# 1NC

### 1

#### Interp: The affirmative must correctly tell the negative which aff they will be reading, including any and all changes, at the time of the online flip result.

#### Violation: screenshots – they refused to give me the aff at the flip

Graphical user interface, text, application, chat or text message

Description automatically generatedGraphical user interface, text, application, chat or text message

Description automatically generated

#### Negate:

#### 1] Prep and clash - they force us to spend pre-round prep prepping multiple different affs which means I’m unprepared to engage - that decks clash and fairness. Also forces us to make a flip decision in the dark since we don't know if the aff is new or one of the 6 across your teammate’s wikis proven by you doing exactly that

#### 2] Academic integrity – you hide the aff for your own advantage which is the definition of being academically disingenuous. That’s a voter since it destroys the constitutive purpose of debate as an educational activity.

#### 3] No offense for disclosure bad - they posted cites on the wiki for all their affs but didn't give us the correct aff at the flip - the only offense was us not being able to anticipate or prep the right aff pre round because they forced us to split our time and make a flip decision without knowing the aff - proves any responses are in bad faith

#### Evaluate disclosure before 1AR theory – a) scope of norming – affects more rounds over time so it rectifies more abuse, b) magnitude – the aff advocacy and disclosure affects a larger portion of the debate since it determines every speech after it and pre round neg prep, c) any 1nc abuse was justified by the aff not being properly disclosed

### 2

#### Interpretation: “medicines” is a generic bare plural. The aff may not defend WTO member nations reducing intellectual property protections for a subset of medicines.

#### The upward entailment test and adverb test determine the genericity of a bare plural

Leslie and Lerner 16 [Sarah-Jane Leslie, Ph.D., Princeton, 2007. Dean of the Graduate School and Class of 1943 Professor of Philosophy. Served as the vice dean for faculty development in the Office of the Dean of the Faculty, director of the Program in Linguistics, and founding director of the Program in Cognitive Science at Princeton University. Adam Lerner, PhD Philosophy, Postgraduate Research Associate, Princeton 2018. From 2018, Assistant Professor/Faculty Fellow in the Center for Bioethics at New York University. Member of the [Princeton Social Neuroscience Lab](http://psnlab.princeton.edu/).] “Generic Generalizations.” Stanford Encyclopedia of Philosophy. April 24, 2016. <https://plato.stanford.edu/entries/generics/> TG

1. Generics and Logical Form

In English, generics can be expressed using a variety of syntactic forms: bare plurals (e.g., “tigers are striped”), indefinite singulars (e.g., “a tiger is striped”), and definite singulars (“the tiger is striped”). However, none of these syntactic forms is dedicated to expressing generic claims; each can also be used to express existential and/or specific claims. Further, some generics express what appear to be generalizations over individuals (e.g., “tigers are striped”), while others appear to predicate properties directly of the kind (e.g., “dodos are extinct”). These facts and others give rise to a number of questions concerning the logical forms of generic statements.

1.1 Isolating the Generic Interpretation

Consider the following pairs of sentences:

(1)a.Tigers are striped.

b.Tigers are on the front lawn.

(2)a.A tiger is striped.

b.A tiger is on the front lawn.

(3)a.The tiger is striped.

b.The tiger is on the front lawn.

The sentence pairs above are prima facie syntactically parallel—both are subject-predicate sentences whose subjects consist of the same common noun coupled with the same, or no, article. However, the interpretation of first sentence of each pair is intuitively quite different from the interpretation of the second sentence in the pair. In the second sentences, we are talking about some particular tigers: a group of tigers in ([1b](https://plato.stanford.edu/entries/generics/#ex1b)), some individual tiger in ([2b](https://plato.stanford.edu/entries/generics/#ex2b)), and some unique salient or familiar tiger in ([3b](https://plato.stanford.edu/entries/generics/#ex3b))—a beloved pet, perhaps. In the first sentences, however, we are saying something general. There is/are no particular tiger or tigers that we are talking about.

The second sentences of the pairs receive what is called an existential interpretation. The hallmark of the existential interpretation of a sentence containing a bare plural or an indefinite singular is that it may be paraphrased with “some” with little or no change in meaning; hence the terminology “existential reading”. The application of the term “existential interpretation” is perhaps less appropriate when applied to the definite singular, but it is intended there to cover interpretation of the definite singular as referring to a unique contextually salient/familiar particular individual, not to a kind.

There are some tests that are helpful in distinguishing these two readings. For example, the existential interpretation is upward entailing, meaning that the statement will always remain true if we replace the subject term with a more inclusive term. Consider our examples above. In ([1b](https://plato.stanford.edu/entries/generics/#ex1b)), we can replace “tiger” with “animal” salva veritate, but in ([1a](https://plato.stanford.edu/entries/generics/#ex1a)) we cannot. If “tigers are on the lawn” is true, then “animals are on the lawn” must be true. However, “tigers are striped” is true, yet “animals are striped” is false. ([1a](https://plato.stanford.edu/entries/generics/#ex1a)) does not entail that animals are striped, but ([1b](https://plato.stanford.edu/entries/generics/#ex1b)) entails that animals are on the front lawn (Lawler 1973; Laca 1990; Krifka et al. 1995).

Another test concerns whether we can insert an adverb of quantification with minimal change of meaning (Krifka et al. 1995). For example, inserting “usually” in the sentences in ([1a](https://plato.stanford.edu/entries/generics/#ex1a)) (e.g., “tigers are usually striped”) produces only a small change in meaning, while inserting “usually” in ([1b](https://plato.stanford.edu/entries/generics/#ex1b)) dramatically alters the meaning of the sentence (e.g., “tigers are usually on the front lawn”). (For generics such as “mosquitoes carry malaria”, the adverb “sometimes” is perhaps better used than “usually” to mark off the generic reading.)

#### It applies to “medicines” – 1] upward entailment test – “reduce intellectual property protections for medicines” doesn’t entail reducing protections for aids, because it doesn’t prove that we should derestrict other beneficial tech, 2] adverb test – member nations “ought to usually reduce intellectual property protections for medicines” doesn’t substantially change resolutional meaning, 3] predicate level – the rez is an individual level predicate not a stage level because moral obligations in ought statements are long-lasting as opposed to fleeting phases

#### **Violation – they only defend women’s health medicines**

#### Vote neg:

#### 1] Limits – you can pick anything from COVID vaccines to HIV/AIDS to random biotech to insulin treatments and there’s no universal disad since each one has a different function and implication for health, tech, and relations – explodes neg prep and leads to random medicine of the week affs which makes cutting stable neg links impossible. PICs don’t solve – it’s absurd to say neg potential abuse justifies the aff being flat out not T, which leads to a race towards abuse. Limits key to reciprocal engagement since they create a caselist for neg prep. 20k affs

FDA 20 [(U.S. Food and Drug Administration, federal agency of the Department of Health and Human Service) “Fact Sheet: FDA at a Glance,” 11/18/2020] JL

There are over 20,000 prescription drug products approved for marketing.

FDA oversees over 6,500 different medical device product categories.

There are over 1,600 FDA-approved animal drug products.

There are about 300 FDA-licensed biologics products.

#### 2] TVA – read the aff as an advantage to a whole rez aff.

#### Voters:

#### Fairness and education are voters – debate’s a game that needs rules to evaluate it and education gives us portable skills for life like research and thinking.

#### Precision o/w – anything else justifies the aff arbitrarily jettisoning words in the resolution at their whim which decks negative ground and preparation because the aff is no longer bounded by the resolution.

#### Drop the debater – a) they have a 7-6 rebuttal advantage and the 2ar to make args I can’t respond to, b) it deters future abuse and sets a positive norm.

#### Use competing interps – a) reasonability invites arbitrary judge intervention since we don’t know your bs meter, b) collapses to competing interps – we justify 2 brightlines under an offense defense paradigm just like 2 interps.

#### No RVIs – a) illogical – you shouldn’t win for being fair – it’s a litmus test for engaging in substance, b) norming – I can’t concede the counterinterp if I realize I’m wrong which forces me to argue for bad norms, c) baiting – incentivizes good debaters to be abusive, bait theory, then collapse to the 1AR RVI, d) topic ed – prevents 1AR blipstorm scripts and allows us to get back to substance after resolving theory

#### Evaluate T before 1AR theory – a) norms – we only have a couple months to set T norms but can set 1AR theory norms anytime, b) magnitude – T affects a larger portion of the debate since the aff advocacy determines every speech after it

### 3

#### CP: The Member Nations of the World Trade Organization, except for the United States, should fund research and development and buy and freely distribute women’s health medicine. The 50 states of the United States and all relevant territories should fund research and development and buy and freely distribute women’s health medicine.

