native American intellectual property. Shabalala mentions the Trademark Law Treaty Implementation Act (,TLTIA) and the Indian Arts and Crafts Act (IACA). The purpose of the TLTIA is “to provide international uniformity of trademark registration’ (par. 77); however, “the Congressional Record regarding TLTIA is absent of any authority or mention of providing protection to Native American tribes” (par. 83). The purpose of the IACA is to prevent fraud in the Indian arts and crafts market. However, according to Shabalala’s research, “the IACA trademark system does not provide sufficiently, and arguably any, protection for Native American tribes' cultural property, nor was it ever intended to” (par. 46). Another act is the Native American Graves Protection and Repatriation Act (NAGPRA), an act with the purpose to provide “protection, return, and repatriation of Native American remains and artifacts found on federal or tribal lands” (par. 66). However, according to the article “An Analysis of the Lack of Protection for Intangible Tribal Cultural Property in the Digital Age,” author Chante Westmoreland states that the NAGPRA did “offer some protection for the tangible cultural property but omit protection for the sacred traditional knowledge the object conveys” (Westmoreland par. 10). There are many acts that try to provide protection concerning intellectual property, but they do not provide enough protection for the Native American intellectual property including traditional property, traditional cultural expressions, and genetic resources. According to the article called “Group Right to Cultural Survival: Intellectual Property Rights in Native American Cultural Symbols,” Terence Dougherty states that, “Intellectual property law in the context of cultural appropriation is particularly relevant to many Native Americans” (Dougherty par. 44). Dougherty also explains that with the significant misuse of the native symbols, cultural appropriation can greatly affect the cultural survival of the native people. Furthermore, in Westmoreland’s article, he states that “sacred traditional knowledge is not merely information, it is essential to the tribal way of life” (par. 9). This demonstrates that the intellectual property of the Native Americans is extremely important to them in their living and their culture. Therefore, to avoid the misuse that can cause a negative impact on the native people, anyone who wants to use the property must have authorization from the native people. Moreover, the federal government needs to provide a law that specifically protects Native American traditional knowledge, traditional cultural expressions, and genetic resources.

**The CP gives indigenous nations resources for self sovereignty and centers discussions around native demands, which better allows for the accessibility of those medicines**

Simon **Brascoupé and** Karin **Endemann**, Fall **1999**, INTELLECTUAL PROPERTY AND ABORIGINAL PEOPLE: A WORKING PAPER <https://www.wipo.int/export/sites/www/tk/en/databases/creative_heritage/docs/ip_aboriginal_people.pdf> //SR

