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#### Drug price controls coming now but Biden PC key

Weisman 8/12 Weisman, Jonathan. Jonathan Weisman is a congressional correspondent, veteran Washington journalist. "Biden Presses Congress to Act on Prescription Drug Prices." N.Y. Times, 12 Aug. 2021, www.nytimes.com/2021/08/12/us/politics/biden-prescription-drugs.html.

WASHINGTON — President Biden implored Congress on Thursday to include strict controls on prescription drug prices in the mammoth social policy bill that Democrats plan to draft this fall, hitting on an issue that his predecessor campaigned on but failed to achieve.

Mr. Biden said he wanted at least three measures included in the $3.5 trillion social policy bill that Democrats hope to pass using budget rules that would protect it from a Republican filibuster. He wants Medicare to be granted the power to negotiate lower drug prices, pharmaceutical companies to face penalties if they raise prices faster than inflation, and a new cap on how much Medicare recipients have to spend on medications.

“There aren’t a lot of things that almost every American could agree on,” the president said at the White House. “But I think it is safe to say that all of us, whatever our background or our age and where we live, could agree that prescription drug prices are outrageously expensive in America.”

The president was pushing on an open door. Congressional Democrats have already said they want to include all three measures in the so-called reconciliation bill that House and Senate committees hope to assemble.

“The Finance Committee will be a central part of the debate when it comes to lowering Americans’ health care costs and making high-quality health care available to more families,” the panel’s chairman, Senator Ron Wyden of Oregon, said as Senate Democrats unveiled the $3.5 trillion budget blueprint that would allow them to pass the legislation without a Republican vote.

#### Passing a WTO patent waiver stops split-lobbying efforts from Big Pharma – they’ll focus on fighting drug pricing reform instead

Stacey and Asgari 5/26 Kiran Stacey, Washington correspondent for the FT; Nikou Asgari, reporter covering the US pharmaceutical industry. "How drugmakers went from vaccine heroes to patent villains within weeks." 26 May. 2021, www.ft.com/content/96d10dc8-8158-4cbc-9876-0b7d0a1e774e.

The tone of that call, followed by the decision to support a patent waver proposal at the World Trade Organization, has triggered concerns among some in the pharmaceutical industry, who fear they will lose political capital amassed during the pandemic at a crucial moment in their fight against drug pricing controls in the US. “One day Bourla is being feted by the president for making vaccines which will help end the pandemic, the next he is being lectured by one of Biden’s senior officials for not supplying vaccines to India — even though the Pfizer vaccine hasn’t been approved there,” said one person briefed on the call. “It did shake the industry a bit.” American drugmakers have been the target of political criticism for years, accused of fuelling the US opioid epidemic and making their treatments unaffordable for millions of Americans. The fact that the Biden administration was willing to support the [patent] waiver shows . . . the pharma industry is not going to be as strong as it was in the past Michael Carrier, Rutgers university Many in the industry hoped their response to the pandemic would help to persuade politicians and the wider public that the US benefits from having a well-funded pharmaceutical industry with strong intellectual property protections. The country has carried out one of the fastest Covid-19 vaccine rollouts in the world, largely thanks to steady supplies from Pfizer and its smaller rival Moderna. “The Covid-19 vaccine is a proof point for the powerful combination of breakthrough science and the private sector,” said Sally Susman, chief corporate affairs officer at Pfizer. The public agrees. Surveys conducted by The Harris Poll found that approval of the pharmaceutical industry had almost doubled from 32 per cent in January last year to 62 per cent in February this year. But the decision to support the move at the WTO to waive international intellectual property rights on Covid vaccines suggests the Biden administration is not entirely convinced by the arguments put forward by drugmakers’ well-funded army of lobbyists. “The fact that the Biden administration was willing to support the waiver shows the argument has shifted and that the pharma industry is not going to be as strong as it was in the past,” said Michael Carrier, a law professor at Rutgers university in Camden, New Jersey. The industry spends far more on lobbying than any other — more than $92m this year, according to figures compiled by the Washington-based Center for Responsive Politics. That is more than double the outlay from the electronics industry, which is the next heaviest spender. It also donates liberally, and increasingly to Democrats. CRP figures show that 2020 was the first year in which the industry gave significantly more to Democratic candidates than Republican ones. Pfizer donated $1m to Biden’s inaugural fund, though the money did not buy the kind of high-level access it would have done in previous years due to the virtual nature of many of the inaugural events. The industry is primarily occupied by two issues in Washington: the WTO’s proposed intellectual property waiver and legislation to curb drug prices. On the former, companies are keen to limit the scope of any waiver. On the latter, they want to stop a bill that would allow the government to negotiate the prices for certain drugs prescribed to seniors covered by the publicly-funded Medicare scheme. The industry’s most prominent voice on such issues is Steve Ubl, chief executive of industry group Phrma and a veteran Washington operator. “The Biden administration made a politically expedient decision [on the WTO waiver], but we think we are still able to lean in on other debates such as drug pricing,” he said. Some are concerned that Ubl, a former aide to the Republican senator Chuck Grassley, is too obviously corporate and Republican to make inroads in the Democratically-controlled administration and Congress. Instead, some say Michelle McMurry-Heath, the chief executive of the smaller Biotechnology Innovation Organization, might have more success. “Steve has been very successful for years, but Michelle is a bit more dynamic and less buttoned-up,” said one industry lobbyist. Before rushing to do the WTO waiver, perhaps we should get our own house in order first Debra Dixon, Ferox Strategies Those in the industry who have deep connections within the Democratic party are in strong demand, such as Susman, who worked as a senior official in the commerce department during the Clinton administration. Another is Debra Dixon, a former chief of staff to the health secretary Xavier Becerra. Dixon works for Ferox Strategies and was recently hired by Eli Lilly, which has been criticised for raising the prices of its insulin drugs. Dixon said the industry should focus on how therapeutics can “alleviate health disparities” when discussing drug prices. She added: “While the US vaccine rollout has gone well, there are still people falling through the cracks. Before rushing to do the WTO waiver, perhaps we should get our own house in order first.” Moderna, meanwhile, has hired Brownstein Hyatt Farber Schreck as one of its external lobbying firms. Its team includes Nadeam Elshami, the former chief of staff to Nancy Pelosi, the Democratic Speaker of the House of Representatives, and Carmencita Whonder, a former aide to Chuck Schumer, the Democratic Senate majority leader. There are some signs that their efforts are paying off. Earlier this month 10 Democrats in the House sent a letter to Pelosi urging her to pursue drug pricing reforms on a bipartisan basis. That missive was interpreted as a criticism of the proposal for the government to negotiate drug prices, which has little support among Republicans. Recommended Pharmaceuticals sector Biden urged to oblige US vaccine makers to share technology Scott Peters, the lead signatory on that letter, was the sixth-highest recipient in the House of money from the pharma industry in the last election cycle, according to the CRP. Others in Congress also continue to champion the industry, especially those in New Jersey and Delaware, where many pharma companies have a significant presence. Industry lobbyists say they expect Chris Coons, the senator from Delaware and a longtime friend of Biden, to prove a vital ally. Many lobbyists hope that Biden will prove receptive to the industry’s arguments, in part because he worked closely with pharmaceutical companies as vice-president while developing his “cancer moonshot” to help find a cure for the disease. But they do not necessarily need to win the president round. With both houses of Congress finely balanced, a handful of Democratic supporters could squash the reforms being proposed by those on the left of the party. “We don’t need many people to block HR3,” said one industry lobbyist, referring to the proposed bill that would allow the government to negotiate some drug prices. “The 10 people that signed that letter could be enough to get us what we want.”

#### And a WTO waiver takes time, energy, and political capital away from domestic legislation – big pharma and EU allies

Bhadrakumar 5/9 M K Bhadrakumar is a former Indian diplomat. "Biden’s talk of vaccine IP waiver is political theater." Asia Times, May 9, 2021, asiatimes.com/2021/05/bidens-talk-of-vaccine-ip-waiver-is-political-theater.

On the other hand, Biden, whose political life of half a century was largely spent in the US Congress, is well aware of the awesome clout of the pharmaceutical companies in American politics. From that lobby’s perspective, the patent waiver “amounts to the expropriation of the property of the pharmaceutical companies whose innovation and financial investments made the development of Covid-19 vaccines possible in the first place,” as a senior scholar at the Johns Hopkins Center for Health Security puts it. The US pharmaceutical industry and congressional Republicans have already gone on the offensive blasting Biden’s announcement, saying it undermines incentives for American innovation. Besides, the argument goes, even with the patent waiver, vaccine manufacturing is a complex process and is not like simply flipping a switch. Senator Richard Burr, the top Republican on the US Senate Health Committee, denounced Biden’s decision. “Intellectual property protections are part of the reason we have these life-saving products,” he said. “Stripping these protections only ensures we won’t have the vaccines or treatments we need when the next pandemic occurs.” The Republican senators backed by Republican Study Committee chairman Jim Banks propose to introduce legislation to block the move. Clearly, Biden would rather spend his political capital on getting the necessary legislation through Congress to advance his domestic reform agenda rather than spend time and energy to take on the pharmaceutical industry to burnish his image as a good Samaritan on the world stage. Conceivably, Biden could be counting on the “text-based negotiations” at the WTO dragging on for months, if not years, without reaching anywhere. The US support for the waiver could even be a tactic to persuade pharmaceutical firms to back less drastic steps like sharing technology and expanding joint ventures to boost global production quickly. So far Covid-19 vaccines have been distributed primarily to the wealthy countries that developed them, while the pandemic sweeps through poorer ones such as India, and the real goal is, after all, expanded vaccine distribution. Biden is well aware that there will be huge opposition to the TRIPS waiver from the United States’ European allies as well. The British press has reported that the UK has been in closed-door talks at the World Trade Organization in recent months along with the likes of Australia, Canada, Japan, Norway, Singapore, the European Union and the US, who all opposed the idea.

#### The threat of a waiver to manipulate Pharma is good but an actual waiver wastes political capital on other health issues

Silverman 6/2 Rachel Silverman is a policy fellow at the Center for Global Development. Master’s of philosophy with distinction in public health from the University of Cambridge, which she attended as a Gates Cambridge Scholar. She also holds a BA with distinction in international relations and economics from Stanford University.Argument’, 'The. "Opinion | Could Spilling Big Pharma’s Secrets Vaccinate the World?" N.Y. Times, 2 June 2021, [www.nytimes.com/2021/06/02/opinion/covid-vaccine-ip-waiver.html](http://www.nytimes.com/2021/06/02/opinion/covid-vaccine-ip-waiver.html). [the original podcast was between multiple people, only person carded is Silverman so they’re the only person cited]

[rachel silverman] So I very much agree with Tahir that a lot of this is theater. And I guess that gets to part of my concern about the waiver, which is, I’m not, again, that opposed to the waiver per se. I’m a little bit wishy-washy on it. I think there are people who yell doom about it. I don’t think it will spell doom. But what I really am concerned about is that while I do think the waiver campaign has been helpful in terms of putting pressure on the pharmaceutical industry, you know, that threat of a stick that we’re talking about, what I do worry about is that it’s sucking up a lot of political oxygen. And it’s the kind of thing where the U.S. can come out with a statement and say, oh, yes, we support the waiver. And what that will really mean is we spend the next 12 months negotiating it down in the W.T.O., and we coordinate with the Europeans to weaken it further. And everyone applauds, and everyone says, oh, great, what a great move towards vaccine equity. And nothing really comes of it. And it takes pressure off them to address the more immediate challenges. And I’d say we had a letter out from my institution, the Center for Global Development, and some other think tanks, calling on the Biden administration to do a lot more, generally, more money, more support, more engagement, better dose sharing, more leadership in this space. And we haven’t seen it. The reality of the world we live in is there’s a limited amount of political capital. And I’m worried we’re sucking it up on this, which will maybe, maybe best case scenario, have an impact six to nine months down the road if everything goes right, and not the immediate measures that we could be taking worldwide.

#### Drug price controls massively reduce healthcare costs across the board – even assuming conservative models

Gamba 6/9 Gamba, Tyler. Author at the AJMC. "Adoption of the Lower Drug Costs Now Act May Lead to Billions in Savings." AJMC, 9 June 2021, www.ajmc.com/view/adoption-of-the-lower-drug-costs-now-act-may-lead-to-billions-in-savings.

H.R.3, the Elijah E. Cummings Lower Drug Costs Now Act would improve efficiency and produce billions in savings for the commercial health care market’s employers and end consumers if fully implemented, according to a new study from Milliman commissioned by the West Health Policy Center.

Among its goals, the act’s provisions seek to reduce prescription drug costs, increase drug price transparency, lower member out-of-pocket spending, and increase potential coverage eligibility. Costs for the most expensive brand drugs in the United States would be negotiated between the manufacturers and the HHS secretary. Significant drug cost increases over the rate of inflation would need to be issued back as rebates to CMS.

To predict the effects of such reforms, the Milliman study sought quantitative estimates for the scope of these changes. Milliman’s models incorporated several variables, including current trends and projected spending based on different percentage adjustments to drug prices, rebates, and public vs private cost rates from 2023 through 2029.