#### Solves the aff – their solvency advocate is super vague and just says access needs to increase.

**1AC Mike 2**: Mike, Jennifer H. [School of Law, American University of Nigeria, Yola, Nigeria, Nigeria] “Access to essential medicines to guarantee women's rights to health: The pharmaceutical patents connection” *Wiley Online Library,* 2020. <https://onlinelibrary.wiley.com/doi/full/10.1111/jwip.12161> JP

The sum total of the arguments and analysis indicates that human rights relate to health and that access to medicines is germane to the enjoyment of the right to health as well as the right to life. **In this manner, human rights provide the basis to argue for the alleviation of problems inhibiting women's access to healthcare**. This rights approach to the issue of accessing medicine is relevant because it provides a guiding standard for national policies, laws and programmes to achieve the goal of fulfilling, protecting, respecting and generally securing their right to health. **To secure women's right to health and ensure that they can fully enjoy their human rights, it is submitted that there is a need to promote their access to affordable medicines. The article highlighted the concern that the patent protection of pharmaceuticals could result in high prices or stifle incremental innovation which could have the effect of impeding the availability of and women's access to affordable drugs for serious medical needs. In this event, one of the ways in which the state can meet its obligation, as to the right to health is to make sure that pharmaceutical patents do not constitute an obstruction to the enjoyment of the rights of women to adequate healthcare.** The foregoing discussion also argued that pharmaceutical companies and patent owners can have a human right to health responsibility within the sphere of their business operations. This responsibility would pertain to the pricing of their drugs, testing and clinical trials, R&D, provision of safe and good quality medicines and the duty to ensure that their practices do not constitute an obstacle, especially to women's enjoyment of human rights and their right to medicines. Notwithstanding the obligations of pharmaceutical companies to the right to access medicines, states are ultimately the duty bearers accountable for the guarantees, and prevention of the violations of the rights to access medicines. It is their duty to monitor and also ensure that pharmaceutical firms do not impede the enjoyment of the right to health. In closing, the argument based on human rights principles is a consideration of women's health needs in regulations and policies to fulfil their demands of healthcare. **Ultimately, if women's access to medicines is to be enhanced, the state must provide medicines and also guarantee the sustainable availability and accessibility of drugs through every avenue.**

### 4

#### Infrastructure passes now due to Biden and Pelosi involvement – Biden PC and tight timetables makes the margin for error literally ZERO

Elliott 9-16 (Philip Elliott is a Washington Correspondent for TIME. Before joining TIME in early 2015, he spent almost a decade at The Associated Press, where he covered politics, campaign finance, education and the White House. He is a graduate of the E.W. Scripps School of Journalism at Ohio University, September 16, 2021, accessed on 9-17-2021, Time, "Democrats Face a Grueling Two Weeks as Infighting Erupts Over Infrastructure", https://time.com/6098810/house-democrats-reconciliation/)//babcii

House Democrats yesterday finished penning a 2,600-page bill that **finally outlines the specifics** of their ambitious “soft” infrastructure plan that won’t attract a single Republican vote. But no one was really rushing to Schneider’s for bottles of bubbly. For a party ready to spend $3.5 trillion to fund its social policy agenda, there were plenty of glum faces on Capitol Hill. In fact, one key piece of the legislation—a deal that would finally let Medicare negotiate lower prices with drug companies—fell apart in the Energy and Commerce Committee when three Democrats voted against it. It found resurrection a short time later when Leadership aides literally plucked it from the Energy and Commerce team and delivered it to the Ways and Means Committee for its approval instead. Even there, though, one Democrat voted against it, saying the threat it posed to pharmaceutical companies’ profits would doom it in the Senate. “Every moment we spend debating provisions that will never become law is a moment wasted and will delay much-needed assistance to the American people,” Rep. Stephanie Murphy of Florida later argued. Put another way? Brace **for some nasty politics** over the next two weeks as House Speaker Nancy Pelosi tries to get this bill to a vote before the budget year ends on Sept. 30. And those 2,600 pages had better be recyclable. Democrats can **only afford three defectors** if they want to usher this bill into law, **and they’re perilously close to failure**. So far, five centrist Democrats in the House have said they prefer a scaled-back version of the Medicare component. But if Pelosi gives the five centrists that win, she risks losing the support of progressives who are already sour that things like a punitive wealth tax and the end to tax loopholes aren’t present in the current version of the bill. As it stands now, letting Medicare negotiate drug prices would save the government about $500 billion over the next decade. The scaled-back version doesn’t have an official cost, but a very similar version got its score in the Senate last year: roughly $100 billion in savings. Because Democrats are using a budgeting loophole to help them avoid a filibuster and pass this with bare majorities, that $400 billion gap matters a lot more than on most bills. Scaling back the Medicare savings means they would also have to scale back their overall spending on the bill—a big line in the sand for progressives who say they’ve already compromised too much. All of this, of course, comes as President Joe Biden and his top aides in the White House have been trying to get Senate **centrists onboard**. Just yesterday, he **met separately with Sens. Kyrsten Sinema and Joe Manchin**, fellow Democrats who have expressed worries about the $3.5 trillion price tag but have been vague about what exactly they want to cut back on. With the Senate evenly divided at 50-50, and Vice President Kamala Harris in position to break the ties to Democrats’ victories, any shenanigans from those two independent thinkers scrambles the whole package. Oh, and that other bipartisan infrastructure plan that carries $550 billion in new spending? It’s still sitting on the shelf in the House. Pelosi said she’d bring it to the floor only when the bigger—and entirely partisan—bill was ready. And there’s plenty of grumbling about that package, too. If this is all beginning to sound like a scratched record that keeps repeating, it’s because this has become something of a pattern here in Washington. Things look pretty grim for legislation in town these days, despite Democrats controlling the House, the Senate and the White House. Their margin for error **is literally zero**, and so hiccups from a half-dozen centrists can forewarn a doomed agenda. So far, Pelosi has been a master of holding the line on crucial votes and has managed to maneuver her team to victories, including on an earlier pandemic relief package that passed with only Democratic votes. Now she’s trying again, but the clock is ticking, and $3.5 trillion is an eye-popping sum of money that rivals the spending the United States unleashed to close out World War II.

#### 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 turns case

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

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.

#### Comprehensive infrastructure investment is key to all facets of the economy

Condon 2/21 [(Christopher, overing the Treasury and U.S. economic policy at Bloomberg News, with Erik Wasson) “Biden’s Economic Legacy at Stake as Next Package Takes Shape,” *Bloomberg*, 2-21-2021, <https://www.bloomberg.com/news/articles/2021-02-21/biden-s-economic-legacy-at-stake-with-next-package-taking-shape>] TDI