Traditional Knowledge and Intellectual Property The Aboriginal legacy of traditional knowledge comes in two distinct forms. On one hand, an Aboriginal community is the custodian of a store of sacred knowledge, including ceremonies, symbols, and masks that is increasingly open to unauthorized commercial exploitation by individuals, companies or institutions. Some Aboriginal people contend it is not appropriate to use IP law to protect sacred traditional knowledge. On the other hand, many products and services associated with traditional lifestyles of Aboriginal people may have commercial value that could help to support the continuation of these lifestyles and the Aboriginal goal of self-sufficiency. The limited Aboriginal use of Canada’s current IP laws suggests that these laws may not be particularly well suited to protecting either of these forms of traditional knowledge. A distinction must be made between traditional knowledge held by an Aboriginal community and the innovations or new creations of an individual or an Aboriginal company. New products and works of art by Aboriginal inventors and artists qualify for protection under existing IP laws. Music, songs, dance, stories, designs and symbols are passed on in many Aboriginal communities from memory and by word of mouth. Each community is both a conveyer and a user of traditional knowledge. This knowledge is dynamic and evolves with the culture, so it is the product of a continuing creative process. Many Aboriginal artists and artisans create works inspired by the traditional knowledge of their community, and use copyright law extensively. Issues that are not addressed widely are: how Aboriginal people relate to their community in the context of the traditional and dynamic aspects of traditional knowledge; and how traditional knowledge itself can be effectively protected. Protecting Traditional Knowledge Within an Aboriginal Community Few legal mechanisms exist to help indigenous communities protect and preserve traditional knowledge. It is urgent that such mechanisms be developed, because of the increasing pace at which control of traditional knowledge is being lost due to misappropriation and pressures from the non-indigenous world. In the meantime, the use of existing legal tools can be part of a “web” of strategies to help Aboriginal communities better protect and control their traditional knowledge, and ensure benefits are shared in a way that meets community needs. These strategies could include: ! developing local mechanisms within communities to control and protect traditional knowledge; ! more effective use of contractual arrangements to recognize traditional customs and knowledge; ! developing guidelines to ensure that third parties secure proper and informed consent before an Aboriginal community shares traditional knowledge; and ! using existing IP laws. Many Aboriginal people have said that they need to consider how they share and protect traditional knowledge within their communities before deciding whether and how they will share this knowledge with others. Once a community identifies its traditional knowledge and adopts community-based measures governing the use of this knowledge, then the community will be more secure in its ownership and more effective in any negotiations to share its knowledge. It is important that Aboriginal communities develop a strategy to protect traditional knowledge. This will help them avoid losing control over this knowledge to third parties seeking academic advancement or commercial gain. Public disclosure of traditional knowledge has the potential to jeopardize an Aboriginal community’s ability to obtain protection under Canada’s IP laws. This is because knowledge that is disclosed may no longer qualify for IP protection because it is in the public domain. Aboriginal communities considering these issues should identify the scope and nature of traditional knowledge in their community. Part of this process is to identify what knowledge is most important to the community, and how the preservation of traditional knowledge and practices is at risk. Is traditional knowledge being lost because elders have been unable to pass their wisdom to the next generation? Is knowledge being lost because Aboriginal people are being displaced from their traditional environment or because they are influenced by outside media and culture? Has traditional knowledge been allowed into the public domain or been misappropriated by commercial or scientific interests from outside the Aboriginal community? Some Aboriginal people have identified a need for dialogue about traditional ways of sharing and preserving traditional knowledge. What are the obligations of individuals to their community when they use or share traditional knowledge? These issues are just beginning to be discussed within Aboriginal communities and First Nations, at the federal level in Canada, and internationally among indigenous peoples and within international organizations. It is also important for Aboriginal communities to consider what traditional knowledge is sacred and what knowledge may be shared with others or used commercially. Only after a full dialogue will these communities be in a position to determine the best mechanisms to control access to their traditional knowledge, and what knowledge they want to share with others. A number of approaches will be needed to reflect the varied nature and use of the community’s traditional knowledge. One option may be for Aboriginal communities to develop guidelines to prevent unwanted disclosure, and to ensure that traditional knowledge remains within the community. The process of developing guidelines will help ensure that the entire community is consulted in decisions concerning the protection of traditional knowledge and control over its commercialization. These guidelines would need to be enforced by the community, since an Aboriginal community may not have any recourse to the courts if one of its members violates the guidelines. Community guidelines might include policies on the publication of traditional knowledge, its use by others or the use of the community’s symbols. Aboriginal communities may also want to ensure that sharing traditional knowledge within the community continues, and is not restricted more than it was traditionally.

# c2

#### Biden’s infrastructure bill will pass through reconciliation but absolute Dem Unity is key.

Pramuk and Franck 8-25 Jacob Pramuk and Thomas Franck 8-25-2021 "Here’s what happens next as Democrats try to pass Biden’s multitrillion-dollar economic plans" <https://www.cnbc.com/2021/08/25/what-happens-next-with-biden-infrastructure-budget-bills-in-congress.html> (Staff Reporter at CNBC)//Elmer