The study estimates 46% of drug spending would be subject to negotiation under the legislation’s Title I by 2026, with an average 2.5% reduction in total commercial market claims by 2029.Overall, successful implementation of H.R. 3 means employers may reduce their health care expenditures by $195 billion while employees would save $61 billion. Of this latter amount, reduced premiums would account for $53 billion and out-of-pocket costs, $8 billion.

Overall, the market covered by the Affordable Care Act (ACA) could see savings of $58 billion, comprising $34 billon in reduced beneficiary premiums, $21 billion in federal savings by reduced Advance-Premium Tax Credits, and $2 billion in lower cost-sharing.

The estimates assume manufacturers could make such increases to the prices at a faster rate than the current yearly trends. This possibility still leads to stronger total savings via H.R. 3’s Title I. The study does not factor in further limitations on increases by plan sponsors and pharmacy benefit managers, which could improve savings for employers and employees, because it mainly applies to Medicare.

Under the most conservative pricing model—where manufacturers hypothetically increase supply costs to unprecedented highs to minimize revenue loses—$250 billion in lower costs are still passed on to employers and employees.

Additionally, the study notes that although end consumers are generally responsible for most of their plan premiums, and thus would get most of the savings, the federal government also would save on the significant portion it pays toward member premiums in the individual marketplaces.

#### Collapses the economy

Howrigon, 16 — Ron Howrigon, M.S. in Economics with a focus on Health Economics from North Carolina State University, President and Founder of Fulcrum Strategies, 18 Years of Experience in Healthcare, 12-30-2016, “Flatlining: How Healthcare Could Kill the U.S. Economy,” Greenbranch Publishing, 1st Edition, Accessed via Minnesota Libraries, Date Accessed: 8-10

Ok, let’s shift from looking at individuals to looking at the big picture—from micro- to macroeconomics. It’s important to understand where healthcare **fits into the big picture** when it comes to the economy at large. Most people who don’t work in the industry don’t clearly understand how much of the U.S. economy healthcare makes up. In fact, given the size of the economy, healthcare in the U.S. can be impactful on the ***world* economy**. This is important to understand because future changes in healthcare not only affect ow we get care and how much we pay for it, but could also significantly affect things like **unemployment**, the **national debt**, and **interest rates**. The influences on the U.S. economy will have **a ripple effect** on other countries around the world. In 1960, healthcare as a market accounted for only 5% of the U.S. economy. For every dollar transacted, only 5 cents were spent for healthcare. The entire U.S. economy was $543 billion, and healthcare accounted for about $27 billion. By itself, in 1960, the U.S. healthcare market would rank as the 15th largest world economy, putting it just in front of the GDP (Gross Domestic Product) of Australia and just behind the GDP of Italy. Think about that for a minute: the U.S., **spent more money on healthcare** than the Australians did on everything! To put this further into perspective, in 1960, the U.S. Department of Defense was twice as large as healthcare. The Defense Department consumed 10% of the U.S. economy, which means it would rank as the 11th largest world economy just in front of Japan and just behind China. Now fast-forward 50 years. In 2010, the United States GDP was $15 trillion. The total healthcare expenditures in the United States for 2010 were $2.6 trillion. At $2.6 trillion, the U.S. healthcare market has moved up from 15th and now ranks as the **5th largest world economy**, just behind Germany and just ahead of both France and the United Kingdom. That means that while healthcare was only 5% of GDP in 1960, it has risen to over 17% of GDP in only 50 years. Over that same time, the Defense Department has gone from 10% of GDP to less than 5% of GDP. This means that in terms in terms of its portion of the U.S. economy, defense spending has been reduced by half while healthcare spending has more than tripled. If **healthcare** continues to trend at the same pace it has for the last 50 years, it will consume more than **50% of the U.S. economy** by the year 2060. Every economist worth their salt will tell you that health-care will never reach 50% of the economy. It’s simply not possible because of **all the other things** it would have to **crowd out to reach** that point. So, if we know healthcare can’t grow to 50% of our economy, **where is the breaking point?** **At what point does healthcare consume so much of the economy that it breaks the bank**, so to speak? This is the big question when it comes to healthcare. If something doesn’t happen to reverse the 50-year trend we’ve been riding, when will the healthcare bubble burst? How bad will it be and how exactly will it happen? While no one knows the **exact answers** to those questions, economists and healthcare experts agree that something needs to **happen**, because we simply **can’t continue on this trend** forever. Another way to look at healthcare is to study its impact on the federal budget and the national debt. In 1998, federal healthcare spending accounted for 19% of the revenue taken in by the government. Just eight years later, in 2006, healthcare spending had increased to 24% of federal revenue. In 2010, the Affordable Healthcare Act passed and significantly increased federal spending accounted for almost one-third of all revenue received by the government and surpassed Social Security as the largest single budget category. What makes this trend even more alarming is the fact that revenue to the federal government double from 1998 to 2016. That means healthcare spending by the federal government has almost quadrupled in terms of actual dollars in that same time period. If this trend continues for the next 20 years, healthcare spending will account for over half the revenue received by the government by the year 2035. Again, the simply can’t happen without causing significant issue for the financial wellbeing of out country. In recent history, the U.S. economy has experienced the near catastrophic failure of two major market segments. The first was the auto industry and the second was the housing industry. While each of these reached their breaking point for different reasons, they both required a significant government bailout to keep them from completely melting down. What is also true about both of **those market failures** is that, looking back, it’s easy to see the warning signs. What happens if health care is the next industry to suffer a major failure and collapse? It’s safe to say that a **health care meltdown** would make both the **auto**motive and **housing** industries’ experiences **seem minor** in comparison. While that may be hard to believe, it becomes clear if you look at the numbers. The **auto industry** contributes around 3.5 percent of this country’s GDP and employs 1.7 million people. This industry was deemed **“too big to fail”** which is the rationale the U.S. government used to finance its bail out. From 2009 through 2014, the federal government invested around $80 billion in the U.S. auto industry to keep it from collapsing. Health care is five times larger than the auto industry in terms of its percentage of GDP, and is ten times larger than the auto industry in terms of the number of people it employs. The construction industry (which includes all construction, not just housing) contributes about 6 percent of our country’s GDP and employs 6.1 million people. Again, the health care market dwarfs this industry. It’s **three times larger** in terms of GDP production and, with 18 million people employed in the health care sector, it’s three times larger than construction in this area, too. These comparisons give you an idea of just how significant a portion health care comprises of the U.S. economy. It also begins to help us understand the impact it would have on the economy if health care melted down like the auto and housing industries did. So, let’s continue the comparison and use our experience with the auto and housing industries to suggest to what order of magnitude the impact a failure in the health care market would cause our economy. The bailout in the auto industry cost the federal government $80 billion over five years. Imagine a similar failure in health care that prompted the federal government to propose a similar bailout program. Let’s imagine the government felt the need to inject cash into hospital systems and doctors’ offices to keep them afloat like they did with General Motors. Since health care is five times the size of the auto industry, a similar bailout could easily cost in excess of $400 billion. That’s about the same amount of money the federal government spends on welfare programs. To pay for a bailout of the health care industry, we’d have to eliminate all welfare programs in this country. Can you imagine the impact it would have on the economy if there were suddenly none of the assistance programs so many have come to rely upon? When the housing market crashed, it caused the loss of about 3 million jobs from its peak employment level of 7.4 million in 1996. Again, if we transfer that experience to the health care market, we come up with a truly frightening scenario. If health care lost 40 percent of its jobs like housing did, it would mean 7.2 million jobs lost. That’s more than four times the number of people who are employed by the entire auto industry — an industry that was considered too big to be allowed to fail. The loss of **7.2 million jobs** would increase the unemployment rate by 5 percent. That means we could easily top the **all-time high unemployment rate** for our country. OK, now it’s time to take a deep breath. I’m not convinced that health care is fated to **unavoidable failure** and economic catastrophe. That’s a worst-case scenario. The problem is that at even a fraction the severity of the auto or housing industry crises we’ve already faced, a health care collapse would still be devastating. Health care **can’t be allowed** to continue its current inflationary trending. I believe we are on the verge of some major changes in health care, and that how they’re **implemented** will determine their impact on the overall **economic picture** in this country and around the world. Continued failure to recognize the truth about health care will only cause the resulting market corrections to be worse than they need to be. I don’t want to diminish the pain and anguish that many people caught up in the housing crash experienced. I think an argument can be made, though, that if the health care market crashes and millions of people end up with no health care, the resulting fallout could be could be much worse than even the housing crisis.

#### Economic decline causes nuclear war

Tønnesson, 15 — Stein Tønnesson, Leader of East Asia Peace program at Uppsala University, Research Professor at the Peace Research Institute Oslo, “Deterrence, Interdependence and Sino–US Peace” International Area Studies Review, Review Essay, Volume 18, Issue 3, Pages 297-311, SAGE Journals, Minnesota Libraries, Date Accessed: 8-4

Several recent works on China and Sino–US relations have made substantial contributions to the current understanding of how and under what circumstances a combination of nuclear deterrence and economic interdependence may reduce the risk of war between major powers. At least four conclusions can be drawn from the review above: first, those who say that interdependence may **both inhibit and drive conflict** are right. Interdependence raises the **cost of conflict** for all sides but asymmetrical or unbalanced dependencies and **negative trade expectations** may generate tensions leading to trade wars among inter-dependent states that in turn increase the risk of military conflict (Copeland, 2015: 1, 14, 437; Roach, 2014). The risk may increase if one of the interdependent countries is governed by an inward-looking socio-economic coalition (Solingen, 2015); second, the risk of war between China and the US should not just be analysed bilaterally but include their allies and partners. Third party countries could drag China or the US into confrontation; third, in this context it is of some comfort that the three main economic powers in Northeast Asia (China, Japan and South Korea) are all deeply integrated economically through production networks within a global system of trade and finance (Ravenhill, 2014; Yoshimatsu, 2014: 576); and fourth, decisions for war and peace are taken by very few people, who act on the basis of their future expectations. International relations theory must be supplemented by foreign policy analysis in order to assess the value attributed by national decision-makers to economic development and their assessments of risks and opportunities. If leaders on either side of the Atlantic begin to seriously fear or **anticipate their own nation’s decline** then they may blame this on **external dependence**, appeal to anti-foreign sentiments, contemplate the use of force to gain respect or credibility, adopt protectionist policies, and ultimately **refuse to be deterred by** either **nuclear arms** or prospects of socioeconomic calamities. Such a dangerous shift could happen **abruptly**, i.e. under the instigation of actions by a third party – or against a third party.

Yet as long as there is both nuclear deterrence and interdependence, the tensions in East Asia are unlikely to escalate to war. As Chan (2013) says, all states in the region are aware that they cannot count on support from either China or the US if they make provocative moves. The greatest risk is **not** that **a territorial dispute** leads to war under present circumstances but that **changes in the world economy** alter those circumstances in ways that render **inter-state peace** more precarious. If China and the US fail to rebalance their financial and trading relations (Roach, 2014) then a trade war could result, interrupting transnational production networks, provoking social distress, and exacerbating nationalist emotions. This could have **unforeseen consequences** in the field of security, with nuclear deterrence remaining the only factor to **protect the world from Armageddon**, and **unreliably so**. Deterrence could **lose its credibility**: one of the two great powers might gamble that the other yield in a cyber-war or conventional limited war, or third-party countries might engage in conflict with each other, with a view to obliging Washington or Beijing to **intervene**.

### 2

#### CP text: States should add more stringent requirements for filing patents for medicines.

Newsome 17, A [(JD candidate George Washington School of Law). (2017). Side effects of evergreening may include decreased competition & increased prices in the pharmaceutical industry. AIPLA Quarterly Journal, 45(4), 791-822] Justin

The current framework for evaluating a patent application, particularly the requirements of utility and nonobviousness, is insufficient for evaluating whether a secondary patent should be issued for a drug. Given that courts are tied to the low bar for utility and inconsistent with their application of nonobviousness,1 04 it is necessary to pass legislation creating a new utility requirement tailored to secondary pharmaceutical patents. This Note's Author proposes legislation language as follows: 35 U.S.C. § 106: Patentable Pharmaceutical Inventions

(a) Utility requirement for secondary patent: In the case of a pharmaceutical invention claiming an improvement on a patented invention, the applicant shall demonstrate through clear and convincing evidence in the written description that such invention has increased efficacy as compared to the original.

(b) Increased efficacy defined: As used in part (a), "increased efficacy" refers to a proven improvement in the mechanism of action, as disclosed in the patent claims. 0 5

(c) Mechanism of action defined: As used in part (b), "mechanism of action" refers to the process by which a drug functions to produce a therapeutic effect, as disclosed in the patent claims. 06

Under this legislation, the USPTO could grant a secondary patent only if the new formula's mechanism of action, or production of the intended pharmacological effect, in fact improves upon the patented drug's mechanism of action. For example, because VidaDrug is a chemotherapy drug, the new formula must include a change in the mechanism of action which causes an improvement in the efficacy of the drug's tumor-shrinking abilities to be eligible for a secondary patent. A formula tweak that reduces side effects is insufficient, because the underlying purpose of the drug - to treat cancer - remains unaffected.