The next phase of President Joe Biden’s legislative agenda is fast taking shape, with an economic-recovery package that will potentially far surpass his $1.9 trillion virus-relief plan in size, complexity and overall ambition. The White House and congressional Democrats are busy plotting strategy for the proposal, which could be unveiled next month, kicking off a legislative process that may culminate by August. The centerpiece will be possibly the biggest infrastructure-spending commitment since the New Deal -- including roads, bridges and rural broadband internet. Progressives are eyeing much more, such as an expansion of Obamacare and a public-sector jobs program, along with tax measures including an increase in the capital-gains levy. But stuffing it with too many controversial proposals could threaten its approval or force it to be broken up, and put in peril the Democrats’ thin majorities in the 2022 midterm elections. Still, Democrats see a narrow opening to forge Biden’s legacy: not just restoring the U.S. economy to its pre-pandemic state, but reversing the trend of sluggish growth in recent years with the most far-reaching measures in decades. U.S. economy has put up more moderate growth in the 2000s versus heydays Biden’s virus-relief package is “going to help us get us back on the growth pattern we were on before,” said Virginia Representative Don Beyer, who, as incoming chair of the Joint Economic Committee, is a leading Democratic macroeconomic-policy voice. “The genius of the second plan is that it gives us the opportunity to punch GDP up above the long-term trend,” he said in an interview. During his campaign, Biden proposed $2 trillion for economic rebuilding, a step up from the $1.5 trillion level proposed in the House last year, which Democrats are now calling a “floor.” China Card Biden is aiming to succeed where Donald Trump and other predecessors have failed, when funding disputes stymied measures that economists say are vital to boosting long-term productivity. The president is selling the package as a way to counter China, which has deployed public investment not only to boost its own growth but to build global influence as well. As challenging as it may be to enact, such arguments may make the core infrastructure piece likely to be the easiest component to get through Congress. Bipartisan support for improved highway, transit, waterway and flood-mitigation work is strong, while deficit concerns are at the lowest level in decades. There’s also a Sept. 30 deadline in Congress for reauthorizing surface-transportation funding -- offering a ready-made vehicle for pursuing infrastructure measures. “Much of our infrastructure is nearing the end of its useful design life,” said Thomas Smith, executive director of the American Society of Civil Engineers, which will issue its latest quadrennial report card on U.S. infrastructure on March 3. “We’ve neglected it for far too long, and we’ve watched other countries continue to invest and continue to move ahead of the United States.” The ASCE’s last assessment, in 2017, was a D+. Back then, it estimated the U.S. needed $4.5 trillion in infrastructure spending over the following 10 years. With about $2.5 trillion in estimated outlays already in train, that left a $2 trillion gap -- which Biden’s proposal could largely fill. Congressional Budget Office figures indicate that a $1.5 trillion package would be equivalent to all federal spending on transportation and water infrastructure in the 14 years through 2017. The Senate Environment and Public Works Committee plans a hearing on transportation investment on Wednesday, when Michigan Governor Gretchen Whitmer, a Democrat, and Maryland Governor Larry Hogan, a Republican, are scheduled to testify. But infrastructure could become ensnared by a push among liberal lawmakers to tack on a raft of other items, from creating a government-run health insurance plan and making unionization easier, to a pathway to citizenship for undocumented immigrants and a carbon tax. Political Risk Meanwhile, House moderates in swing districts are facing the perils of redistricting ahead of the midterms, and could insist on limiting the scope of the bill to rein in its cost and limit partisan battles. Fights could also emerge over formulas for divvying up the money among states and cities. Congressional Progressive Caucus Chair Pramila Jayapal said Thursday her large cohort of House Democrats will decide in the coming weeks which elements to advocate in the package -- including whether to use it as an opportunity to roll back Trump’s tax cuts for the wealthy. Jayapal’s group was instrumental in attaching to the pandemic-relief plan an increase in the hourly minimum wage to $15, something that’s become easily the most controversial potential holdup for that bill. The progressive caucus has proposed a $2 trillion infrastructure bill, and is already advocating that it include expanded child and elder care. The question of funding, whether by raising taxes or issuing more debt, also looms large, and many Republicans are set to be vociferous in opposing much of the plan. Senate Finance Committee Chairman Ron Wyden is expected to propose tax hikes, including equalizing ordinary income and capital-gains levies for those making more than $1 million a year and ending the deferral of capital gains. He’d also change international tax provisions in the 2017 tax law and close the carried-interest loophole, according to a Democratic aide. Some lawmakers favor raising the federal gasoline tax -- now 18.4 cents a gallon and 24.4 cents for diesel -- for the first time since 1993, though Wyden in 2019 expressed opposition to the idea, calling it regressive. Treasury Secretary Janet Yellen, who argues that deficit spending makes more sense with interest rates historically low, said on CNBC last week that “certainly part of the package, the parts that are permanent, will be paid for in order to not raise long-term deficits.” While the yield on 10-year Treasury notes has risen markedly in recent weeks, Friday’s level of 1.34% is far below the 50-year average of about 6.16%. U.S. government's borrowing costs are historically low “There’s a lot of appetite to do something this year,” said Jeff Davis, a senior fellow at the Eno Center for Transportation. “But there seems to be no appetite to pay for it.” Despite all the hurdles, Biden has a strong hand. Upgrading and maintaining infrastructure acts as its own stimulus, unleashing real demand for equipment makers, materials suppliers and, most importantly, workers. Nucor Corp., Cleveland-Cliffs Inc. and U.S. Steel Corp., the country’s three largest steel producers, have been lobbying through their industry groups since the election to persuade lawmakers to back whatever infrastructure package the Biden administration puts forth. Productivity Potential Such spending would also be a huge boon for Caterpillar Inc., one of the world’s largest machinery makers, which attributed a drop in North American construction-equipment sales to weaker demand for pipelines and road construction. There’s also the potential for a long-term payoff, if investments translate into productivity gains -- such as savings on shipping and commuting costs when roads, rails and ports are improved, or avoiding the kind of power-grid failures on display this month in Texas. “We cannot throw all fiscal discipline to the wind, but the standards for fiscal prudence have indeed changed in light of the global decline in the normal structure of interest rates,” said David Wilcox, a senior fellow at the Peterson Institute for International Economics, and a former Federal Reserve and Treasury official. “If the rate of return on an investment exceeds your borrowing cost, it makes sense to do that investment, and with lower borrowing costs, more investments today can clear that bar.”

#### Post-COVID economic rebound secures geopolitical dominance---the alternative is global conflict, EU collapse and Chinese authoritarian dominance

Kempe 20 [(Frederick, best-selling author, prize-winning journalist and president & CEO of the Atlantic Council, one of the United States’ most influential think tanks on global affairs. He worked at The Wall Street Journal for more than 25 years as a foreign correspondent, assistant managing editor and as the longest-serving editor of the paper’s European edition.) “Op-ed: How the US can win the post-coronavirus race for global dominance,” CNBC, 4-18-2020, https://www.cnbc.com/2020/04/18/op-ed-how-us-can-win-the-post-coronavirus-race-for-global-dominance.html] TDI

Place your bets for the coming race to growth. It will be an epic contest among the world’s most significant economies, with generational and geopolitical consequences. For context, think back to what the United States accomplished after World War II, when it rose as an economic power to shape a better world. The post-COVID19 race could determine whether the U.S. rebounds in a manner that allows it to retain the mantle of global leadership. More likely for the moment, Beijing could leverage its first-mover advantage – alongside a faster economic recovery across Asian markets – accelerating the trend toward a Chinese-centric globalization. Elsewhere, as President Macron [argued](https://www.ft.com/content/3ea8d790-7fd1-11ea-8fdb-7ec06edeef84) this week to the Financial Times, the coming months could determine whether the European Union collapses as a political and economic project. The days ahead also could trigger a dangerous widening of the economic gap between emerging markets and the developed world – with escalating conflict and surging migration. It may seem premature to reflect on which of the globe’s economies is likely to have the most robust and lasting economic comeback – and with what geopolitical impact. After all, this was a week in which the International Monetary Fund [projected](https://www.imf.org/en/Publications/WEO/Issues/2020/04/14/weo-april-2020) a 3% contraction in global GDP for 2020, the most dramatic drop since the Great Depression. Yet it is the details behind that dismal forecast that should raise concerns within the U.S. and Europe. Their steeper economic decline and slower recovery could lay the seeds for a long-lasting shift of global tectonic plates to China’s advantage. The IMF projected a U.S. economic decline of about 6% in 2020 and a contraction of the eurozone of 7.5%. That compares to projected Chinese economic growth for 2020 of 1.2% after a first quarter real decline of 6.7% – far less than the 10%-plus dip many experts had expected. The only group of countries in the world projected to be in positive territory are East Asian, at roughly 1%. Even if one accepts that Chinese coronavirus fatalities likely are greater than their public figures and that the growth decline is likely larger, that doesn’t change the potential for a scenario that Deloitte and Salesforce this week [referred to](https://www2.deloitte.com/global/en/pages/about-deloitte/articles/covid-19/covid-19-scenarios-and-impacts-for-business-and-society-world-remade.html) as “Sunrise in the East.” Describing this scenario, as one of four possibilities they list, they write, “The global center of power shifts decisively east as China and other East Asian nations take the reigns as primary powers on the world stage and lead global coordination of the health system and other multilateral institutions.” That comes with the broader acceptance of greater surveillance mechanisms as part of the public good, a faster recovery of East Asian countries with less economic impact from COVID19, and a significant ramping up of Chinese foreign direct investment to burnish its global reputation. Still, the U.S. has a host of incumbent advantages that could serve it well if it uses its economic recovery to also strengthen its infrastructure, if it reverses runaway unemployment quickly, if it can tame political polarization and, most significantly, if it rediscovers its taste for collaborative global leadership. In the economic race, no advantage is greater than the dollar. China may be the world’s second largest economy, but the Chinese yuan [makes up](https://asiatimes.com/2019/12/yuan-globalization-remains-a-long-way-off/) only 2% of global payments and reserves while the dollar [accounts](https://asiatimes.com/2019/12/yuan-globalization-remains-a-long-way-off/) for roughly two thirds of foreign exchange reserves. The dollar [underpins](https://www.economist.com/finance-and-economics/2020/04/16/the-dollars-dominance-masks-chinas-rise-in-finance) four-fifths of global supply chains. The Economist [reckons](https://www.economist.com/finance-and-economics/2020/04/16/the-dollars-dominance-masks-chinas-rise-in-finance) China could chip away at U.S. economic advantages through three underestimated strengths of its own: as a trusted debtor, an attractive creditor, and increasingly as a tech partner. As a debtor, China’s $13 trillion bond market is the world’s second largest and [has weathered the crisis well](https://www.ft.com/content/41044876-6ab4-11ea-a3c9-1fe6fedcca75). Chinese debt [returned](https://www.cbsnews.com/news/china-cuts-us-treasury-debt-holding-by-13/) 1.3% in the first quarter, vastly better than the 15.5% [decline](https://www.economist.com/finance-and-economics/2020/04/16/the-dollars-dominance-masks-chinas-rise-in-finance) for other emerging market bonds. Over the same period, the Chinese market added $8.5 billion (60 billion yuan) in net inflows. As a creditor, China has remained willing and generous, an approach that served the U.S. well after World War II. For example, it [declared](https://www.ft.com/content/5f296d54-d29e-4e87-ae7d-95ca6c0598d5) its willingness to back a G20 deal to suspend bilateral loan repayments by poorer countries, a sizable benefit also at its own cost. On the tech front, few countries were as ready as China for money and people to go entirely online. Tencent and Ant Financial have more than a billion users each for their digital wallets, and they are expanding rapidly throughout Asia. OneConnect, an offshoot of China’s largest insurer, provides financial institutions in sixteen Asian countries with cloud-based services. So, what other advantages can the United States leverage in this race? Never underestimate the brittleness of an authoritarian country under stress. Its broad censorship, it’s opaque legal system, and the nature of its surveillance state are hardly models to emulate. Beyond that, Japanese Prime Minister Shinzo Abe is not alone [in proposing](https://asia.nikkei.com/Editor-s-Picks/China-up-close/Xi-fears-Japan-led-manufacturing-exodus-from-China) that his country relocate high-value supply chains from China. If many countries do the same, the manufacturing foundation of China’s economy could erode. The Financial Times’ Gideon Rachman [adds](https://www.ft.com/content/2e8c8f76-7cbd-11ea-8fdb-7ec06edeef84) that the global trust in the dollar is just one of two built-in U.S. advantages that are difficult to dislodge. The other? “Where, outside your home country, would you most like your children to go to university or to work?” he writes. Most significant in this race would be if the United States regained its appetite for political and economic leadership as the world’s premier “convening power.” That need not be done at the cost of China – or anyone else. The race still can be won if U.S. leaders see it as a marathon and recall that much of the world long embraced their global leadership because partners learned they were more likely to win as American partners. This economic rebound from COVID19 will be patchy and uneven. Being first out the gate will be significant, and that is likely to be China. Yet history has taught the United States that it’s victory will be longest lasting if it can achieved alongside partners and allies.