WASHINGTON — **House Democrats just patched up a party fracture** **to take a critical step forward with a mammoth economic agenda**. But the **path ahead could get trickier** as party leaders try to thread a legislative needle to pass more than $4 trillion in new spending. **In** the **coming weeks**, **Democrats** **aim to approve** a $1 trillion bipartisan **infrastructure** plan and up to $3.5 trillion in investments in social programs. Passing both **will require a heavy lift**, as leaders will need to **satisfy** **competing demands of centrists** wary of spending **and progressives** who want to reimagine government’s role in American households. The House is leaving Washington **until Sept. 20** after taking key steps toward pushing through the sprawling economic plans. The chamber on Tuesday approved a $3.5 trillion budget resolution and advanced the infrastructure bill, as House Speaker Nancy Pelosi, D-Calif., promised centrist Democrats to take up the bipartisan plan by Sept. 27. The Senate already passed the infrastructure legislation, so **a final House vote would send it to Biden’s desk for his** signature. Now that both chambers have passed the budget measure, **Democrats can move without Republicans** to push through their spending plan **via reconciliation**. Party leaders want committees to write their pieces of the bill by Sept. 15 before budget committees package them into one massive measure that can move through Congress. Committees could start marking up legislation in early September. Party leaders **face a challenge** in coming up with a bill that will satisfy centrists who want to trim back the $3.5 trillion price tag and progressives who consider it the minimum Congress should spend. As **one defection in the Senate** — **and four in the House** — **would sink legislation,** **Democrats have to satisfy a diverse range of views** to pass their agenda. “We write a bill with the Senate because it’s no use doing a bill that’s not going to pass the Senate, in the interest of getting things done,” Pelosi told reporters on Wednesday. Given the magnitude of the legislation, passing it quickly could prove difficult. To appease congressional progressives who have prioritized passage of the budget bill, Democrats could move to pass both proposals at about the same time. While Pelosi gave a Sept. 27 target date to approve the infrastructure plan, the commitment is not binding. Still, she noted Wednesday that Congress needs to pass the bill before surface transportation spending authorization expires Sept. 30. “We have long had an eye to having the infrastructure bill on the President’s desk by the October 1, the effective date of the legislation,” she wrote in a separate letter to Democrats on Wednesday. Democrats say the bills combined will provide a jolt to the economy and a lifeline for households. Supporters of the Democratic spending plan, including Pelosi and Senate Budget Committee Chair Bernie Sanders, I-Vt., have cast it as the biggest expansion of the U.S. social safety net in decades. “This is a truly historic opportunity to pass the **most transformative** and consequential **legislation for families** in a century, and will stand alongside the New Deal and Great Society as pillars of **economic security**,” Pelosi wrote to colleagues Wednesday. The plan would **expand Medicare**, **paid leave** and child care, extend enhanced household tax credits and encourage **green energy adoption**, **while hiking taxes on corporations and the wealthy**. Democrats hope to sell a wave of new support for families as they campaign to keep control of Congress in next year’s midterms. Those elections, though, have helped to generate staunch opposition on the other side of the aisle. The GOP has cited the trillions in new spending and the proposed reversal of some of its 2017 tax cuts in trying to take down the Democratic budget bill. Republicans and some Democrats have in recent weeks said that another $4.5 trillion in fiscal stimulus could not only boost economic growth but have the adverse effect of fueling inflation.

#### 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.

#### 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.

# c3

#### Pleasure and pain are intrinsically valuable. people consistently regard pleasure and pain as good reasons for action, despite the fact that pleasure doesn’t seem to be instrumentally valuable for anything.

Moen 16 [Ole Martin Moen, Research Fellow in Philosophy at University of Oslo “An Argument for Hedonism” Journal of Value Inquiry (Springer), 50 (2) 2016: 267–281] SJDI

Let us start by observing, empirically, that a widely shared judgment about intrinsic value and disvalue is that pleasure is intrinsically valuable and pain is intrinsically disvaluable. On virtually any proposed list of intrinsic values and disvalues (we will look at some of them below), pleasure is included among the intrinsic values and pain among the intrinsic disvalues. This inclusion makes intuitive sense, moreover, for there is something undeniably good about the way pleasure feels and something undeniably bad about the way pain feels, and neither the goodness of pleasure nor the badness of pain seems to be exhausted by the further effects that these experiences might have. “Pleasure” and “pain” are here understood inclusively, as encompassing anything hedonically positive and anything hedonically negative.2 The special value statuses of pleasure and pain are manifested in how we treat these experiences in our everyday reasoning about values. If you tell me that you are heading for the convenience store, I might ask: “What for?” This is a reasonable question, for when you go to the convenience store you usually do so, not merely for the sake of going to the convenience store, but for the sake of achieving something further that you deem to be valuable. You might answer, for example: “To buy soda.” This answer makes sense, for soda is a nice thing and you can get it at the convenience store. I might further inquire, however: “What is buying the soda good for?” This further question can also be a reasonable one, for it need not be obvious why you want the soda. You might answer: “Well, I want it for the pleasure of drinking it.” If I then proceed by asking “But what is the pleasure of drinking the soda good for?” the discussion is likely to reach an awkward end. The reason is that the pleasure is not good for anything further; it is simply that for which going to the convenience store and buying the soda is good.3 As Aristotle observes: “We never ask [a man] what his end is in being pleased, because we assume that pleasure is choice worthy in itself.”4 Presumably, a similar story can be told in the case of pains, for if someone says “This is painful!” we never respond by asking: “And why is that a problem?” We take for granted that if something is painful, we have a sufficient explanation of why it is bad. If we are onto something in our everyday reasoning about values, it seems that pleasure and pain are both places where we reach the end of the line in matters of value.