#### Solves best.

Newsome 17, A [(JD candidate George Washington School of Law). (2017). Side effects of evergreening may include decreased competition & increased prices in the pharmaceutical industry. AIPLA Quarterly Journal, 45(4), 791-822] Justin

Pharmaceutical patents are inherently different from software or manufacturing patents. 144 Pharmaceutical companies create life-saving drugs that carry a very serious benefit for a vulnerable group of consumers - patients. Because of this, the pharmaceutical industry should be held to a higher standard if its companies seek to prohibit affordable generic drugs from coming to the marketplace.

1. An Efficacy-Focused Standard Will Motivate Pharmaceutical Companies to Channel Resources to Creating Real Innovation Pharmaceutical companies argue that patent-life-cycle-management strategies (their preferred name for those tactics described herein as evergreening) are essential to ensuring they recoup R&D costs. 145 However, creation of a standard such as the one proposed here would ensure that pharmaceutical companies are properly incentivized to channel R&D resources to creating measurable change in the drugs, rather than creating minor changes that prolong the time they can profit off of monopolies at the expense of patients. For those industries in which R&D is more productive, like the pharmaceutical industry, "patent procedures should be refined to tighten the relationship between patents and the underlying inventions."14 6
2. A Higher Standard for Secondary Pharmaceutical Patents Will Increase Competition & Lead to Lower Prices The patent system enables pharmaceutical companies to retain market exclusivity for their drugs, allowing them to set high prices without an eye toward competition.1 47 The companies cite the need to recoup R&D costs as the driving factor for their pricing decisions,148 but critics say their main motivation is making a profit.'49 While the pharmaceutical companies' argument may hold weight, high prices for drugs have a negative impact on those patients who need those drugs, but cannot afford them.150 Tightening patent laws to prevent pharmaceutical companies from retaining patent protection for minor changes in their patented drugs will allow other companies to enter the marketplace sooner and drive prices down through competition. 5

## **3**

#### WTO is near consensus on fisheries subsidies – success will require continued focus, flexibility, and cooperation among members

WTO 7/15 [(World Trade Organization) “WTO members edge closer to fisheries subsidies agreement,” News and Events, 7/15/2021] JL

During an all-day meeting with 104 ministers and heads of delegation, WTO members pledged to conclude the negotiations soon and certainly before the WTO's Ministerial Conference in early December, and to empower their Geneva-based delegations to do so. Members also confirmed that the negotiating text currently before them can be used as the basis for the talks to strike the final deal.

“I feel new hope this evening. Because ministers and heads of delegation today demonstrated a strong commitment to moving forward and doing the hard work needed to get these negotiations to the finish line. I applaud you for this. In 20 years of negotiations, this is the closest we have ever come towards reaching an outcome — a high-quality outcome that would contribute to building a sustainable blue economy,” said Director-General Ngozi Okonjo-Iweala.

“One fundamental conclusion that I draw from your interventions today is that members are ready to use the text as the basis for future negotiations. A second takeaway from today was that there is universal agreement about the importance of the food and livelihood security of artisanal fishers in developing and least developed countries. The prospect for a deal in the autumn ahead of our Ministerial Conference has clearly improved.”

The UN Food and Agriculture Organization estimates that one-third of global fish stocks are overfished and most of the rest is fully exploited. This is up from 10% in 1970 and 27% in 2000. Depleted stocks threaten the food security of low-income coastal communities, and the livelihoods of poor and vulnerable fishers who must go further and further from shore only to bring back smaller and smaller hauls.

Each year, governments hand out around $35 billion in fisheries subsidies, two-thirds of which go to commercial fishers. These subsidies keep at sea vessels which would otherwise be economically unviable. World leaders in 2015 made a fisheries subsidies agreement by 2020 part of the Sustainable Development Goals and trade ministers reaffirmed this pledge in 2017.

The negotiations on fisheries subsidies disciplines have been ongoing for nearly 20 years. Although there has been recent progress thanks to the intensive work that led to the development of the negotiating text on which members are working, the lack of political impetus in the talks to close the remaining gaps inspired Director-General Okonjo-Iweala to call this meeting of ministers.

Among the thorniest issues to resolve has been how to extend special and differential treatment to developing and least developed country WTO members while preserving the overall objective of enhanced sustainability of the oceans. Ministers said that the livelihoods and food security of poor and vulnerable artisanal fishers in developing and least developed countries were of great importance, as was preserving the sustainability objective of the negotiations.

Amb. Santiago Wills of Colombia, who chairs the Rules Negotiating Group overseeing the fisheries subsidies negotiations, said he had received some valuable inputs from the discussions. He now has greater clarity on the path forward and the next steps that would be required to harvest an agreement. He will be consulting with the Director-General and WTO members about charting the path forward for the next stage of the talks.

“I am very heartened by the responses and messages that we have heard today. What we sought from ministers today was political guidance to help close these negotiations soon. And we did hear that guidance. We have been given the ingredients to reach a successful conclusion; a commitment to finish well ahead of our Ministerial Conference a text that can be the platform for this final stage of the negotiations and fully empowered heads of delegations in Geneva. This represents a real success,” said Amb. Wills.

The Director-General said that delegations needed to prepare for an intensive period of line by line negotiations.

“As we enter this new phase of text-based discussions, the responsibility to conclude these negotiations is truly in the hands of members. To get from here to an agreement, it will be your job to find the necessary trade-offs and flexibilities. A successful outcome by MC12 is ultimately your responsibility,” she said. “The world is watching. The fisheries subsidies negotiations are a test both of the WTO's credibility as a multilateral negotiating forum and of the trading system's ability to respond to problems of the global commons.  If we wait another 20 years, there may be no marine fisheries left to subsidise — or artisanal fishing communities to support.”

#### IP disputes fragment WTO unity and trade off with subsidies negotiation

Patnaik 3/12 [(Priti, journalist in Geneva, Switzerland, master’s in Development Studies from The Graduate Institute in Geneva and a master’s in Business and Economic Reporting from New York University) “Could Vaccine Nationalism Spur Disputes At The WTO?” Geneva Health Files, 3/12/2021] JL

To protect domestic manufacturers and constituencies, countries may resort to filing disputes, if only to send a signal to other members, experts believe. To be sure, this is not only about vaccines. Going forward, export restrictions on raw materials can have implications for therapeutics as well. So the threat of a dispute may be a tool to deal with competition for scarce medical products during the pandemic, experts say.

Although trade restrictive measures are short-sighted and not a preferred policy option, governments see them as powerful instruments to meet political goals, to send a message to domestic stakeholders, sources said.

“My hunch is that all countries are sort of sitting on both sides of the fence. On the one hand, governments would like to maintain the discretion and the ability to impose export restrictions if they need to or if they think they need to. Whether that is medical products or personal protective equipment. On the other hand, everybody dislikes it when other countries impose export restrictions. So I think there is enough of an incentive for countries to sit down and negotiate,” one legal expert noted.

Sources also pointed to political declarations last year where WTO members came together and said that they would not impose restrictive trade measures. “In order to be constructive, countries decided that they were going to signal to members that will not introduce exports restrictive measures even though it may be expedient to do so,” one trade expert said. The way out, some feel, is to find solution to placing limits on export restrictions.

It is not just trade restrictive measures that could result in trade disputes. The heated political discussions on the TRIPS waiver at WTO is also aggravating the potential for disputes, according to experts involved in litigations in international trade in Geneva. Therefore these ostensibly independent processes, can catalyse disputes.

“The waiver discussion is very heated and it is aggravating the discussion on the EU's export restrictions. If the waiver succeeds, then the opposing members cannot do anything about it. So they will be looking at other ways to beat up on behavior they do not like on the COVID-19 front,” one trade law expert said.  Do not rule out disputes against supporters of the TRIPS waiver proposal, in case the waiver is adopted, the source added.

In their statement at the WTO General Council meeting last week, the EU said, “In order to ensure that vaccines and their ingredients are not directed to export destinations in unjustified volumes, the European Union had no choice but to introduce a transparency mechanism on Covid-19 vaccine export transactions.” The EU has said that the measures are WTO-consistent.

It added “Since the entry into force of the scheme on the 1 February, we have received 150 requests for export authorisation. All of them have been accepted. I repeat, all of them.” This week, the European Commission extended transparency and authorisation mechanism for exports of COVID-19 vaccines.

The EU is also a part of the Ottawa Group proposal on Trade and Health that also spells out commitments towards export restrictions. (See also *E.U. Exports Millions of Covid Vaccine Doses Despite Supply Crunch at Home*)

“Members bring disputes all the time, even when they know that it's going to take a long time to get a result and often they bring a dispute as leverage for negotiations. Filing a dispute does not mean they are looking for a solution. It does not mean the dispute will be litigated all the way to the end,” a trade lawyer said.

It could also result in a negotiated arrangement, like it was in 2001 in the U.S.-Brazil case. “Why did the U.S. bring a case against Brazil? It gave them leverage in negotiations, and to satisfy domestic stakeholders,” the lawyer added.

The impasse at the Appellate Body may not be a deterrent for countries to dissuade countries from bringing a dispute, some believe.

“The Appellate Body not being functional is not a problem. Countries have recourse to Article 25 under the Dispute Settlement Understanding (DSU) that provides for ‘expeditious arbitration as a alternate means to dispute settlement’,” a source involved in the WTO litigation process said. (The EU, for example, is a signatory to the Multi-party interim appeal arbitration arrangement, MPIA.)

While disputes may take up precious energy and resources of members already stretched in fighting to address the pandemic, it may likely be a strategy to address trade protectionism. Not all agree.

“I think the law is not really an answer here, I hate to say that because I'm a lawyer. But I really don't think the law is an answer because the law is so generically drafted right that and it's politically so sensitive. Which WTO panel will tell a member that restricting vaccines is not legitimate? It will ultimately harm the legitimacy of the trading system,” the person added.

#### Overfishing collapses biodiversity

DUJS 12 [(Dartmouth Undergraduate Journal of Science, official open access science journal of Dartmouth College, publishing original scientific research, multidisciplinary review articles, and science news) “The Threats of Overfishing: Consequences at the Commercial Level,” 3/11/2012] JL

According to marine ecologists, overfishing is the greatest threat to ocean ecosystems today (1). Overfishing occurs because fish are captured at a faster rate than they can reproduce (2). Advanced fishing technology and an increased demand for fish have led to overfishing, causing several marine species to become extinct or endangered as a result (3, 4). In the long-term, overfishing can have a devastating impact on ocean communities as it destabilizes the food chain and destroys the natural habitats of many aquatic species (2).

In the past, fishing was more sustainable because fishermen could not access every location and because they had a limited capacity for fish aboard their vessels. Today, however, small trawlers and fishing boats have been replaced by giant factory ships that can capture and process extremely large amounts of prey at a given time (2). These ships use sonar instruments and global positioning systems (GPS) to rapidly locate large schools of fish (1). Fishing lines are deployed with thousands of large hooks that can reach areas up to 120 kilometers deep. The trawling vessels and machines can even reach depths of 170 kilometers and can store an extraordinarily large volume of fish. Each year, these huge trawling ships comb an area twice the size of the United States. They use massive nets 50 meters wide with the capacity to pull the weight of a medium-sized plane (2). They also have several plants for processing and packing fish, large freezing systems, fishmeal processing plants, and powerful engines that can carry this enormous fishing gear around the ocean. Because these ships have all the equipment necessary to freeze and tin fish, they only need to return to their base once they are full. Even when the ships are filled, however, the fish are often transferred to refrigerated vessels in the middle of the ocean and are processed for consumption later (4). As such, industrial fishing has expanded considerably and fishermen can now explore new shores and deeper waters to keep up with the increased demand for seafood. In fact, it has been reported by the United Nations Food and Agricultural Organization (FAO) that over 70 percent of the world’s fisheries are either ‘fully exploited’, ‘over exploited’ or ‘significantly depleted’ (5). The annual total global catch of fish is 124 million metric tons, which is equivalent in weight to 378 Empire State Buildings (2).

Fishing gear is often non-selective in the fish it targets. For example, any fish that are too big to get through the mesh of a net are captured. Therefore, overfishing does not only threaten the species of fish that is targeted for food, but also many non-target species. As a result, these other species, including marine mammals and seabirds, are accidentally caught in the fishing gear and killed (6). For example, for every ton of prawn caught, three tons of other fish are killed and thrown away. Those in the trade refer to this practice of inadvertent catching of other species as bycatch (4). The FAO has pointed out that about 25 percent of the world’s captured fish end up thrown overboard because they are caught unintentionally, are illegal market species, or are of inferior quality and size. Many of the fish caught this way include endangered and over exploited species, 95 percent of which are eventually thrown away (2). Bycatch is not just limited to just unwanted fish, but rather affects all types of marine life, including whales, dolphins, porpoises, fur seals, albatrosses, and turtles. For example, tuna fisheries are indirectly responsible for the deaths of an estimated one million sharks annually due to bycatch. Small cetaceans, such as dolphins and porpoises, are also targets of bycatch as they are often caught in fishing nets. In fact, hundreds of dolphin corpses are washed up on the beaches of Europe every year, bringing attention to the growing scale of this problem (6).