#### Nuclear war

Henricksen 17, emeritus senior fellow at the Hoover Institution (Thomas, “Post-American World Order,” *Hoover Institution*, <http://www.hoover.org/research/post-american-world-order>)

The tensions stoked by the assertive regimes in the Kremlin or Tiananmen Square could spark a political or military incident that might set off a chain reaction leading to a large-scale war. Historically, powerful rivalries nearly always lead to at least skirmishes, if not a full-blown war. The anomalous Cold War era spared the United States and Soviet Russia a direct conflict, largely from concerns that one would trigger a nuclear exchange destroying both states and much of the world. Such a repetition might reoccur in the unfolding three-cornered geopolitical world. It seems safe to acknowledge that an ascendant China and a resurgent Russia will persist in their geo-strategic ambitions. What Is To Be Done? The first marching order is to dodge any kind of perpetual war of the sort that George Orwell outlined in “1984,” which engulfed the three super states of Eastasia, Eurasia, and Oceania, and made possible the totalitarian Big Brother regime. A long-running Cold War-type confrontation would almost certainly take another form than the one that ran from 1945 until the downfall of the Soviet Union. What prescriptions can be offered in the face of the escalating competition among the three global powers? First, by staying militarily and economically strong, the United States will have the resources to deter its peers’ hawkish behavior that might otherwise trigger a major conflict. Judging by the history of the Cold War, the coming strategic chess match with Russia and China will prove tense and demanding—since all the countries boast nuclear arms and long-range ballistic missiles. Next, the United States should widen and sustain willing coalitions of partners, something at which America excels, and at which China and Russia fail conspicuously. There can be little room for error in fraught crises among nuclear-weaponized and hostile powers. Short- and long-term standoffs are likely, as they were during the Cold War. Thus, the playbook, in part, involves a waiting game in which each power looks to its rivals to suffer grievous internal problems which could entail a collapse, as happened to the Soviet Union.

### 5

#### CP: The member nations of the World Trade Organization should enter into a prior and binding consultation with the World Health Organization over whether to [plan]. Member nations should support the proposal and adopt the results of consultation.

#### WHO says yes – it supports increasing the availability of generics and limiting TRIPS

Hoen 03 [(Ellen T., researcher at the University Medical Centre at the University of Groningen, The Netherlands who has been listed as one of the 50 most influential people in intellectual property by the journal Managing Intellectual Property, PhD from the University of Groningen) “TRIPS, Pharmaceutical Patents and Access to Essential Medicines: Seattle, Doha and Beyond,” Chicago Journal of International Law, 2003] JL

However, subsequent resolutions of the World Health Assembly have strengthened the WHO’s mandate in the trade arena. In 2001, the World Health Assembly adopted two resolutions in particular that had a bearing on the debate over TRIPS [30]. The resolutions addressed:

– the need to strengthen policies to increase the availability of generic drugs;

– and the need to evaluate the impact of TRIPS on access to drugs, local manufacturing capacity, and the development of new drugs

#### Consultation boosts strong leadership, authority, and cohesion among member states – key to WHO legitimacy

Gostin et al 15 [(Lawrence O., Linda D. & Timothy J. O’Neill Professor of Global Health Law at Georgetown University, Faculty Director of the O’Neill Institute for National & Global Health Law, Director of the World Health Organization Collaborating Center on Public Health Law & Human Rights, JD from Duke University) “The Normative Authority of the World Health Organization,” Georgetown University Law Center, 5/2/2015] JL

Members want the WHO to exert leadership, harmonize disparate activities, and set priorities. Yet they resist intrusions into their sovereignty, and want to exert control. In other words, ‘everyone desires coordination, but no one wants to be coordinated.’ States often ardently defend their geostrategic interests. As the Indonesian virus-sharing episode illustrates, the WHO is pulled between power blocs, with North America and Europe (the primary funders) on one side and emerging economies such as Brazil, China, and India on the other. An inherent tension exists between richer ‘net contributor’ states and poorer ‘net recipient’ states, with the former seeking smaller WHO budgets and the latter larger budgets.

Overall, national politics drive self-interest, with states resisting externally imposed obligations for funding and action. Some political leaders express antipathy to, even distrust of, UN institutions, viewing them as bureaucratic and inefficient. In this political environment, it is unsurprising that members fail to act as shareholders. Ebola placed into stark relief the failure of the international community to increase capacities as required by the IHR. Guinea, Liberia and Sierra Leone had some of the world's weakest health systems, with little capacity to either monitor or respond to the Ebola epidemic.20 This caused enormous suffering in West Africa and placed countries throughout the region e and the world e at risk. Member states should recognize that the health of their citizens depends on strengthening others' capacity. The WHO has a central role in creating systems to facilitate and encourage such cooperation.

The WHO cannot succeed unless members act as shareholders, foregoing a measure of sovereignty for the global common good. It is in all states' interests to have a strong global health leader, safeguarding health security, building health systems, and reducing health inequalities. But that will not happen unless members fund the Organization generously, grant it authority and flexibility, and hold it accountable.

#### WHO is critical to disease prevention – it is the only international institution that can disperse information, standardize global public health, and facilitate public-private cooperation

Murtugudde 20 [(Raghu, professor of atmospheric and oceanic science at the University of Maryland, PhD in mechanical engineering from Columbia University) “Why We Need the World Health Organization Now More Than Ever,” Science, 4/19/2020] JL

WHO continues to play an indispensable role during the current COVID-19 outbreak itself. In November 2018, the US National Academies of Sciences, Engineering and Medicine organised a workshop to explore lessons from past influenza outbreaks and so develop recommendations for pandemic preparedness for 2030. The salient findings serve well to underscore the critical role of WHO for humankind.

The world’s influenza burden has only increased in the last two decades, a period in which there have also been 30 new zoonotic diseases. A warming world with increasing humidity, lost habitats and industrial livestock/poultry farming has many opportunities for pathogens to move from animals and birds to humans. Increasing global connectivity simply catalyses this process, as much as it catalyses economic growth.

WHO coordinates health research, clinical trials, drug safety, vaccine development, surveillance, virus sharing, etc. The importance of WHO’s work on immunisation across the globe, especially with HIV, can hardly be overstated. It has a rich track record of collaborating with private-sector organisations to advance research and development of health solutions and improving their access in the global south.

It discharges its duties while maintaining a dynamic equilibrium between such diverse and powerful forces as national securities, economic interests, human rights and ethics. COVID-19 has highlighted how political calculations can hamper data-sharing and mitigation efforts within and across national borders, and WHO often simply becomes a convenient political scapegoat in such situations.

International Health Regulations, a 2005 agreement between 196 countries to work together for global health security, focuses on detection, assessment and reporting of public health events, and also includes non-pharmaceutical interventions such as travel and trade restrictions. WHO coordinates and helps build capacity to implement IHR.