#### **The standard is maximizing expected well being.**

Prefer:

#### **1]outweighs on actor specificity since governments make policies as a whole that benefit and help some people and side constraints freeze action – actor spec outweighs and turns since it’s better than no action, states don’t have wills and intentions since they are not indivuals actors, different agents have different obligations**

#### **2] no act omission distinction -- governments control everything that happens in the public sphere since they yes/no bills – act omission distinction would make the yemen war moral**

#### 3] use epistemic modesty – multiply probability of the fwk times the magnitude of the impacts A) clash – encourages both substantive and phil debates so that we talk about all the offense B) leads to the net most morality and proves that only beating fwk is not enough to win the debate

#### **4] extinction first**

Pummer 15 [Theron, Junior Research Fellow in Philosophy at St. Anne's College, University of Oxford. “Moral Agreement on Saving the World” Practical Ethics, University of Oxford. May 18, 2015] AT

There appears to be lot of disagreement in moral philosophy. Whether these many apparent disagreements are deep and irresolvable, I believe there is at least one thing it is reasonable to agree on right now, whatever general moral view we adopt: that it is very important to reduce the risk that all intelligent beings on this planet are eliminated by an enormous catastrophe, such as a nuclear war. How we might in fact try to reduce such existential risks is discussed elsewhere. My claim here is only that we – whether we’re consequentialists, deontologists, or virtue ethicists – should all agree that we should try to save the world. According to consequentialism, we should maximize the good, where this is taken to be the goodness, from an impartial perspective, of outcomes. Clearly one thing that makes an outcome good is that the people in it are doing well. There is little disagreement here. If the happiness or well-being of possible future people is just as important as that of people who already exist, and if they would have good lives, it is not hard to see how reducing existential risk is easily the most important thing in the whole world. This is for the familiar reason that there are so many people who could exist in the future – there are trillions upon trillions… upon trillions. There are so many possible future people that reducing existential risk is arguably the most important thing in the world, even if the well-being of these possible people were given only 0.001% as much weight as that of existing people. Even on a wholly person-affecting view – according to which there’s nothing (apart from effects on existing people) to be said in favor of creating happy people – the case for reducing existential risk is very strong. As noted in this seminal paper, this case is strengthened by the fact that there’s a good chance that many existing people will, with the aid of life-extension technology, live very long and very high quality lives. You might think what I have just argued applies to consequentialists only. There is a tendency to assume that, if an argument appeals to consequentialist considerations (the goodness of outcomes), it is irrelevant to non-consequentialists. But that is a huge mistake. Non-consequentialism is the view that there’s more that determines rightness than the goodness of consequences or outcomes; it is not the view that the latter don’t matter. Even John Rawls wrote, “All ethical doctrines worth our attention take consequences into account in judging rightness. One which did not would simply be irrational, crazy.” Minimally plausible versions of deontology and virtue ethics must be concerned in part with promoting the good, from an impartial point of view. They’d thus imply very strong reasons to reduce existential risk, at least when this doesn’t significantly involve doing harm to others or damaging one’s character. What’s even more surprising, perhaps, is that even if our own good (or that of those near and dear to us) has much greater weight than goodness from the impartial “point of view of the universe,” indeed even if the latter is entirely morally irrelevant, we may nonetheless have very strong reasons to reduce existential risk. Even egoism, the view that each agent should maximize her own good, might imply strong reasons to reduce existential risk. It will depend, among other things, on what one’s own good consists in. If well-being consisted in pleasure only, it is somewhat harder to argue that egoism would imply strong reasons to reduce existential risk – perhaps we could argue that one would maximize her expected hedonic well-being by funding life extension technology or by having herself cryogenically frozen at the time of her bodily death as well as giving money to reduce existential risk (so that there is a world for her to live in!). I am not sure, however, how