Many modern fishing methods are also irreversibly destructive. For example, bottom trawling, a technique that uses extremely wide nets armed with heavy metal rollers, can crush everything in the path of the gear, destroying fragile corals, smashing rock formations, and killing several tons of fish and animals as bycatch (7). As such, these practices can wreak havoc on delicate marine ecosystems.

Not surprisingly, it has been reported that industrial fishing takes between only 10 and 15 years to wipe out a tenth of whichever species it targets (2). In fact, several marine species have already been fished to commercial extinction, and this number is rapidly increasing (1). One of the reasons for this is that the regulation of fishing vessels and the fishing industry is universally inadequate. Roughly two-thirds of the ocean is free of laws and fishing vessels only follow the laws ratified by their country of origin. However, most fishing countries have not ratified any international convention to protect the sea or marine life (2). Moreover, fishing factory ships and companies are given access to fisheries before the long–term impact of their fishing practices is understood (1).

Today, the number of fish caught worldwide is actually shrinking as the fishing industry is in decline from many years of overfishing (2). The year 1988 was the first time in human history that global wild fish catches dropped and they have continued to fall ever since. In European waters, four out of every five known fish stocks are already beyond safe biological limits (7). Illegal and unreported fishing have also contributed a great deal to the depletion of the oceans and continues to be a serious problem.

A new study conducted by the International Union for Conservation of Nature (IUCN) found that 5 out of the 8 tuna species are at risk of extinction (8). All three species of bluefin tuna, for example, are threatened with extinction and are at a population that makes their recovery practically irreversible (2). The IUCN has also reported that freshwater fish are among the most endangered species, with more than a third facing extinction. Not surprisingly, among those at the greatest risk are species like the Mekong giant catfish, the freshwater stingray, and the European eel, which are used to make some of the most expensive caviars. The Mekong giant catfish is the closest to extinction, with as few as 250 left. Overfishing has reduced the numbers of Mekong freshwater stingray by over 50 percent in Southeast Asia and has reduced the giant Mekong salmon carp population by over 90 percent (9).

As previously mentioned, shark populations have also been greatly affected by overfishing. There are already more than 135 species of shark on the IUCN’s list of endangered animals and more are being added each year. For example, the number of scalloped hammerhead shark has decreased by 99% over the past 30 years. Other species recently added to the endangered list include the smooth hammerhead, shortfin mako, common thresher, big-eye thresher, silky, tiger, bull, and dusky (10). Besides being caught as bycatch, sharks are now also being targeted by commercial fishermen for their fins which can fetch a substantial price on the Asian food market. Sharks are particularly vulnerable to exploitation because they have long life spans, are exceptionally slow to mature (taking as long as 16 years in some cases), and are relatively unprolific breeders (11). Recent reports suggest that over fishing has caused a 90% decline in shark populations across the world’s oceans and up to 99% along the US east coast, which are some of the best managed waters in the world. Because sharks are at the top of the food chain, a decline in their numbers has devastating consequences on marine ecosystems (10).

Overfishing impacts not just the particular species that is exploited, but also damages other species of fish and disrupts local ecosystems. The stability of ecological communities depends largely on the interactions between predators and prey (12). Thereby, the balance of the food chain is disturbed when certain species are removed. As a result, many ocean species are disappearing and losing their habitats. The evolutionary process of marine species is also being altered, causing cycles of premature reproduction and relative decreases in the size of fish across generations. As predators diminish, the populations of smaller fish escalate because they were previously the food source of the bigger fish. In addition, the disappearance of these species affects many other species, like seabirds and sea mammals, which are vulnerable to the lack of food (2).

A recent study found that overfishing is also decreasing the genetic diversity of fish worldwide. Diversity is projected to be reduced further if overfishing continues at the same rate (13). This has serious effects on nutrient recycling in marine ecosystems because fish species vary widely in their rates of nitrogen and phosphorus excretion. As such, altering fish communities creates divergent nutrient recycling patterns and disrupts the functioning of the ecosystem. Recently conducted studies in lakes affected by overfishing show that loss of species contributes to a decline in nutrient recycling and destabilizes the ecosystem (14).

While it is often overlooked for other environmental issues, overfishing has historically caused more ecological extinction than any other human influence on coastal ecosystems, including water pollution (5). Unfortunately, due to a lack of data, the extent of this damage has only recently been recognized (15).

#### Continued biodiversity loss causes extinction

Carrington 18 [(Damian, the Guardian's Environment editor) "Humanity has wiped out 60% of a animal populations since 1970, report finds," The Guardian, 10/29/18] TDI

Humanity has wiped out 60% of mammals, birds, fish and reptiles since 1970, leading the world’s foremost experts to warn that the annihilation of wildlife is now an emergency that threatens civilisation.

The new estimate of the massacre of wildlife is made in a major report produced by WWF and involving 59 scientists from across the globe. It finds that the vast and growing consumption of food and resources by the global population is destroying the web of life, billions of years in the making, upon which human society ultimately depends for clean air, water and everything else.

“We are sleepwalking towards the edge of a cliff” said Mike Barrett, executive director of science and conservation at WWF. “If there was a 60% decline in the human population, that would be equivalent to emptying North America, South America, Africa, Europe, China and Oceania. That is the scale of what we have done.”

“This is far more than just being about losing the wonders of nature, desperately sad though that is,” he said. “T**his is** actually now jeopardising the future of people. Nature is not a ‘nice to have’ – it is our life-support system.”

“We are rapidly running out of time,” said Prof Johan Rockström, a global sustainability expert at the Potsdam Institute for Climate Impact Research in Germany. “Only by addressing both ecosystems and climate do we stand a chance of safeguarding a stable planet for humanity’s future on Earth.”

Many scientists believe the world has begun a sixth mass extinction, the first to be caused by a species – Homo sapiens. Other recent analyses have revealed that humankind has destroyed 83% of all mammals and half of plants since the dawn of civilisation and that, even if the destruction were to end now, it would take 5-7 million years for the natural world to recover.

The Living Planet Index, produced for WWF by the Zoological Society of London, uses data on 16,704 populations of mammals, birds, fish, reptiles and amphibians, representing more than 4,000 species, to track the decline of wildlife. Between 1970 and 2014, the latest data available, populations fell by an average of 60%. Four years ago, the decline was 52%. The “shocking truth”, said Barrett, is that the wildlife crash is continuing unabated.

Wildlife and the ecosystems are vital to human life, said Prof Bob Watson, one of the world’s most eminent environmental scientists and currently chair of an intergovernmental panel on biodiversity that said in March that the destruction of nature is as dangerous as climate change.

“Nature contributes to human wellbeing culturally and spiritually, as well as through the critical production of food, clean water, and energy, and through regulating the Earth’s climate, pollution, pollination and floods,” he said. “The Living Planet report clearly demonstrates that human activities are destroying nature at an unacceptable rate, threatening the wellbeing of current and future generations.”

The biggest cause of wildlife losses is the destruction of natural habitats, much of it to create farmland. Three-quarters of all land on Earth is now significantly affected by human activities. Killing for food is the next biggest cause – 300 mammal species are being eaten into extinction – while the oceans are massively overfished, with more than half now being industrially fished.

Chemical pollution is also significant: half the world’s killer whale populations are now doomed to die from PCB contamination. Global trade introduces invasive species and disease, with amphibians decimated by a fungal disease thought to be spread by the pet trade.

The worst affected region is South and Central America, which has seen an 89% drop in vertebrate populations, largely driven by the felling of vast areas of wildlife-rich forest. In the tropical savannah called cerrado, an area the size of Greater London is cleared every two months, said Barrett.

“It is a classic example of where the disappearance is the result of our own consumption, because the deforestation is being driven by ever expanding agriculture producing soy, which is being exported to countries including the UK to feed pigs and chickens,” he said. The UK itself has lost much of its wildlife, ranking 189th for biodiversity loss out of 218 nations in 2016.

The habitats suffering the greatest damage are rivers and lakes, where wildlife populations have fallen 83%, due to the enormous thirst of agriculture and the large number of dams. “Again there is this direct link between the food system and the depletion of wildlife,” said Barrett. Eating less meat is an essential part of reversing losses, he said.

The Living Planet Index has been criticised as being too broad a measure of wildlife losses and smoothing over crucial details. But all indicators, from extinction rates to intactness of ecosystems, show colossal losses. “They all tell you the same story,” said Barrett.

Conservation efforts can work, with tiger numbers having risen 20% in India in six years as habitat is protected. Giant pandas in China and otters in the UK have also been doing well.

But Marco Lambertini, director general of WWF International, said the fundamental issue was consumption: “We can no longer ignore the impact of current unsustainable production models and wasteful lifestyles.”

## **Case**

### 1NC – Circumvention

#### Companies will just obtain a patent in a different sector.

Thomas 15 [John R; Visiting Scholar, CRS; “Tailoring the Patent System for Specific Industries, Congressional Research Service,” CRS; 2015; <https://crsreports.congress.gov/product/pdf/R/R43264/7>] Justin

In view of the concerns noted above, commentators have gone so far to say that “it has become increasingly difficult to believe that a one-size-fits-all approach to patent law can survive.”75 To the extent the current patent system creates a blanket set of rules that apply comparably to distinct industries, it likely over-encourages innovation in some contexts and under-incentivizes it in others.76 Further, some observers have asserted that the need of firms to identify and access the patented inventions of others may differ among industries.77 As a result, the case can be made that distinct industrial, technological, and market characteristics that exist across the breadth of the U.S. economy compel industry-specific patent statutes. However, others have questioned the wisdom and practicality of such line-drawing.78 The following concerns, among others, have been identified:

• Over its long history, the U.S. patent system has flexibly adapted to new technologies such as biotechnology and computer software. Legislative adoption of technology-specific categories may leave unanticipated, cutting-edge technologies outside the patent system.79

• Defining a specific industry or category of technologies may prove to be a contested proposition.

80 • Over time, new industries may emerge and old industries may consolidate. The dynamic nature of the U.S. economy suggests greater need for legislative oversight within a differentiated patent regime.

81 • Even if an industry or technology remains relatively stable, the innovation environment within it might change. For example, technological or scientific advances might open new possibilities for research and development within hidebound industries—but also increase expense and risk for those firms.

82 • Distinct patent rights among industries or technologies may lead to strategic behavior on behalf of patent applicants. For example, a computer program that controls a fuel injector within an automobile could possibly be identified as either an automobile-related or a computer-related invention.

83 •The legislative effort to enact sector-specific patent laws may provide an opportunity for politically savvy firms to exert more lobbying and political power, at the possible expense of less sophisticated firms.

### 1NC - UQ

#### Pharma innovation high now – monetary incentive is the biggest factor.

**Swagel 21** Phillip L. Swagel, Director of the Congressional budget office 4-xx-2021, "Research and Development in the Pharmaceutical Industry," Congressional Budget Office, <https://www.cbo.goc/publication/57126#_idTextAnchor020> SJ//DA