#### WHO diplomacy solves great power conflict

Murphy 20 [(Chris, U.S. senator from Connecticut serving on the U.S. Senate Foreign Relations Committee) “The Answer is to Empower, Not Attack, the World Health Organization,” War on the Rocks, 4/21/2020] JL

The World Health Organization is critical to stopping disease outbreaks and strengthening public health systems in developing countries, where COVID-19 is starting to appear. Yemen announced its first infection earlier this month, and other countries in Africa, Asia and the Middle East are at severe risk. Millions of refugees rely on the World Health Organization for their health care, and millions of children rely on the WHO and UNICEF to access vaccines.

The World Health Organization is not perfect, but its team of doctors and public health experts have had major successes. Their most impressive claim to fame is the eradication of smallpox – no small feat. More recently, the World Health Organization has led an effort to rid the world of two of the three strains of polio, and they are close to completing the trifecta.

These investments are not just the right thing to do; they benefit the United States. Improving health outcomes abroad provides greater political and economic stability, increasing demand for U.S. exports. And, as we are all learning now, it is in America’s national security interest for countries to effectively detect and respond to potential pandemics before they reach our shores.

As the United States looks to develop a new global system of pandemic prevention, there is absolutely no way to do that job without the World Health Organization. Uniquely, it puts traditional adversaries – like Russia and the United States, India and Pakistan, or Iran and Saudi Arabia – all around the same big table to take on global health challenges. It has relationships with the public health leaders of every nation, decades of experience in tackling viruses and diseases, and the ability to bring countries together to tackle big projects. This ability to bridge divides and work across borders cannot be torn down and recreated – not in today’s environment of major power competition – and so there is simply no way to build an effective international anti-pandemic infrastructure without the World Health Organization at the center.

#### Ought means should

Merriam Webster n.d. – Merriam Webster’s Learner’s Dictionary, “ought”, <http://www.learnersdictionary.com/definition/ought>  
ought /ˈɑːt/ verb  
Learner's definition of OUGHT [modal verb] 1 ◊ Ought is almost always followed by to and the infinitive form of a verb. The phrase ought to has the same meaning as should and is used in the same ways, but it is less common and somewhat more formal. The negative forms ought not and oughtn't are often used without a following to. — used to indicate what is expected They ought to be here by now. You ought to be able to read this book. There ought to be a gas station on the way. 2 — used to say or suggest what should be done You ought to get some rest. That leak ought to be fixed. You ought to do your homework.

#### Should means must and is immediate

Summers 94 (Justice – Oklahoma Supreme Court, “Kelsey v. Dollarsaver Food Warehouse of Durant”, 1994 OK 123, 11-8, http://www.oscn.net/applications/oscn/DeliverDocument.asp?CiteID=20287#marker3fn13)

¶4 The legal question to be resolved by the court is whether the word "should"[13](http://www.oscn.net/applications/oscn/DeliverDocument.asp?CiteID=20287#marker3fn13) in the May 18 order connotes futurity or may be deemed a ruling in praesenti.[14](http://www.oscn.net/applications/oscn/DeliverDocument.asp?CiteID=20287#marker3fn14) The answer to this query is not to be divined from rules of grammar;[15](http://www.oscn.net/applications/oscn/DeliverDocument.asp?CiteID=20287#marker3fn15) it must be governed by the age-old practice culture of legal professionals and its immemorial language usage. To determine if the omission (from the critical May 18 entry) of the turgid phrase, "and the same hereby is", (1) makes it an in futuro ruling - i.e., an expression of what the judge will or would do at a later stage - or (2) constitutes an in in praesenti resolution of a disputed law issue, the trial judge's intent must be garnered from the four corners of the entire record.[16](http://www.oscn.net/applications/oscn/DeliverDocument.asp?CiteID=20287#marker3fn16) [CONTINUES – TO FOOTNOTE] [13](http://www.oscn.net/applications/oscn/DeliverDocument.asp?CiteID=20287#marker2fn13) "*Should*" not only is used as a "present indicative" synonymous with *ought* but also is the past tense of "shall" with various shades of meaning not always easy to analyze. See 57 C.J. Shall § 9, Judgments § 121 (1932). O. JESPERSEN, GROWTH AND STRUCTURE OF THE ENGLISH LANGUAGE (1984); St. Louis & S.F.R. Co. v. Brown, 45 Okl. 143, 144 P. 1075, 1080-81 (1914). For a more detailed explanation, see the Partridge quotation infra note 15. Certain contexts mandate a construction of the term "should" as more than merely indicating preference or desirability. Brown, supra at 1080-81 (jury instructions stating that jurors "should" reduce the amount of damages in proportion to the amount of contributory negligence of the plaintiff was held to imply an *obligation* *and to be more than advisory*); Carrigan v. California Horse Racing Board, 60 Wash. App. 79, [802 P.2d 813](http://www.oscn.net/applications/oscn/deliverdocument.asp?box1=802&box2=P.2D&box3=813) (1990) (one of the Rules of Appellate Procedure requiring that a party "should devote a section of the brief to the request for the fee or expenses" was interpreted to mean that a party is under an *obligation* to include the requested segment); State v. Rack, 318 S.W.2d 211, 215 (Mo. 1958) ("should" would mean the same as "shall" or "must" when used in an instruction to the jury which tells the triers they "should disregard false testimony"). [14](http://www.oscn.net/applications/oscn/DeliverDocument.asp?CiteID=20287#marker2fn14) In praesenti means literally "at the present time." BLACK'S LAW DICTIONARY 792 (6th Ed. 1990). In legal parlance the phrase denotes that which in law is presently or immediately effective, as opposed to something that will or would become effective in the future *[in futurol*]. See Van Wyck v. Knevals, [106 U.S. 360](http://www.oscn.net/applications/oscn/deliverdocument.asp?box1=106&box2=U.S.&box3=360), 365, 1 S.Ct. 336, 337, 27 L.Ed. 201 (1882).

## Case

### Toplevel

#### Framework – the role of the judge is to vote for the better debater and the role of the ballot is to determine whether the plan is a good idea through evaluation of consequences.

#### 1] Don’t let them weigh the sum total of their impact—they only get to weigh the unique amount solved by the affirmative. Filter the debate through scope of solvency—there’s no impact to root cause if they don’t solve it

#### 2] No performative or methodological offense, only offense from the plan—reject it cuz it explodes predictable limits, spiking out of neg ground making any discussion qualitatively worse

#### 3] Our impacts matter

#### A] Existential threats outweigh – all life has infinite value and extinction eliminates the possibility for future generations – err negative, because of innate cognitive biases

GPP 17 (Global Priorities Project, Future of Humanity Institute at the University of Oxford, Ministry for Foreign Affairs of Finland, “Existential Risk: Diplomacy and Governance,” Global Priorities Project, 2017, <https://www.fhi.ox.ac.uk/wp-content/uploads/Existential-Risks-2017-01-23.pdf>,