strong the reasons to do this would be. But views which imply that, if I don’t care about other people, I have no or very little reason to help them are not even minimally plausible views (in addition to hedonistic egoism, I here have in mind views that imply that one has no reason to perform an act unless one actually desires to do that act). To be minimally plausible, egoism will need to be paired with a more sophisticated account of well-being. To see this, it is enough to consider, as Plato did, the possibility of a ring of invisibility – suppose that, while wearing it, Ayn could derive some pleasure by helping the poor, but instead could derive just a bit more by severely harming them. Hedonistic egoism would absurdly imply she should do the latter. To avoid this implication, egoists would need to build something like the meaningfulness of a life into well-being, in some robust way, where this would to a significant extent be a function of other-regarding concerns (see chapter 12 of this classic intro to ethics). But once these elements are included, we can (roughly, as above) argue that this sort of egoism will imply strong reasons to reduce existential risk. Add to all of this Samuel Scheffler’s recent intriguing arguments (quick podcast version available here) that most of what makes our lives go well would be undermined if there were no future generations of intelligent persons. On his view, my life would contain vastly less well-being if (say) a year after my death the world came to an end. So obviously if Scheffler were right I’d have very strong reason to reduce existential risk. We should also take into account moral uncertainty. What is it reasonable for one to do, when one is uncertain not (only) about the empirical facts, but also about the moral facts? I’ve just argued that there’s agreement among minimally plausible ethical views that we have strong reason to reduce existential risk – not only consequentialists, but also deontologists, virtue ethicists, and sophisticated egoists should agree. But even those (hedonistic egoists) who disagree should have a significant level of confidence that they are mistaken, and that one of the above views is correct. Even if they were 90% sure that their view is the correct one (and 10% sure that one of these other ones is correct), they would have pretty strong reason, from the standpoint of moral uncertainty, to reduce existential risk. Perhaps most disturbingly still, even if we are only 1% sure that the well-being of possible future people matters, it is at least arguable that, from the standpoint of moral uncertainty, reducing existential risk is the most important thing in the world. Again, this is largely for the reason that there are so many people who could exist in the future – there are trillions upon trillions… upon trillions. (For more on this and other related issues, see this excellent dissertation). Of course, it is uncertain whether these untold trillions would, in general, have good lives. It’s possible they’ll be miserable. It is enough for my claim that there is moral agreement in the relevant sense if, at least given certain empirical claims about what future lives would most likely be like, all minimally plausible moral views would converge on the conclusion that we should try to save the world. While there are some non-crazy views that place significantly greater moral weight on avoiding suffering than on promoting happiness, for reasons others have offered (and for independent reasons I won’t get into here unless requested to), they nonetheless seem to be fairly implausible views. And even if things did not go well for our ancestors, I am optimistic that they will overall go fantastically well for our descendants, if we allow them to. I suspect that most of us alive today – at least those of us not suffering from extreme illness or poverty – have lives that are well worth living, and that things will continue to improve. Derek Parfit, whose work has emphasized future generations as well as agreement in ethics, described our situation clearly and accurately: “We live during the hinge of history. Given the scientific and technological discoveries of the last two centuries, the world has never changed as fast. We shall soon have even greater powers to transform, not only our surroundings, but ourselves and our successors. If we act wisely in the next few centuries, humanity will survive its most dangerous and decisive period. Our descendants could, if necessary, go elsewhere, spreading through this galaxy…. Our descendants might, I believe, make the further future very good. But that good future may also depend in part on us. If our selfish recklessness ends human history, we would be acting very wrongly.” (From chapter 36 of On What Matters)

# Case

\

### Contention

#### 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 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.

#### 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.