**Every year, the U.S. pharmaceutical industry develops a variety of new drugs that provide valuable medical benefits. Many of those drugs are expensive and contribute to rising health care costs for the private sector and the federal government. Policymakers have considered policies that would lower drug prices and reduce federal drug expenditures. Such policies would probably reduce the industry’s incentive to develop new drugs.** In this report, the Congressional Budget Office assesses trends in spending for drug research and development (R&D) and the introduction of new drugs. CBO also examines factors that determine how much drug companies spend on R&D: expected global revenues from a new drug; cost to develop a new drug; and federal policies that affect the demand for drug therapies, the supply of new drugs, or both. What Are Recent Trends in Pharmaceutical R&D and New Drug Approvals? T**he pharmaceutical industry devoted $83 billion to R&D expenditures in 2019. Those expenditures covered a variety of activities, including discovering and testing new drugs, developing incremental innovations such as product extensions, and clinical testing for safety-monitoring or marketing purposes. That amount is about 10 times what the industry spent per year in the 1980s, after adjusting for the effects of inflation.** The share of revenues that drug companies devote to R&D has also grown: **On average, pharmaceutical companies spent about one-quarter of their revenues (net of expenses and buyer rebates) on R&D expenses** in 2019, which is **almost twice as large a share of revenues as they spent in 2000.** That revenue share is larger than that for other knowledge-based industries, such as semiconductors, technology hardware, and software. The number of new drugs approved each year has also grown over the past decade. On averace, the Food and Drug Administration (FDA) approved 38 new drugs per year from 2010 through 2019 (with a peak of 59 in 2018), which is 60 percent more than the yearly average over the previous decade. **Many of the drugs that have been approved in recent years are “specialty drugs.” Specialty drugs generally treat chronic, complex, or rare conditions, and they may also require special handling or monitoring of patients**. Many specialty drugs are biologics (large-molecule drugs based on living cell lines), **which are costly to develop, hard to imitate, and frequently have high prices.** Previously, most drugs were small-molecule drugs based on chemical compounds. Even while they were under patent, those drugs had lower prices than recent specialty drugs have. Information about the kinds of drugs in current clinical trials indicates that much of the industry’s innovative activity is focused on specialty drugs that would provide new cancer therapies and treatments for nervous-system disorders, such as Alzheimer’s disease and Parkinson’s disease. **What Factors Influence Spending for R&D?** Drug companies’ R&D spending decisions depend on three main factors: Anticipated lifetime global revenues from a new drug, **Expected costs to develop a new drug**, and Policies and programs that influence the supply of and demand for prescription drugs. Various considerations inform companies’ expectations about a drug’s revenue stream, including the anticipated prices it could command in different markets around the world and the expected global sales volume at those prices (given the number of people who might use the drug). The prices and sales volumes of existing drugs provide information about consumers’ and insurance plans’ willingness to pay for drug treatments. Importantly, when drug companies set the prices of a new drug, they do so to maximize future revenues net of manufacturing and distribution costs. A drug’s sunk R&D costs—that is, the costs already incurred in developing that drug—do not influence its price. **Developing new drugs is a costly and uncertain process, and many potential drugs never make it to market. Only about 12 percent of drugs entering clinical trials are ultimately approved for introduction by the FDA. In recent studies, estimates of the average R&D cost per new drug range from less than $1 billion to more than $2 billion per drug**. Those estimates include the costs of both laboratory research and clinical trials of successful new drugs as well as expenditures on drugs that do not make it past the laboratory-development stage, that enter clinical trials but fail in those trials or are withdrawn by the drugmaker for business reasons, or that are not approved by the FDA. Those estimates also include the company’s capital costs—the value of other forgone investments—incurred during the R&D process. Such costs can make up a substantial share of the average total cost of developing a new drug. The development process often takes a decade or more, and during that time the company does not receive a financial return on its investment in developing that drug. The federal government affects R&D decisions in three ways. First, it increases demand for prescription drugs, which encourages new drug development, by fully or partially subsidizing the purchase of prescription drugs through a variety of federal programs (including Medicare and Medicaid) and by providing tax preferences for employment-based health insurance. Second, the federal government increases the supply of new drugs. It funds basic biomedical research that provides a scientific foundation for the development of new drugs by private industry. Additionally, tax credits—both those available to all types of companies and those available to drug companies for developing treatmentscof uncommon diseases—provide incentives to invest in R&D. Similarly, deductions for R&D investment can be used to reduce tax liabilities immediately rather than over the life of that investment. Finally, the patent system and certain statutory provisions that delay FDA approval of generic drugs provide pharmaceutical companies with a period of market exclusivity, when competition is legally restricted. During that time, they can maintain higher prices on a patented product than they otherwise could, which makes new drugs more profitable and thereby increases drug companies’ incentives to invest in R&D. Third, some federal policies affect the number of new drugs by influencing both demand and supply. For example, federal recommendations for specific vaccines increase the demand for those vaccines and provide an incentive for drug companies to develop new ones. Additionally, federal regulatory policies that influence returns on drug R&D can bring about increases or decreases in both the supply of and demand for new drugs. Trends in R&D Spending and New Drug Development Private spending on pharmaceutical R&D and the approval of new drugs have both increased markedly in recent years, resuming a decades-long trend that was interrupted in 2008 as generic versions of some top-selling drugs became available and as the 2007–2009 recession occurred. **In particular, spending on drug R&D increased by nearly 50 percent between 2015 and 2019.** Many of the drugs approved in recent years are high-priced specialty drugs for relatively small numbers of potential patients. By contrast, the top-selling drugs of the 1990s were lower-cost drugs with large patient populations. R&D Spending R&D spending in the pharmaceutical industry covers a variety of activities, including the following: Invention, or research and discovery of new drugs; Development, or clinical testing, preparation and submission of applications for FDA approval, and design of production processes for new drugs; Incremental innovation, including the development of new dosages and delivery mechanisms for existing drugs and the testing of those drugs for additional indications; Product differentiation, or the clinical testing of a new drug against an existing rival drug to show that the new drug is superior; and Safety monitoring, or clinical trials (conducted after a drug has reached the market) that the FDA may require to detect side effects that may not have been observed in shorter trials when the drug was in development. In real terms**, private investment in drug R&D among member firms of the Pharmaceutical Research and Manufacturers of America (PhRMA), an industry trade association, was about $83 billion in 2019, up from about $5 billion in 1980 and $38 billion in 2000**.1 Although those spending totals do not include spending by many smaller drug companies that do not belong to PhRMA, the trend is broadly representative of R&D spending by the industry as a whole.2 A survey of all U.S. pharmaceutical R&D spending (including that of smaller firms) by the National Science Foundation (NSF) reveals similar trends.3 Although total R&D spending by all drug companies has trended upward, small and large firms generally focus on different R&D activities. **Small companies not in PhRMA devote a greater share of their research to developing and testing new drugs,** many of which are ultimately sold to larger firms (see Box 1). By contrast, a greater portion of the R&D spending of larger drug companies (including those in PhRMA) is devoted to conducting clinical trials, developing incremental “line extension” improvements (such as new dosages or delivery systems, or new combinations of two or more existing drugs), and conducting postapproval testing for safety-monitoring or marketing purposes.

### 1NC - Evergreening

#### Evergreening is a myth – this card ends the debate.

Lietzan 20 [Erika; Professor of Law, University of Missouri School of Law, Research interests in Pharmaceutical Regulation, Device Regulation, Intellectual Property; “The Evergreening Myth Claims that drug innovators extend their patents obscure a radical policy‐​making goal.,” Cato Institute; Fall 2020; <https://www.cato.org/regulation/fall-2020/evergreening-myth>/] Justin

In recent years, U.S. policymakers have considered proposals intended to prevent — or at least reduce — “evergreening” by pharmaceutical companies. Some proposals would change the antitrust enforcement landscape, others the intellectual property landscape, and still others the regulatory framework that governs new medicines. Some proposals — such as those creating new causes of action under the antitrust laws or limiting the availability of patents for discoveries — are profound and their proponents cite a body of academic and policy literature that decries supposed “evergreening” by companies to justify their ideas.

The term “evergreening” is a metaphor, meant to remind audiences of evergreen trees, which have green foliage year‐​round. It implies that something has been extended, and users of the metaphor view this extension as improper or undesirable. When offering descriptions and examples of evergreening, they focus on drug companies continuing to innovate after first introducing a new molecule, and on the broader marketplace for medicines after subsequent innovations have been introduced to the market. But proponents are frustratingly inconsistent and unclear about what, exactly, has been “extended” in these situations. A close look at the regulatory landscape in which continuing pharmaceutical innovation occurs shows that arguments for reform are grounded in myths, such as the myth that pharmaceutical companies continuing to innovate somehow “extend” their patents.

Once the myths of “evergreening” are laid bare, it becomes apparent that proponents of these proposals really want for the government to limit medical innovators to one medical product in the marketplace for each useful new molecule discovered. They are arguing that an innovator should not enjoy an exclusive market — and the resulting advantageous pricing — for innovations that, though discrete and independently satisfying the standard for a patent under U.S. law, stem in some fashion from an earlier innovation for which that innovator separately enjoyed exclusivity and the resulting pricing advantages. Or, at least, that drug innovators should not. This is a radical proposal that merits careful reflection and discussion, and it is not ripe for action. Understanding that this is the true policymaking objective requires unpacking the regulatory landscape and market more carefully, and paying closer attention to word choice, than proponents of reform often do. The Evergreening Allegation In the United States, every new medicinal product requires premarket approval from the Food and Drug Administration. The drug statute refers to approval of a “new drug,” and ambiguity in the term “drug” provides fertile ground for confusion and rhetorical mischief, as discussed later in this article. A firm that wants to market a new drug must prove to the FDA that the drug is safe and effective. Generating this information takes years, beginning with work in the laboratory and on animals, and progressing through several rounds of “clinical” testing in humans. For new molecules, the clinical portion of this research and development program averages six years. The process is also expensive: the Tufts Center for the Study of Drug Development now estimates the average cost of developing a new molecular entity at $2.6 billion. That figure includes average out‐​of‐​pocket costs of $1.4 billion and reflects the cost of unsuccessful projects. Most research and development programs fail. When new drugs are first launched by innovators, they tend to be sold under brand names and protected by patents as well as statutory rights in the data that supported FDA approval (known as “data exclusivity”). Although the pricing of these products may reflect competitive pressure from other branded products, it also reflects the fact that patent rights and statutory data exclusivity delay the launch of cheaper copies. But no more than five years later, and often earlier, the innovator’s competitors may file applications seeking approval of their own products based on the innovator’s research, rather than performing their own. They file what are known as “abbreviated applications” — abbreviated because they omit some, or all, of the research needed to prove safety and effectiveness. Abbreviated applications are much less expensive and time‐​consuming to assemble, and the competitors’ drugs correspondingly much less expensive than the original drugs they copy. When a competitor seeks to market an exact copy through an abbreviated application, we call its drug a “generic” drug. Pharmacists usually dispense generic copies even when doctors prescribe the corresponding branded products by name. Some people use the “evergreening” label when an innovator holds more than one patent protecting its product, especially if some patents expire later than others. More often, though, these people use the label when an innovator introduces a newer version of its own product that is already on the market. These newer products tend to be sold under brand names and protected by their own patents and statutory data exclusivity. Sometimes the innovator also stops selling its older product. If purchasers shift to the innovator’s newer product rather than purchasing cheap copies of the innovator’s older product, some say the innovator has engaged in evergreening. Although the term “evergreening” is a metaphor and signifies an extension of something, proponents of reform proposals do not agree on the particulars of the term’s use. Some say the company has evergreened its invention, its drug, or its product. Others say the company has evergreened the drug’s patent or patent life, or its exclusivity. Some say it has extended the drug’s patents, or the drug’s patent coverage or patent life, or the drug’s exclusivity period. Some say the company has evergreened the drug’s price, or its own profits or monopoly, or the company has extended its market power. Many argue that through evergreening — whatever the term means — the innovator has improperly blocked other firms from competing with it. On this basis, they seek government intervention. For instance, one recent proposal would allow the Federal Trade Commission to bring antitrust actions against innovators who introduced newer products to replace their older products. Three Myths of Evergreening The circumstances that trigger the “evergreening” label occur at the intersection of several complex bodies of law: the federal framework requiring premarket approval of new medicines and their copies, federal intellectual property laws, federal and state laws governing promotion of medicines, and federal laws and practices and state laws relating to prescribing and dispensing medicines. Many who propose aggressive government intervention because of evergreening give short shrift to this landscape, which allows the perpetuation of three myths that distort policymaking discussions. Before reviewing the myths, it will help to understand two points about the framework in which innovators compete with the companies that submit abbreviated applications. First, the FDA approves products, not active ingredients. And second, patents protect inventions, not products. Federal law states that every “new drug” requires an approved application. But at the FDA the term “drug” has more than one meaning. It includes a medicine’s active ingredient, to be sure. But it also includes drug products. A drug product is a medicine in its finished form, meaning the form that will be sold in the market and administered to patients. And the FDA approves a particular product described in a particular application — the specific combination of active and inactive ingredients (often called a drug’s “formulation”), in a particular dosage form (such as capsule or tablet), for a particular route of administration (such as oral or topical), at a particular strength, for particular medical uses (also known as the product’s “indications”), manufactured as described in the application, and accompanied by labeling written for prescribers based on the data in the application. Federal law allows a patent to issue for any new, useful, non‐​obvious invention, including a process, a composition of matter, and an improvement to an existing process or composition of matter. The patent usually expires 20 years after its application date. For any particular drug product approved by the FDA, the innovator might own patents on various types of inventions. The innovator usually owns a patent claiming the product’s active ingredient, and because the innovator generally files this patent before starting clinical trials, it is usually the first to expire. Other inventions protected by patent might include the product’s formulation or a dosage form and dosage of the active ingredient (or formulation). These inventions may emerge later in the premarket development process. If the resulting patent applications refer to the active ingredient patent, the patents will expire when the active ingredient patent expires, but otherwise they will expire later. The innovator may also own other patents claiming inventions embodied in the product, such as a patent claiming methods of using or administering the product, a patent claiming the manufacturing process, or a patent claiming a metabolite of the active ingredient. These, too, could expire later than the first patent — sometimes much later. These two points work together. A single active ingredient associated with a single brand name might be the subject of a half dozen, dozen, or more discrete products. Suppose an active ingredient was formulated into tablets and the innovator sold six strengths. Suppose the innovator also formulated an injectable version, which it sold in two strengths. Suppose it also developed a disintegrating tablet for oral administration, which it sold in four strengths. This innovator would sell 12 discrete products with the same active ingredient and probably (though not necessarily) the same brand name. And because a single product might incorporate many discrete inventions, the patents relevant to one product might differ from the patents relevant to another. Failure to realize this — and its regulatory significance — leads to three myths, as follows.

Myth of evergreening patents / The first myth is that innovators extend their patents. This is legally impossible. In the United States, a patent expires 20 years after its application date.

There are only two ways a patent’s expiration date can shift later in time: (1) When it issues a patent, the U.S. Patent and Trademark Office (PTO) adjusts the expiry date later to compensate for routine delays at the PTO. And (2), if the marketing application proposed a new active ingredient, then if the company asks the PTO for a patent term extension within 60 days of FDA approval, the PTO will use a statutory formula to extend one patent claiming the product to compensate partially for the lapse of patent life during premarket testing and regulatory review. There is no other mechanism by which a patent might be extended. In particular, a patent on one invention — no matter when it expires — does not extend the patent on another invention.