1.2. THE ETHICS OF EXISTENTIAL RISK In his book Reasons and Persons, Oxford philosopher Derek Parfit advanced an influential argument about the importance of avoiding extinction: I believe that if we destroy mankind, as we now can, this outcome will be much worse than most people think. Compare three outcomes: (1) Peace. (2) A nuclear war that kills 99% of the world’s existing population. (3) A nuclear war that kills 100%. (2) would be worse than (1), and (3) would be worse than (2). Which is the greater of these two differences? Most people believe that the greater difference is between (1) and (2). I believe that the difference between (2) and (3) is very much greater. ... The Earth will remain habitable for at least another billion years. Civilization began only a few thousand years ago. If we do not destroy mankind, these few thousand years may be only a tiny fraction of the whole of civilized human history. The difference between (2) and (3) may thus be the difference between this tiny fraction and all of the rest of this history. If we compare this possible history to a day, what has occurred so far is only a fraction of a second.65 In this argument, it seems that Parfit is assuming that the survivors of a nuclear war that kills 99% of the population would eventually be able to recover civilisation without long-term effect. As we have seen, this may not be a safe assumption – but for the purposes of this thought experiment, the point stands. What makes existential catastrophes especially bad is that they would “destroy the future,” as another Oxford philosopher, Nick Bostrom, puts it.66 This future could potentially be extremely long and full of flourishing, and would therefore have extremely large value. In standard risk analysis, when working out how to respond to risk, we work out the expected value of risk reduction, by weighing the probability that an action will prevent an adverse event against the severity of the event. Because the value of preventing existential catastrophe is so vast, even a tiny probability of prevention has huge expected value.67 Of course, there is persisting reasonable disagreement about ethics and there are a number of ways one might resist this conclusion.68 Therefore, it would be unjustified to be overconfident in Parfit and Bostrom’s argument. In some areas, government policy does give significant weight to future generations. For example, in assessing the risks of nuclear waste storage, governments have considered timeframes of thousands, hundreds of thousands, and even a million years.69 Justifications for this policy usually appeal to principles of intergenerational equity according to which future generations ought to get as much protection as current generations.70 Similarly, widely accepted norms of sustainable development require development that meets the needs of the current generation without compromising the ability of future generations to meet their own needs.71 However, when it comes to existential risk, it would seem that we fail to live up to principles of intergenerational equity. Existential catastrophe would not only give future generations less than the current generations; it would give them nothing. Indeed, reducing existential risk plausibly has a quite low cost for us in comparison with the huge expected value it has for future generations. In spite of this, relatively little is done to reduce existential risk. Unless we give up on norms of intergenerational equity, they give us a strong case for significantly increasing our efforts to reduce existential risks. 1.3. WHY EXISTENTIAL RISKS MAY BE SYSTEMATICALLY UNDERINVESTED IN, AND THE ROLE OF THE INTERNATIONAL COMMUNITY In spite of the importance of existential risk reduction, it probably receives less attention than is warranted. As a result, concerted international cooperation is required if we are to receive adequate protection from existential risks. 1.3.1. Why existential risks are likely to be underinvested in There are several reasons why existential risk reduction is likely to be underinvested in. Firstly, it is a global public good. Economic theory predicts that such goods tend to be underprovided. The benefits of existential risk reduction are widely and indivisibly dispersed around the globe from the countries responsible for taking action. Consequently, a country which reduces existential risk gains only a small portion of the benefits but bears the full brunt of the costs. Countries thus have strong incentives to free ride, receiving the benefits of risk reduction without contributing. As a result, too few do what is in the common interest. Secondly, as already suggested above, existential risk reduction is an intergenerational public good: most of the benefits are enjoyed by future generations who have no say in the political process. For these goods, the problem is temporal free riding: the current generation enjoys the benefits of inaction while future generations bear the costs. Thirdly, many existential risks, such as machine superintelligence, engineered pandemics, and solar geoengineering, pose an unprecedented and uncertain future threat. Consequently, it is hard to develop a satisfactory governance regime for them: there are few existing governance instruments which can be applied to these risks, and it is unclear what shape new instruments should take. In this way, our position with regard to these emerging risks is comparable to the one we faced when nuclear weapons first became available. Cognitive biases also lead people to underestimate existential risks. Since there have not been any catastrophes of this magnitude, these risks are not salient to politicians and the public.72 This is an example of the misapplication of the availability heuristic, a mental shortcut which assumes that something is important only if it can be readily recalled. Another cognitive bias affecting perceptions of existential risk is scope neglect. In a seminal 1992 study, three groups were asked how much they would be willing to pay to save 2,000, 20,000 or 200,000 birds from drowning in uncovered oil ponds. The groups answered $80, $78, and $88, respectively.73 In this case, the size of the benefits had little effect on the scale of the preferred response. People become numbed to the effect of saving lives when the numbers get too large. 74 Scope neglect is a particularly acute problem for existential risk because the numbers at stake are so large. Due to scope neglect, decision-makers are prone to treat existential risks in a similar way to problems which are less severe by many orders of magnitude. A wide range of other cognitive biases are likely to affect the evaluation of existential risks.75

#### B] We access their role of the ballot—extinction by any process would cause massive suffering and obviously affects minorities. Proves even if they win their framing, extinction is still a tiebreaker – we’re not abstraction/inconsistent w their framing if we win our scenario

#### C] Anything other than probability \* magnitude is arbitrary and ethically irresponsible because it would justify a 100% chance of resolving a small amount of current suffering outweighs a 99% chance of preventing extinction, which is ethically disastrous and proves magnitude has to matter

#### 4] Yes 2n answers to 1ar cross apps of 1ac ev – a] clash, b] neg strat

#### Focus on large scale catastrophes is good and they outweigh – appeals to social costs, moral rules, and securitization play into cognitive biases and flawed risk calculus – 2020 is living proof

Weber 20 (ELKE U. WEBER is Gerhard R. Andlinger Professor in Energy and the Environment and Professor of Psychology and Public Affairs at Princeton University.), November-December 2020 Issue, "Heads in the Sand," Foreign Affairs, <https://www.foreignaffairs.com/articles/2020-10-13/heads-sand> mvp

We are living in a time of crisis. From the immediate challenge of the COVID-19 pandemic to the looming existential threat of climate change, the world is grappling with massive global dangers—to say nothing of countless problems within countries, such as inequality, cyberattacks, unemployment, systemic racism, and obesity. In any given crisis, the right response is often clear. Wear a mask and keep away from other people. Burn less fossil fuel. Redistribute income. Protect digital infrastructure. The answers are out there. What’s lacking are governments that can translate them into actual policy. As a result, the crises continue. The death toll from the pandemic skyrockets, and the world makes dangerously slow progress on climate change, and so on.

It’s no secret how governments should react in times of crisis. First, they need to be nimble. Nimble means moving quickly, because problems often grow at exponential rates: a contagious virus, for example, or greenhouse gas emissions. That makes early action crucial and procrastination disastrous. Nimble also means adaptive. Policymakers need to continuously adjust their responses to crises as they learn from their own experience and from the work of scientists. Second, governments need to act wisely. That means incorporating the full range of scientific knowledge available about the problem at hand. It means embracing uncertainty, rather than willfully ignoring it. And it means thinking in terms of a long time horizon, rather than merely until the next election. But so often, policymakers are anything but nimble and wise. They are slow, inflexible, uninformed, overconfident, and myopic.

Why is everyone doing so badly? Part of the explanation lies in the inherent qualities of crises. Crises typically require navigating between risks. In the COVID-19 pandemic, policymakers want to save lives and jobs. With climate change, they seek a balance between avoiding extreme weather and allowing economic growth. Such tradeoffs are hard as it is, and they are further complicated by the fact that costs and benefits are not evenly distributed among stakeholders, making conflict a seemingly unavoidable part of any policy choice. Vested interests attempt to forestall needed action, using their money to influence decision-makers and the media. To make matters worse, policymakers must pay sustained attention to multiple issues and multiple constituencies over time. They must accept large amounts of uncertainty. Often, then, the easiest response is to stick with the status quo. But that can be a singularly dangerous response to many new hazards. After all, with the pandemic, business as usual would mean no social distancing. With climate change, it would mean continuing to burn fossil fuels.

But the explanation for humanity’s woeful response to crises goes beyond politics and incentives. To truly understand the failure to act, one must turn to human psychology. It is there that one can grasp the full impediments to proper decision-making—the cognitive biases, emotional reactions, and suboptimal shortcuts that hold policymakers back—and the tools to overcome them.

AVOIDING THE UNCOMFORTABLE

People are singularly bad at predicting and preparing for catastrophes. Many of these events are “black swans,” rare and unpredictable occurrences that most people find difficult to imagine, seemingly falling into the realm of science fiction. Others are “gray rhinos,” large and not uncommon threats that are still neglected until they stare you in the face

(such as a coronavirus outbreak). Then there are “invisible gorillas,” threats in full view that should be noticed but aren’t—so named for a psychological experiment in which subjects watching a clip of a basketball game were so fixated on the players that they missed a person in a gorilla costume walking through the frame. Even professional forecasters, including security analysts, have a poor track record when it comes to accurately anticipating events. The COVID-19 crisis, in which a dystopic science-fiction narrative came to life and took everyone by surprise, serves as a cautionary tale about humans’ inability to foresee important events.

Not only do humans fail to anticipate crises; they also fail to respond rationally to them. At best, people display “bounded rationality,” the idea that instead of carefully considering their options and making perfectly rational decisions that optimize their preferences, humans in the real world act quickly and imperfectly, limited as they are by time and cognitive capacity. Add in the stress generated by crises, and their performance gets even worse.

Because humans don’t have enough time, information, or processing power to deliberate rationally, they have evolved easier ways of making decisions. They rely on their emotions, which serve as an early warning system of sorts: alerting people that they are in a positive context that can be explored and exploited or in a negative context where fight or flight is the appropriate response. They also rely on rules. To simplify decision-making, they might follow standard operating procedures or abide by some sort of moral code. They might decide to imitate the action taken by other people whom they trust or admire. They might follow what they perceive to be widespread norms. Out of habit, they might continue to do what they have been doing unless there is overwhelming evidence against it.

Not only do humans fail to anticipate crises; they also fail to respond rationally to them.

Humans evolved these shortcuts because they require little effort and work well in a broad range of situations. Without access to a real-time map of prey in different hunting grounds, for example, a prehistoric hunter might have resorted to a simple rule of thumb: look for animals where his fellow tribesmen found them yesterday. But in times of crisis, emotions and rules are not always helpful drivers of decision-making. High stakes, uncertainty, tradeoffs, and conflict—all elicit negative emotions, which can impede wise responses. Uncertainty is scary, as it signals an inability to predict what will happen, and what cannot be predicted might be deadly. The vast majority of people are already risk averse under normal circumstances. Under stress, they become even more so, and they retreat to the familiar comfort of the status quo. From gun laws to fossil fuel subsidies, once a piece of legislation is in place, it is hard to dislodge it, even when cost-benefit analysis argues for change.