Myth of blocked competitors / The second myth is that when an innovator holds patents that expire after its active ingredient patent, or when it introduces newer products to market, it can prevent its competitors from bringing their copies to market. Instead, once the initial patent and (if applicable) statutory exclusivity on the innovator’s active ingredient have expired, its competitors have substantial freedom to operate. This freedom reflects two facts that are often overlooked.

First, the innovator’s competitor does not have to propose an exact copy. Federal law permits the competitor to rely on the innovator’s research but propose competing products that are not identical. To be sure, a competitor may submit an ANDA for a product that essentially duplicates the innovator’s product — that is, a generic. Ordinarily, the company shows in the ANDA that its product has the same active ingredient, route of administration, dosage form, strength, and labeling as the innovator’s product. The generic must also be “bioequivalent” to the original drug that it references, meaning that its active ingredient must reach the site of action in the body to the same extent and at the same rate as the active ingredient of the referenced product. But even a generic can be a little different. For example, it usually does not need the same inactive ingredients in the same quantities. And the generic competitor need not use the same manufacturing process.

If a competitor wants to offer a different route of administration, dosage form, or strength — for instance, to avoid infringing a patent — it may still be able to use the generic drug approval pathway. It simply files a “suitability petition” asking the FDA’s permission. The agency will approve the petition unless more data are needed to establish the proposed product’s safety and effectiveness. And at this point, the competitor may file an ANDA. More significantly, though, a competitor can always use a different abbreviated application pathway: a “505(b)(2)” application for a product that differs more substantially from the innovator’s product. Although the changes proposed in this hybrid application must be supported by new data, the competitor otherwise relies on the innovator’s data, avoiding the expensive and time‐​consuming research and development process the innovator went through. In addition to using this mechanism to propose modifications that avoid a patent, a competitor might use the mechanism to propose innovations that will offer an advantage in the market — such as changes to the active ingredient and new medical uses.

Second, an abbreviated application cites a specific innovative product, not the active ingredient or brand writ large. The competitor selects one innovative product as the reference product on which it relies — for instance, one of the 12 products in the hypothetical above. Its regulatory burden is tied to that specific product alone. The requirement to show sameness and bioequivalence (for an ANDA) and, critically, the obligation to contend with patents and wait for statutory exclusivity to expire are linked to the one specific product, alone. (In rare circumstances, when filing a hybrid application, a competitor might cite two innovative products, but the same point applies.)

To be sure, the patents associated with the cited innovative product affect when the FDA may approve the abbreviated application. Whether it files an ANDA or a hybrid application, a competitor must address the unexpired patents listed in the FDA’s “Orange Book” for the specific innovative product it has chosen to cite. For each listed patent, it has two choices, and its selection dictates the timing of FDA approval as far as that patent is concerned. The competitor may state the date on which the patent will expire, signaling that it does not plan to market its product until expiry. This precludes final approval of its product until patent expiry. Or it may assert that the patent is invalid or will not be infringed by its product, notifying the innovator of this position. If the innovator sues within 45 days, the drug statute stays final approval of its abbreviated application for 30 months. Under changes to the law made in 2003, though, unless the competitor changes its position on a patent after filing its abbreviated application, approval of its application is stayed only once. At the end of the 30 months, the FDA must approve the abbreviated application if the approval standard is met, even if there is ongoing patent litigation.

Although a competitor using the abbreviated application pathway must contend with the innovator’s patents and approval of its product may be delayed because of those patents, this is true of only the patents associated with the specific product that it references. The competitor does not have to contend with patents associated with other products that happen to contain the same active ingredient or bear the same brand name. Similarly, the competing applicant grapples with only the statutory exclusivity associated with the product it references. The drug statute provides five years of exclusivity in the data supporting new chemical entities and three years of exclusivity for most new products that are not new chemical entities. Separately, if an innovator introduces what the FDA calls a new “condition of approval” — such as a new strength or dosage form — the drug statute may provide three years of exclusivity. This delays approval of abbreviated applications proposing products with the same active ingredient for the same condition of approval. But a competitor that proposed a different strength or dosage form — or that cited a product with a different strength or dosage form (such as the innovator’s original product) — would not need to grapple with that exclusivity.

This debunks the myth that an innovator with later‐​expiring patents and an innovator that introduces newer products can prevent its competitors from bringing copies to market. Instead, competitors have several options. For instance, empirical studies show that competitors file abbreviated applications as early as the law permits them to do so, arguing that the innovator’s patents are invalid or, if applicable, not infringed by the new drug. They tend to lose these arguments when the active ingredient patent is at issue, but they tend to win if a formulation patent is at issue. If a competitor believed it would infringe a patent or feared it would lose the patent infringement suit brought by the innovator, it could seek a license. Settlements of patent litigation between innovators and competitors seeking to market generic copies usually include a license allowing the competitor to bring its product to market earlier than the date of patent expiry. There are also other options.

Once the patent on the active ingredient expires, a competitor can use the ingredient in its own product and file an abbreviated application, relying on the research performed and submitted by the innovator. Even in an ANDA, a true generic application, only the active ingredient must be the same. A competitor may be able to design around patents claiming other aspects of the innovator’s product (such as its strength and route of administration) and still file a true generic application. The competitor would simply file a suitability petition and, upon approval of that petition, a generic application proposing the difference that allowed it to avoid patent infringement. Then it would assert non‐​infringement in its application. If it could not file a generic application (for instance, because the FDA requested data to support the changes made), it could always file a hybrid application. It would still rely on the innovator’s research and it would similarly assert non‐​infringement in its application. In either case, the innovator might not sue if the competitor clearly avoided its patents.

It is thus misleading for advocates of intervention to complain about the number of “patents” associated with a “drug.” A competitor filing an abbreviated application does not copy a “drug” in the broad sense of the term. Accurately describing a company’s freedom to operate in the market would require focusing on discrete products that can serve as references for abbreviated applications and on the number, scope, and breadth of the patent claims held by the innovator for those products. This would tell policymakers more about the market effects of a firm’s innovation and patenting practices than the number of patents associated with a particular brand name or the number of patents associated with the many finished products containing a particular active ingredient.

Myth that automatic substitution is critical / The final myth of evergreening is that continuing innovation — especially when an innovator introduces a newer version of its product and stops selling its old version — precludes uptake of less expensive medicines by interfering with automatic pharmacy substitution under state pharmacy law. This myth reflects an assumption that competitors who file abbreviated applications depend on automatic pharmacy substitution — rather than the ordinary rough and tumble of a competitive marketplace — to obtain market share. The truth may be more complicated.

Automatic pharmacy substitution arises through a combination of longstanding FDA practices and state pharmacy law. Once the agency has approved two products with the same active ingredient, it assesses whether they are “therapeutically equivalent.” Designating two as therapeutically equivalent means that they have the same clinical profile and that they can be “substituted”: either can be dispensed instead of the other. A true generic drug, an exact copy of the innovator’s product approved based on an ANDA, will be deemed therapeutically equivalent. Every state either permits or requires pharmacists to dispense a therapeutically equivalent generic drug when a doctor prescribes an innovator’s drug by its brand name, unless the doctor has said not to. The notion advanced by critics of alleged “evergreening” is that once an innovator introduces a newer version of its branded product, doctors will prescribe the newer version. And because the generic company instead copied the older version, pharmacists will not — cannot under state law — substitute the generic product when the patient presents a prescription for the newer innovator product.

The problem with this argument is that actual dispensing decisions probably reflect a more complex interaction of prescriber decisions, payer preferences, and state law. To begin with, a doctor may specify either branded drugs or generic drugs. A doctor could write the brand name, to be sure, but the doctor could also simply identify the active ingredient, which will usually lead the pharmacist to dispense one of the available generic drugs. In theory, the doctor could even identify a particular generic company’s drug containing a particular active ingredient. And while drugmakers rarely promote generic drugs to doctors and patients, nothing prevents them from doing so. They do promote their therapeutically equivalent generic drugs to pharmacies and payers, focusing on the lower prices they offer. And a company that filed a hybrid application for a product that differed from the innovator’s product might brand its product and promote the distinguishing features, or (depending on the reason it filed the hybrid application) position the product as a near‐​duplicate of the more expensive branded alternatives and promote it as such.

In short, an innovator’s newer product creates a new choice for doctors and payers. To be sure, if doctors select this product, pharmacists will dispense it rather than generic copies of the innovator’s older product. Doctors might shift their prescribing to the newer product for many reasons, including persuasive advertising and promotion — meaning they come to believe (based on advertising that, per FDA rules, must be truthful and not misleading) that there are benefits to the newer product. They might shift for other reasons, including experience treating patients with the two options. But companies may advertise and promote generic products to doctors and patients as well, and based on this advertising (or for other reasons, such as experience with the older innovative product that the competitor copied) doctors might not select the innovator’s newer product. They might specify the innovator’s older product (which would lead to automatic substitution, even if the innovator no longer markets the product) or, again, a generic product itself.

Generic companies will be able to introduce copies of the innovator’s first product and they may or may not enjoy sales depending on the choices they make and the choices made by others in the market.

The assumption that competing companies depend on automatic substitution for market share may be simplistic. Only a minority of states require substitution; most instead have permissive laws. In these states, if a generic product is therapeutically equivalent to the prescribed product and the payer requires its use, the permissive state pharmacy law makes it possible for a pharmacist to substitute, in accordance with the patient’s insurance, without consulting the physician. In these cases, the patient’s insurance drives the product selection. State law just makes it possible to comply with the insurance without contacting the doctor. If a payer perceives the innovator’s new product as less cost effective than available generic drugs containing the same active ingredient, it may decline to cover the product. A rational payer will adopt strategies that steer doctors and patients to less expensive products that are equally or adequately effective — not only those that are therapeutically equivalent, but also those that are not. In these cases, even if a doctor specifies a branded product, the patient’s insurance might prompt a conversation among the doctor, pharmacist, and patient, ultimately leading to modification of the prescription and dispensing of the cheaper copy of the innovator’s first‐​version product.

In short, when an innovator introduces a new product into the market, generic companies will be able to introduce copies of the innovator’s first product and they may or may not enjoy sales depending on the choices they make and the choices made by others in the market. In this scenario, products compete for the business of rational payers based on their comparative benefits and cost. Substitution may play almost no true role, and whether the innovator still markets its older branded product may be irrelevant.

#### Prefer legal studies.

Parker and Mooney 7 [Scott and Kevin; “Is ‘evergreening’ a cause for concern? A legal perspective,” Journal of Commercial Biotechnology; 2007; <https://link.springer.com/article/10.1057/palgrave.jcb.3050066>] Justin

THE LEGAL BACKGROUND The patent system provides an incentive for companies to incur the cost and risk of research by providing the time-limited exclusive right to commercialise a patented product. At the heart of the patent system in the UK (and all other fully TRIPs compliant countries) is the requirement that to qualify for the monopoly right that the patent confers (20 years from the date of filing the patent application) the invention covered by the patent must be novel, non-obvious (ie it involves an inventive step) and capable of industrial application (‘utility’ or ‘usefulness’ in the US). The novelty and inventiveness of the patent is evaluated against the ‘state of the art’, which consists in general of every item of information which has ever been made available to the public by any kind of publication, or by use, anywhere in the world, at any point in time before the first filing date of the patent. It is a basic principle of patent law that once details of a product have entered the public domain (by being published anywhere without patent protection, or when any patents for the product or proposal expire or lapse), then everyone has freedom to use that information and any obvious developments of it. So before assuming that any new development relating to a known compound can be patented, we have to ask: 1 Is this new? Any previous publication or use, no matter how obscure, of the same invention destroys novelty and prevents a patent being issued or, if issued in ignorance of such a publication, this will subsequently cause the patent to be declared invalid if sought to be enforced. 2 Is there an inventive step? A patent cannot be granted for anything which is simply an obvious development or variant on any individual piece of information which is part of the state of the art. It is no answer that the piece of information in question may never have come to the attention of the fictitious ‘person skilled in the art’ who is central to any determination of ‘obviousness’. 3 Is there a proposed industrial application for the invention (in the broad sense of having some useful purpose)? The invention does not have to demonstrate an improvement on what is already known, but it cannot be speculative. It must have a use. For example, a DNA sequence for a recombinant gene fragment with a well-defined function is a patentable invention whereas a DNA sequence alone without any indication of function or of its useful attributes is not. 4 Does the patent describe how to put the invention into effect? The patent must be ‘enabling’; it must add to public knowledge, and contribute in its own right to the state of the art. In this way each new patent moves the frontier of the state of the art forward and makes it more difficult to find improvements which are neither old nor obvious. This disclosure enables third parties to implement the invention once the patent has expired and, is the consideration (in the legal sense) for the monopoly right granted by a patent. HOW THE PATENT SYSTEM DEALS WITH ‘EVERGREENING’ The criteria of patentability set out above apply equally to all inventions from the most basic mechanical patent to the most complex microelectronic or biotechnological invention. Similarly patent law does not distinguish between the invention of a wholly new product and inventions relating to improvements upon an existing product. The same criteria for patentability apply. ‘Double patenting’ is prohibited. That is to say the same invention cannot be covered by more than one patent. Thus for an improvement upon an existing pharmaceutical product to be patentable in its own right it will need to satisfy the criteria of novelty and non-obviousness taking into account the earlier product and all that is known about it in the public domain at the time that the second patent is applied for. If a patent is granted in respect of this improvement it will only cover the improvement to which it relates and will not extend to the originator product. That is to say a patent for a new product in a class will always be broader than any subsequent patent covering an improvement, modification or derivative of that product and so the exclusivity granted is in broad terms commensurate with the scope of the scientific advance that it reflects. An important corollary to the prohibition on ‘double patenting’ is that a patent covering an improved version of a pharmaceutical (or any other) product does not preclude a generic company from copying all forms of the originator product once the patents protecting these forms have expired. For example, if a company selling a patented pharmaceutical reformulates that product as a syrup for paediatric administration and then patents the new formulation, generic competition to the original adult formulation will be possible once the patents covering it expire or are invalidated. The existence of the patent on the paediatric formulation will not delay or prevent generic competition on the original formulation. The innovator company will, however, continue to have the exclusive right to sell the paediatric formulation for the remainder of the life of the patent covering this specific improvement. If in the above example the improvement made is not a paediatric formulation but a slow release formulation that allows once daily dosing and so improves patient compliance as a result of increased convenience, doctors and patients will have a choice between generic versions of the original formulation or the new once-daily product once any patent on the original formulation expires. The patents on the slow release formulation will not delay or prevent marketing of the original formulation. The market will then decide whether the benefits offered by the improved formulation make it worth paying for in the face of cheaper versions of the original product. The answer to this question will inevitably vary from market to market and between different patient populations. Either way the patient would appear to benefit from the increased choice available. A simple and further example of this is ibuprofen. The supermarket shelf carries premium-priced ibuprofen formulations which typically are quicker acting or easier to take than the traditional tablet. These formulations may be patent protected. Customers can, however, decide for themselves whether the added benefit is worth the extra cost. The patents do not prevent anybody from buying the ordinary, cheapest kind of tablet. Reference to patents covering the colour and scoring of tablets has been made in several articles criticising the pharmaceutical industry (without the specific patents that are complained of being identified).4 It is informative to consider how the patent system would apply to such ‘developments’. To the best of the authors’ knowledge no patents have ever been granted for the colour of pharmaceutical products. In fact, since UK patent law (and most others) expressly excludes the patenting of ‘aesthetic creations’ the colour of a pharmaceutical product could only ever be patentable if either: (a) it could be established that the colour itself produces a technical effect, such as a therapeutic benefit caused by increased compliance, that is novel and not obvious; or (b) that the means of obtaining that colour, the manufacturing process of colouring the tablet, is itself novel and not obvious. It goes without saying that for a ‘pink pill’ patent application the technical effect, novelty and inventiveness would be scrutinised carefully. Nevertheless, the application would be looked at on its own facts and applying the patentability criteria described above. Similarly, as regards the scoring of tablets, the same standard of patentability and scrutiny must be satisfied. It would need to be established that tablets had never been scored in this way before and that to do so was not an obvious departure from what has gone before. Without further investigation it should not be assumed that such an invention would be of no value to patients (eg it could be that compliance among children would be improved if the tablet is more cleanly cut as a result of the means of scoring employed). There are plenty of examples of developments (reformulations, new salts, combinations and the like) that have real therapeutic benefit but which at first blush may seem trivial. Again, the more minor that a variation is (eg a pink tablet or means of scoring the tablet) the more narrow the relevant patent protection will be and the easier it should be for a competitor to design around the patent without needing to seek to invalidate it. For example, if a patent is (or has been) granted that covers a particular colour of tablet or a particular means of scoring such tablet then such a patent would not stop a competitor from marketing (respectively) a different colour tablet or a tablet that is not scored or that is scored in a different way. In summary, therefore, the patent system is inherently adapted to reflect how much innovation in fact takes place (by way of improvements to existing technology) and to prevent ‘evergreening’. It allows the use of ‘old’ technology while protecting (and thus providing incentives for) improvements to that technology. Another factor to be taken into account in any debate on the patenting of ‘minor variations’ is that it is not only the company that owns the patents covering the originator product that can patent improvements thereto. Other companies (including generics) can (and do) do this, with the consequence that there may be a number of companies having similar products (some of which may for a variety of reasons be better suited to particular patients) and healthy competition in the marketplace. ‘STRATEGIC PATENTING’ A related charge that is sometimes made against innovator companies is that they file numerous patents on multiple attributes of a single product so as to create a ‘patent thicket’ that so complicates third-party research that it strangles innovation, or that they are guilty of what is sometimes referred to as ‘strategic patenting’.5 Implicit in these charges is that the only reason for filing these patents is maintenance of market share for as long as possible after the expiry of the patents covering the originator product itself. This is a serious charge that deserves to be looked at in more detail. Of course, pharmaceutical and biotechnology companies (like companies in all other R&D-based industries) have patenting strategies. In no other industry is there any suggestion that companies should restrict themselves to patenting inventions that meet some higher standard over and above the basic criteria for patentability or that companies should not seek protection for certain types of technological advance or that exceeding a certain number of patents in a technical area is per se reprehensible. When one considers that intellectual property rights are the life-blood that propels pharmaceutical advances in the private sector (and to an increasing extent in the public sector as well) and takes into account the sums that are typically spent on a new product during the 10–15-year-period from discovery through pre-clinical and clinical trials to regulatory approval and market launch, any company that did not do all that it could to protect its inventions would be acting negligently towards its shareholders. On the subject of patenting strategies in the pharmaceutical industry the UK Patents Court judge Mr Justice Jacob (now Lord Justice Jacob) said in the case of Synthon v SmithKline Beecham ‘I ask myself whether SB have done anything blameworthy…and I cannot see that they have. On the contrary, so far as I can see, they have employed competent and careful patent agents to obtain for them the best patent position which they think they can get. It may be good, it may be bad, but they are doing their job and I see no criticism whatever in the conduct of SB’.6 If one accepts that the nature of pharmaceutical and biotechnological innovation (as with other R&D based industries) is most often incremental and cumulative then it follows that the patent system should reflect this reality. This is indeed the case. As we have seen above, the patent system does not distinguish between ‘breakthroughs’ and ‘incremental improvements’ in terms of the patentability requirements that apply. At the same time a greater reward (a broader patent) is granted in respect of the ground breaking research than for inventions directed at solving further technical hurdles and optimisation of the initial invention. In the experience of the authors most of the patents that have been challenged by generic companies wishing to enter the market were applied for during the development of the originator product rather than once it has been established as a commercial success. This reflects the organic process of drug discovery and development and the time lag between drug discovery development, clinical testing and regulatory approval (ie that inventions are made in overcoming the various technical challenges faced during drug development). Nevertheless, some innovations are made at a later stage. For example, it may be that it is only after the product has been prescribed to a population of patients post-launch that it will become evident that further improvements need to be made to improve efficacy, deal with a compliance (or other) problem or expand the target patient population or disease indications. Such improvements may stem from greater experience of the product, problems unexpectedly encountered in particular patient populations or other advances made in the field. Given that the purpose of the patent system is to encourage innovation and (in the pharmaceutical sector) to lead to better medicines, it would be strange indeed if this incentive was removed or diminished once the first product of a particular type has been launched.

### 1NC – Disease

#### Infectious diseases don’t cause extinction

Owen Cotton-Barratt 17, et al, PhD in Pure Mathematics, Oxford, Lecturer in Mathematics at Oxford, Research Associate at the Future of Humanity Institute, 2/3/2017, Existential Risk: Diplomacy and Governance, https://www.fhi.ox.ac.uk/wp-content/uploads/Existential-Risks-2017-01-23.pdf

For most of human history, natural pandemics have posed the greatest risk of mass global fatalities.37 However, there are some reasons to believe that natural pandemics are very unlikely to cause human extinction. Analysis of the International Union for Conservation of Nature (IUCN) red list database has shown that of the 833 recorded plant and animal species extinctions known to have occurred since 1500, less than 4% (31 species) were ascribed to infectious disease.38 None of the mammals and amphibians on this list were globally dispersed, and other factors aside from infectious disease also contributed to their extinction. It therefore seems that our own species, which is very numerous, globally dispersed, and capable of a rational response to problems, is very unlikely to be killed off by a natural pandemic.

One underlying explanation for this is that highly lethal pathogens can kill their hosts before they have a chance to spread, so there is a selective pressure for pathogens not to be highly lethal. Therefore, pathogens are likely to co-evolve with their hosts rather than kill all possible hosts.39

#### Solves warming

#### Disease outbreaks will be defeated with quarantines

**Szalai 7/26** [(Jennifer Szalai - author for the NYT) “The Extradordinary History (and likely busy future) of quarantine” The New York Times. 7-26-2021]

**Quarantine can be lifesaving**; it can also be dangerous, an exercise of extraordinary power in the name of disease control, a presumption of guilt instead of innocence.

In “Until Proven Safe,” a new book about quarantine’s past and future, Geoff Manaugh and Nicola Twilley do an impressively judicious job of explaining exactly why fears of quarantine are understandable and historically justified, while also showing how in coming years “we will almost certainly find ourselves more dependent on quarantine, not less.” Quarantine has to do with risk and uncertainty, and its logic is simple: “There might be something dangerous inside you — something contagious — on the verge of breaking free.”

**While medical advances have made some diseases more diagnosable** and less deadly, newfound knowledge can also accentuate the depths of our ignorance. The more we know, the more we know how much we don’t know — not to mention that **modern life, with escalating numbers of people and goods churning** their way **around the world**, has **increased the opportunities for contagion.**

Quarantine is distinct from isolation, even if the terms are often used interchangeably. Someone is isolated when they are known to be sick; **someone is quarantined when they might be but we cannot be sure**. Manaugh, an architecture and technology blogger, and Twilley, the co-host of a podcast about the science and history of food, bring an impressively wide range of interests to bear on a subject that involves not only infectious disease but also — in their ambitious yet seamless narration — politics, agriculture, surveillance and even outer space.

#### Quarantines solve climate change – COVID was responsible for the largest drop in emissions ever

**Alexander 20** [(Kurtis, a general assignment reporter for The San Francisco Chronicle, frequently writing about water, wildfire, climate and the American West. His recent work has focused on the impacts of drought, the widening rural-urban divide and state and federal environmental policy. Before joining the Chronicle, Alexander worked as a freelance writer and as a staff reporter for several media organizations, including The Fresno Bee and Bay Area News Group, writing about government, politics and the environment.) "Coronavirus has altered the global warming trajectory. But for how long?" San Francisco Chronicle, 5/20/20, https://www.sfchronicle.com/health/article/Greenhouse-gas-emissions-on-track-for-record-drop-15279312.php] TDI

The disruption caused by the coronavirus has been so profound that it’s altered the trajectory of global warming.

Not since World War II — and perhaps never before — have the emissions of heat-trapping gases dropped as much around the planet as they have during the COVID-19 outbreak.

The latest and most detailed study yet on the pandemic’s impact on climate pollution, published Tuesday and authored by the research group Global Carbon Project chaired by Stanford University’s Rob Jackson, finds that the Earth will see up to a 7% decrease in carbon dioxide this year. The dip is five times the decline in emissions in 2009, when the recession choked the world’s economy, and double what it was in 1992, after the fall of the Soviet Union.

The paper’s findings mirror other reports that have similarly found sharp drops in greenhouse gases recently. The emerging research also is in agreement that the lull will likely be short-lived and, at best, buy time before the most devastating effects of climate change take hold. The lockdown that has halted factories, energy plants and automobiles during the pandemic is already lifting, and without deliberate action, carbon-intense activities are bound to resume.

“That’s the danger here,” said Jackson, a professor of earth system science and senior fellow at Stanford Woods Institute for the Environment. “We’ve decreased emissions for the wrong reasons. Will they jump back up starting this fall, or could the virus allow us to rethink transportation and other parts of the economy?”

The answer to the question, say Jackson and others, may not be so straightforward. Greenhouse gases could rebound in some areas, and there could be lasting decreases in others.

Measuring heat-trapping gas emissions, for which carbon dioxide is a proxy, is not easy to do, especially in real time. The researchers at the Global Carbon Project analyzed daily economic activity in 69 countries from January through April and modeled the carbon pollution that likely resulted, then compared it to last year. The countries included have historically produced almost all of the world’s carbon dioxide.

The researchers found that China, the largest polluter, reduced emissions by nearly 24% on some days in mid-February. The United States, the second-largest polluter, cut emissions by nearly 32% for almost two weeks in mid-April. The European Union, including Great Britain, trimmed emissions by about 27% during the first week of April.

The dates of peak reductions varied in different parts of the globe because each locked down at a different time. The biggest cumulative drop in carbon dioxide was on April 7 and measured about 17%, according to the study.

While a variety of activity explains the declines, fewer people driving was the largest contributor worldwide. Less industrial pollution was also a big contributor.