### Case

#### Contamination, poor-quality ingredients, falsified data, and lax FDA regulations abroad ensure generics are worse quality and even adverse effects – their authors are suspect because most experts consistently downplay valid public concerns.

(We aren’t biased against generics cuz most people WANT generics to work – it’s the only way they can afford medication)

Brown 2/10 [Harriet Brown, 2-10-2021, "My Generic Medications Failed Me. I’m Not Alone," No Publication, [https://www.vice.com/en/article/v7mnm3/my-generic-medication-gave-me-constant-nosebleeds-im-not-alone //](https://www.vice.com/en/article/v7mnm3/my-generic-medication-gave-me-constant-nosebleeds-im-not-alone%20//) belle]

I’m kneeling on my driveway, watching blood pour from my nose and stream toward the street. It’s my fourth big nosebleed in four days, and as my husband bundles me into the car, I’m thinking the worst. After a gauntlet of tests, all of which are negative, my doctor says she thinks the nosebleeds were triggered by my antidepressant—specifically by my switching from a generic version to the brand-name. A few months earlier, when the generic hadn’t diminished my panic attacks, she had suggested trying the brand-name, and I’d started it a few days earlier. “You’re suddenly getting a lot more of the active ingredient,” she explains now. “Which you were supposed to get before, on the generic, but clearly weren’t. That’s why you’re having nosebleeds. They’ll stop in a few days.” Most people think generic medications are identical to brand-name drugs; I certainly did. After all, that’s what pharmacists, insurance companies, and doctors tell us. But it’s not exactly true. For one thing, most generics are manufactured abroad, where lax standards, lack of regulation, and outright fraud compromise their quality. Those issues have gotten some well-deserved attention in recent years. For another, while generics are considered “bio-equivalent” to brand-name drugs—meaning they behave the same way in the body—they are not required by the Food and Drug Administration (FDA) to contain exactly the same amount of active ingredient or to deliver it at the same rate or in the same way. In fact, they can’t deliver it the same way, since patents on brand-name medications often include the delivery system. Most people think generic medications are identical to brand-name drugs; I certainly did. After all, that’s what pharmacists, insurance companies, and doctors tell us. But it’s not exactly true. While many people tolerate the differences between generic and brand-name formulations, some of us—as I learned the day I found myself bleeding in the driveway—do not. When I went looking into those differences, I found significant evidence to support this conclusion. Yet for the most part, western medicine insists it cannot be true. Ever since the 1984 Hatch-Waxman Act cleared the way for the wide-scale marketing of generic drugs in the U.S., the FDA has required that generic drugs have the same active ingredient, strength, and dosage form as brand names. “The generic manufacturer must prove its drug is the same (bioequivalent) as the brand-name drug,” said Sandy Walsh, an FDA press officer, in an email. Given that generics make up close to 90% of the U.S. drug supply, and that Americans spend around $300 billion a year on prescriptions, a lot is riding on this system working—about $117 billion a year. So it helps to understand the ways in which brand names and generics hit the market. Pharmaceutical companies that are developing a new (brand name) medication file a New Drug Application (NDA) with the FDA, showing that the drug is both safe and effective for humans. This is done by submitting meticulous documentation of animal and human studies, detailed records of the manufacturing process, analysis of dosage and inactive ingredients, and other evidence that the benefits of the new drug outweigh any risks. Putting together an NDA takes years and costs millions of dollars, much of it spent on research. The road to generic approval is a lot shorter. When the patent on a brand-name drug is about to run out, companies typically file an Abbreviated New Drug Application (ANDA), signaling their intent to produce a generic version of the drug. An ANDA requires no animal trials and very limited human trials.

While a generic is supposed to be chemically similar to its brand-name counterpart, with the same active ingredient in roughly the same amount, it is allowed to vary in quantity by about 10% in either direction. Manufacturers need only test their generic against the brand name in a tiny group of healthy volunteers to show it is bioequivalent. They don’t have to show therapeutic equivalency—that is, they don’t have to prove that patients respond to the generic in the same way they respond to the brand name. It is instead assumed that the generic will produce the same effect because the active ingredient is supposed to be the same. Many ANDAs are aspirational, first filed before a manufacturer has figured out how exactly to produce a generic version of a brand-name drug. And since FDA approval can take as little as six months, an ANDA might be approved before a manufacturer has finalized a generic formulation. Many medical professionals believe this approval process is enough to protect patients and ensure consistency. Experts like Michel Berg, a neurologist who directs the University of Rochester’s Epilepsy Center, say that when people complain about generics not working the way brand names do, it’s usually because they didn’t take the medication correctly: They skipped or added a dose, took it at the wrong time of day, swallowed it with or without food, or in some other way violated what Berg calls good “medication hygiene.” The road to generic approval is a lot shorter. Richard Hansen, dean of Auburn University’s Harrison School of Pharmacy, points to another contributing factor: the nocebo effect. People expect generics to cause more side effects and be less effective, so that’s what they experience. Hansen calls this the public perception bias. “There’s actual clinical studies that show if you give 100 people the exact same thing but tell half of them that they received a generic, the half you told are going to have more adverse events and lower efficacy,” he said. His solution: education. Teach people that generics are just as good as brand-name drugs and their attitudes will change. But human error and the power of suggestion can’t possibly be the whole story. What about experiences like mine, in which switching to a brand-name drug from the generic caused the problem? Clearly that wasn’t the nocebo effect. And while I’m as fallible as anyone else, I’m certain that in this case I was taking the medication correctly. Many of the experts I talked to for this story dismissed or downplayed questions about generics. One researcher who didn’t is Jacinthe Leclerc, an assistant professor of nursing at the University of Québec at Trois-Rivieres. Leclerc and her colleagues noticed an interesting pattern when they studied cardiac drugs: When a new generic became available and patients switched, they saw many more adverse effects. “For example, switching from a brand name anti-hypertensive drug to a generic one, the patients got more swollen,” she explained. Leclerc and her team analyzed data for a number of widely prescribed cardiac medications and found that when new generics were introduced, and people switched to them, hospitalizations and emergency room visits went up. Leclerc says the nocebo effect can’t possibly explain this finding. In fact, there’s a counterargument to the nocebo premise, one Hansen and others don’t take into account: Most people want generics to work because that’s the only way they can afford their medication. (When asked if his team had considered this, Hansen said, “That’s not something we’ve looked at in particular.”) Erica Smith, a 50-year-old software designer in Oakland, California, found herself in this situation after her pharmacy switched her to a generic antidepressant made in India. Smith began having symptoms like brain “zaps” and extreme irritability, signs that she wasn’t getting as much of the active ingredient as she had before. She looked into getting the brand-name, which cost $400 for a month’s supply. “Insurance of course did not cover that, so of course I didn’t get it,” she recalled. Charlynn Schmiedt, a 36-year-old entrepreneur in San Dimas, California, was one of hundreds of patients who reported massive side effects and symptoms after switching from the brand-name Wellbutrin, a popular antidepressant, to Teva Pharmaceuticals’s generic extended-release, version, bupropion XL. Schmiedt’s doctor had given her a few weeks’ worth of brand-name samples, and as she took them her depression and anxiety began to subside. When the samples ran out, she filled a prescription and got the Teva generic. “It was a massive 180-degree shift,” she remembered. “It was horrible. I got really angry, I got agitated, I would cry at the drop of a hat. I was a wreck.” Schmiedt lasted three weeks on the generic before she quit. Like many patients, she couldn’t afford the brand-name, so she went through months of trial and error before finding another medication that helped her symptoms. In 2012, after years of complaints from patients like Schmiedt, the FDA more or less acknowledged that Teva’s generic was problematic by pulling it from sale, a step the agency almost never takes. Journalist Katherine Eban, author of the book Bottle of Lies: The Inside Story of the Generic Drug Boom, was surprised by the FDA’s reversal but not by Teva’s problems. The vast majority of generics—no one seems to know exactly what percentage—used in the U.S. are sourced or manufactured in India, China, and other countries. Eban spent 10 years investigating overseas manufacturers and found a jaw-dropping range of problems, including poor-quality ingredients, contamination, dangerous plant conditions, and outright fraud and deception. Pharmaceutical companies like Ranbaxy, a former Indian manufacturer, deliberately falsified data to fool regulators, lying to regulators about safety tests and results and then covering up those lies with more falsehoods. The reality is that the FDA simply doesn’t have the resources to monitor overseas drug makers the way they do U.S. manufacturers. The result, according to Eban, is that many of the medications we take today are ineffective or worse. “We need systematic surveillance testing of our drugs, which is not happening,” she told me. And that doesn’t apply just to medicine made overseas. No matter where they’re made, generics are subject to far less testing than original brand-name drugs. As the FDA’s Walsh explained, “Generic drug applications are termed ‘abbreviated’ because they are not required to include preclinical (animal) and clinical (human) data to establish safety and effectiveness. Instead, generic applicants must scientifically demonstrate that their product performs in the same manner as the innovator drug.” Pharmaceutical companies like Ranbaxy, a former Indian manufacturer, deliberately falsified data to fool regulators, lying to regulators about safety tests and results and then covering up those lies with more falsehoods. “We’ve got a lot of companies that lie, that manipulate data,” said Joe Graedon, a pharmacologist and co-founder of the pharmaceutical watchdog site People’s Pharmacy. “There’s examples of fraud left and right. Quality control has been clearly a huge problem both in China and India but many other countries as well, and the FDA is probably not monitoring many of these countries as well as it should.” Douglas Kamerow, a family doctor and medical researcher in Washington, D.C., put it this way in an article in The BMJ: “Full clinical trials are not required to approve generics—that’s why they are so inexpensive, after all—so true clinical equivalence is never tested.” But what about the Wellbutrin example? Presumably that wasn’t the result of fraud or low standards. How could something like this happen if, as the FDA insists, generics makers are required to prove that their products are bioequivalent? The problem in this case turned out to be the rate at which the extended-release generic was absorbed into the body. “[Levels of] the brand name peaked somewhere around five or six hours. The generic peaked around one or two hours,” said Graedon. So people who took the generic got a big dump of the active ingredient too quickly, and then it left their systems too soon. “That was what, in my estimation, led to all the complications people experienced,” he added. “They had a lot of side effects from the generic and they didn’t get the clinical benefit of this antidepressant.” (Teva did not respond to multiple requests for comment.) To visualize the process, Graedon asked me to imagine a spreadsheet tracking a city’s water usage over a 24-hour period, showing peaks and valleys depending on the time of day. For instance, a lot more water would be used at 7 a.m., when people are showering and cooking, than at 2 a.m., when most people are asleep. That, he says, is the kind of detailed data needed to follow exactly how a generic is absorbed. “You want to know how much was absorbed at half an hour, an hour, two hours, all the way through,” he said. The bupropion XL problems would have been obvious with this kind of tracking over time. According to Graedon, the FDA asks for this information from drug companies but doesn’t incorporate it in decisions about which generics are approved. Another reason generics sometimes don’t behave the way brand drugs do involves what’s known as inter-subject variability. William Ravis, a retired professor of drug discovery and development at Auburn University, spent four decades studying pharmacokinetics, or how drugs move through the body. He pointed out that certain drugs have a lot of variability in terms of how they metabolize and behave. “The majority of patients might not show a difference in exchanging one product for another,” he explained. “But if you handle the drug too much differently from somebody else or you’re taking other medications than somebody else, that may put you right on the edge where it’s toxic or you lose the therapeutic effects.” For example, Ravis said, it’s been well documented that switching from one thyroid medication to another, even if they’ve been shown to be bioequivalent, can cause problems. “There are things going on there in absorption, or body sensitivity to T4 or T3 products, or thyroid hormones, that is different in different patients,” he said. “Drugs produce their effects on receptors in the body and those all don’t respond the same way in every patient.” In fact, one member of his own family pays out of pocket for a brand-name thyroid drug that’s not covered by their insurance, because the generics don’t work for them. Neurologist Gregory Krauss of Johns Hopkins University actually filed Freedom of Information Act requests to get bioequivalence data from the FDA on five generic versions of the epilepsy drug carbamazepine, and learned that maximal concentrations—the peak amount of active ingredient—differed by as much as 40 percent. While many people tolerate those kinds of discrepancies, many don’t. And they might never realize that the problem is the generic version they’re taking rather than the medication itself. Finally, there’s the issue of what experts call the therapeutic index, meaning the margin between an effective dose and a toxic one. If that margin is large, manufacturing discrepancies don’t matter as much; a little more or less of the active ingredient will go unnoticed by most patients. But the smaller the margin—the narrower the therapeutic index—the more likely patients are to experience side effects and failures. While many people tolerate those kinds of discrepancies, many don’t. And they might never realize that the problem is the generic version they’re taking rather than the medication itself. Many psychiatric drugs fall into this category, which might explain why they’re among the most problematic. Studies of antidepressants like Effexor and Celexa, along with anti-psychotics like Risperdal, Clozaril, and Dogmatil, all highlight the fact that some patients do worse on the generic versions than on the brand-name medications. Research on other drugs with narrow therapeutic indexes, or NTIs, like cardiac drugs, immunosuppressants for transplant patients, and epilepsy drugs suggest similar discrepancies, though other studies on seizure medications showed no significant differences between brands and generics. “The narrow therapeutic index drug class, those are tricky,” agrees Jingjing Qian, an associate professor in health outcomes and research at Auburn University. “But in order to verify if that difference is perception or real difference—that needs more research. And there’s no incentive for industry to study generic drugs.” Which is unfortunate for those of us who take those drugs. One of my daughters had a terrifying experience after a change in her insurance forced her to switch from a brand-name antidepressant to a generic one. When her depression roared back following the switch, the psychiatrist upped her dose. A month later, the pharmacy switched her prescription from the Indian generic she had been taking to what’s called an authorized generic, meaning it’s the same exact drug made by the same company that produces the brand-name, but it’s marketed as a generic. And now something was clearly, scarily wrong. Even from a thousand miles away I could tell she was not in good shape. She was speaking so fast I could barely follow; what I did understand was that her anxiety was off the charts, her muscles were twitching and spasming, she hadn’t slept properly in days, and she was talking about suicide. Because I’ve had my own history with generics, I wondered about the medication change. Her symptoms were consistent with serotonin syndrome, a potentially fatal condition caused by a sudden overload of serotonin. Maybe her depression symptoms came back on the generic because it didn’t contain enough active ingredients; then, when the pharmacy switched her to the authorized generic, maybe she was suddenly getting way too much of the active ingredient. She cut back the dose, and thankfully her symptoms subsided. I now pay out of pocket for her to take the brand-name version. She’s had no further problems. Raising these kinds of questions about generics is deeply unpopular. And it’s understandable, in a way, because our healthcare system relies so heavily on generics. Michel Berg, who directs the University of Rochester’s Epilepsy Center, represents the views of many medical professionals when he says, “There’s no perfect here. I think mostly [generics are] pretty good. The cost savings of generics is just so great. I think the advantage of the generics by far in that sense outweighs what problems that might exist that I think are fairly infrequent.” Whether Berg is right or not, without generics, we’d be seeing much higher drug prices and even more drug shortages. Atorvastatin, a generic cholesterol medication, costs about $15 a month, while its brand-name equivalent, Lipitor, goes for between $450 and $500 a month. Abilify, an antipsychotic and antidepressant made by Bristol-Myers Squibb, costs between $700 and $900 a month; the generic version, aripiprazole, goes for around $8. And these aren’t even extreme examples. Cuprimine, a brand-name drug made by Bausch Health to treat rheumatoid arthritis, retails for $26,000 a month; the generic version, penicillamine, costs $7,000. Raising these kinds of questions about generics is deeply unpopular. And it’s understandable, in a way, because our healthcare system relies so heavily on generics. Last September, the Trump administration approved a plan to let states import cheaper medications from Canada and elsewhere, though it is still unclear how exactly this will affect consumers. Several years ago AARP, whose more than 38 million members take an average of 4.5 medications apiece, announced an initiative called Stop Rx Greed, inviting people to “tell Congress to stop Rx greed and cut drug prices now!” Media coverage about profit-hungry pharmaceutical companies like Mylan, the makers of EpiPen that infamously jacked up its price 400 percent, make it politically untenable to do anything that makes the situation worse for consumers. “There’s no plan B for our drug supply,” Eban told me. “We’re facing critical drug shortages, we are reliant on these medications, and there is no meaningful price regulation for brand-name drugs. There is a tremendous amount of political pressure for these low-cost generics.” In a recent story about Eban’s book, published in a trade magazine for biopharma executives, a reviewer commented, “The entire U.S. pharma industry is under attack for its pricing policies, so who wants to question the quality of generics . . . that keep drug costs down?” Who indeed. We’d much rather believe that patients who report issues with generics are biased or victims of misperception because if they’re not, if they’re right about these problems, the whole system is screwed. So where does that leave people like Erica Smith, Charlynn Schmiedt, and the rest of us who have struggled with generics? Awareness is key, starting with awareness of our own perceptions and behaviors. While reporting this story I bought a pill dispenser so I could, as Michel Berg suggested, practice better medication hygiene. But we also need to be aware that there are major manufacturing and safety concerns with some generics. If you think something’s wrong with any medication, generic or not, report it on the FDA’s MedWatch site so the agency can track complaints about it and, ideally, investigate. There is clear scientific evidence that some drugs do affect some people differently, no matter what doctors and pharmacists and insurance companies say. LeClerc of the University of Quebec thinks people need to learn to advocate for themselves when things don’t feel right, and medical professionals need to listen. “When we listen carefully to patients, they say there is something wrong once they switch [from a brand to a generic],” she said. “It cannot only be in their heads.”