Based on the observed drops in emissions, the researchers estimate that going forward, carbon dioxide will fall between 4% and 7% for the year worldwide, depending on how quickly countries end their lockdowns.

Jackson said the amount of the decline can be viewed as both considerable, given that it’s the largest ever seen, and humbling because it’s the minimum needed annually to put the planet on track to meet the Paris climate agreement — enough of a drop to prevent the global temperature from rising 2 degrees Celsius above preindustrial levels.

“We would need to do this every year,” he said.

The International Energy Agency recently projected an 8% dip in greenhouse gases for the year while the International Monetary Fund came up with an estimate closer to 6%. Both organizations said carbon pollution would likely rise again in 2021.

After the decline in emissions in 2009 of about 1.4%, the following year saw an increase of 5.1%.

The Global Carbon Project says there’s reason to think that at least some parts of the globe will try to prevent heat-trapping gases from bouncing back. Stimulus programs aimed at developing clean energy and new carbon-friendly ways of living adopted during the pandemic, such as working from home, could help limit emissions.

“Cities from Seattle to Milan are keeping roads closed to cars and letting them stay open to bikes and pedestrians even after the shelter-in-place,” Jackson said. “And maybe COVID-19 and stimulus funding will jump-start electric cars.”

* 1. **Warming causes extinction**

**Ramanathan et al. 17** [Veerabhadran Ramanathan is Victor Alderson Professor of Applied Ocean Sciences and director of the Center for Atmospheric Sciences at the Scripps Institution of Oceanography, University of California, San Diego, Dr. William Collins is an internationally recognized expert in climate modeling and climate change science. He is the Director of the Climate and Ecosystem Sciences Division (CESD) for the Earth and Environmental Sciences Area (EESA) at the Lawrence Berkeley National Laboratory (LBNL), Prof. Dr Mark Lawrence, Ph.D. is scientific director at the Institute for Advanced Sustainability Studies (IASS) in Potsdam, Örjan Gustafsson is a Professor in the Department of Environmental Science and Analytic Chemistry at Stockholm University, Shichang Kang is Professor, Cold and Arid Regions Environmental and Engineering Research Institute, Chinese Academy of Sciences (CAS); CAS Center for Excellence in Tibetan Plateau Earth Sciences, and Molina, M.J., Zaelke, D., Borgford-Parnell, N., Xu, Y., Alex, K., Auffhammer, M., Bledsoe, P., Croes, B., Forman, F., Haines, A., Harnish, R., Jacobson, M.Z., Lawrence, M., Leloup, D., Lenton, T., Morehouse, T., Munk, W., Picolotti, R., Prather, K., Raga, G., Rignot, E., Shindell, D., Singh, A.K., Steiner, A., Thiemens, M., Titley, D.W., Tucker, M.E., Tripathi, S., & Victor, D., authors come from the following 9 countries - US, Switzerland, Sweden, UK, China, Germany, Australia, Mexico, India, “Well Under 2 Degrees Celsius: Fast Action Policies to Protect People and the Planet from Extreme Climate Change,” Report of the Committee to Prevent Extreme Climate Change, September 2017, http://www.igsd.org/wp-content/uploads/2017/09/Well-Under-2-Degrees-Celsius-Report-2017.pdf] TDI

**Climate change is becoming an existential threat with warming in excess of 2°C within the next three decades and 4°C to 6°C within the next several decades. Warming of such magnitudes will expose as many as 75% of the world’s population to deadly heat stress in addition to disrupting the climate and weather worldwide. Climate change is an urgent problem requiring urgent solutions**. This paper lays out urgent and **practical solutions that are ready for implementation now, will deliver benefits in the next few critical decades**, and places the world on a path to achieving the longterm targets of the Paris Agreement and near-term sustainable development goals. The approach consists of four building blocks and 3 levers to implement ten scalable solutions described in this report by a team of climate scientists, policy makers, social and behavioral scientists, political scientists, legal experts, diplomats, and military experts from around the world. These solutions will enable society to decarbonize the global energy system by 2050 through efficiency and renewables, drastically reduce short-lived climate pollutants, and stabilize the climate well below 2°C both in the near term (before 2050) and in the long term (post 2050). It will also reduce premature mortalities by tens of millions by 2050. As an insurance against policy lapses, mitigation delays and faster than projected climate changes, the solutions include an Atmospheric Carbon Extraction lever to remove CO2 from the air. The amount of CO2 that must be removed ranges from negligible, if the emissions of CO2 from the energy system and SLCPs start to decrease by 2020 and carbon neutrality is achieved by 2050, to a staggering one trillion tons if the carbon lever is not pulled and emissions of climate pollutants continue to increase until 2030.

There are numerous living laboratories including 53 cities, many universities around the world, the state of California, and the nation of Sweden, who have embarked on a carbon neutral pathway. These laboratories have already created 8 million jobs in the clean energy industry; they have also shown that **emissions of greenhouse gases and air pollutants can be decoupled from economic growth**. Another favorable sign is that **growth rates of worldwide carbon emissions have reduced from 2.9% per year during the first decade of this century to 1.3% from 2011 to 2014 and near zero growth rates during the last few years. The carbon emission curve is bending, but we have a long way to go and very little time for achieving carbon neutrality**. We need institutions and enterprises that can accelerate this bending by scaling-up the solutions that are being proven in the living laboratories. We have less than a decade to put these solutions in place around the world to preserve nature and our quality of life for generations to come. The time is now.

The Paris Agreement is an historic achievement. For the first time, effectively all nations have committed to limiting their greenhouse gas emissions and taking other actions to limit global temperature change. Specifically, 197 nations agreed to hold “the increase in the global average temperature to well below 2°C above pre-industrial levels and pursue efforts to limit the temperature increase to 1.5°C above pre-industrial levels,” and achieve carbon neutrality in the second half of this century.

**The climate has already warmed by 1°C. The problem is running ahead of us, and under current trends we will likely reach 1.5°C in the next fifteen years and surpass the 2°C guardrail by mid-century with a 50% probability of reaching 4°C by end of century**. Warming in excess of 3°C is likely to be a global catastrophe for three major reasons:

• **Warming in the range of 3°C to 5°C is suggested as the threshold for several tipping points in the physical and geochemical systems; a warming of about 3°C has a probability of over 40% to cross over multiple tipping points, while a warming close to 5°C increases it to nearly 90%, compared with a baseline warming of less than 1.5°C, which has only just over a 10% probability of exceeding any tipping point.**

**• Health effects of such warming are emerging as a major if not dominant source of concern. Warming of 4°C or more will expose more than 70% of the population, i.e. about 7 billion by the end of the century, to deadly heat stress and expose about 2.4 billion to vector borne diseases such as Dengue, Chikengunya, and Zika virus among others**. Ecologists and paleontologists have proposed that warming in excess of 3°C, accompanied by increased acidity of the oceans by the buildup of CO2 , can become a major causal factor for exposing more than 50% of all species to extinction. 20% of species are in danger of extinction now due to population, habitat destruction, and climate change.

The good news is that **there may still be time to avert such catastrophic changes**. The Paris Agreement and **supporting climate policies must be strengthened substantially within the next five years to bend the emissions curve down faster, stabilize climate, and prevent catastrophic warming**. To the extent those efforts fall short, societies and **ecosystems will be forced to contend with substantial needs for adaptation—a burden that will fall disproportionately on the poorest three billion who are least responsible for causing the climate change problem.**

Here we propose a policy roadmap with a realistic and reasonable chance of limiting global temperature to safe levels and preventing unmanageable climate change—an outline of specific science-based policy pathways that serve as the building blocks for a three-lever strategy that could limit warming to well under 2°C. The projections and the emission pathways proposed in this summary are based on a combination of published recommendations and new model simulations conducted by the authors of this study (see Figure 2). We have framed the plan in terms of four building blocks and three levers, which are implemented through 10 solutions. The first building block would be fully implementing the nationally determined mitigation pledges under the Paris Agreement of the UN Framework Convention on Climate Change (UNFCCC). In addition, several sister agreements that provide targeted and efficient mitigation must be strengthened. Sister agreements include the Kigali Amendment to the Montreal Protocol to phase down HFCs, efforts to address aviation emissions through the International Civil Aviation Organization (ICAO), maritime black carbon emissions through the International Maritime Organization (IMO), and the commitment by the eight countries of the Arctic Council to reduce black carbon emissions by up to 33%. There are many other complementary processes that have drawn attention to specific actions on climate change, such as the Group of 20 (G20), which has emphasized reform of fossil fuel subsidies, and the Climate and Clean Air Coalition (CCAC). HFC measures, for example, can avoid as much as 0.5°C of warming by 2100 through the mandatory global phasedown of HFC refrigerants within the next few decades, and substantially more through parallel efforts to improve energy efficiency of air conditioners and other cooling equipment potentially doubling this climate benefit.

For the second building block, numerous subnational and city scale climate action plans have to be scaled up. One prominent example is California’s Under 2 Coalition signed by over 177 jurisdictions from 37 countries in six continents covering a third of world economy. The goal of this Memorandum of Understanding is to catalyze efforts in many jurisdictions that are comparable with California’s target of 40% reductions in CO2 emissions by 2030 and 80% reductions by 2050—emission cuts that, if achieved globally, would be consistent with stopping warming at about 2°C above pre-industrial levels. Another prominent example is the climate action plans by over 52 cities and 65 businesses around the world aiming to cut emissions by 30% by 2030 and 80% to 100% by 2050. There are concerns that the carbon neutral goal will hinder economic progress; however, real world examples from California and Sweden since 2005 offer evidence that economic growth can be decoupled from carbon emissions and the data for CO2 emissions and GDP reveal that growth in fact prospers with a green economy.

The third building block consists of two levers that we need to pull as hard as we can: one for drastically reducing emissions of short-lived climate pollutants (SLCPs) beginning now and completing by 2030, and the other for decarbonizing the global energy system by 2050 through efficiency and renewables. Pulling both levers simultaneously can keep global temperature rise below 2°C through the end of the century. If we bend the CO2 emissions curve through decarbonization of the energy system such that global emissions peak in 2020 and decrease steadily thereafter until reaching zero in 2050, there is less than a 20% probability of exceeding 2°C. This call for bending the CO2 curve by 2020 is one key way in which this report’s proposal differs from the Paris Agreement and it is perhaps the most difficult task of all those envisioned here. Many cities and jurisdictions are already on this pathway, thus demonstrating its scalability. Achieving carbon neutrality and reducing emissions of SLCPs would also drastically reduce air pollution globally, including all major cities, thus saving millions of lives and over 100 million tons of crops lost to air pollution each year. In addition, these steps would provide clean energy access to the world’s poorest three billion who are still forced to resort to 18th century technologies to meet basic needs such as cooking. For the fourth and the final building block, we are adding a third lever, ACE (Atmospheric Carbon Extraction, also known as Carbon Dioxide Removal, or “CDR”). This lever is added as an insurance against surprises (due to policy lapses, mitigation delays, or non-linear climate changes) and would require development of scalable measures for removing the CO2 already in the atmosphere. The amount of CO2 that must be removed will range from negligible, if the emissions of CO2 from the energy system and SLCPs start to decrease by 2020 and carbon neutrality is achieved by 2050, to a staggering one trillion tons, if CO2 emissions continue to increase until 2030, and the carbon lever is not pulled until after 2030. This issue is raised because the NDCs (Nationally Determined Contributions) accompanying the Paris Agreement would allow CO2 emissions to increase until 2030. We call on economists and experts in political and administrative systems to assess the feasibility and cost-effectiveness of reducing carbon and SLCPs emissions beginning in 2020 compared with delaying it by ten years and then being forced to pull the third lever to extract one trillion tons of CO2

The fast mitigation plan of requiring emissions reductions to begin by 2020, which means that many countries need to cut now, is urgently needed to limit the warming to well under 2°C. Climate change is not a linear problem. Instead, we are facing non-linear climate tipping points that can lead to self-reinforcing and cascading climate change impacts. Tipping points and selfreinforcing feedbacks are wild cards that are more likely with increased temperatures, and many of the potential abrupt climate shifts could happen as warming goes from 1.5°C in 15 years to 2°C by 2050, with the potential to push us well beyond the Paris Agreement goals.

Where Do We Go from Here?

**A massive effort will be needed to stop warming at 2°C, and time is of the essence. With unchecked business-as-usual emissions, global warming has a 50% likelihood of exceeding 4ºC and a 5% probability of exceeding 6ºC in this century, raising existential questions for most, but especially the poorest three billion people. A 4ºC warming is likely to expose as many as 75% of the global population to deadly heat.** Dangerous to catastrophic impacts on the health of people including generations yet to be born, on the health of ecosystems, and on species extinction have emerged as major justifications for mitigating climate change well below 2ºC, although we must recognize that the uncertainties intrinsic in climate and social systems make it hard to pin down exactly the level of warming that will trigger possibly catastrophic impacts. To avoid these consequences, we must act now, and we must act fast and effectively. This report sets out a specific plan for reducing climate change in both the near- and long-term. With aggressive urgent actions, we can protect ourselves. Acting quickly to prevent catastrophic climate change by decarbonization will save millions of lives, trillions of dollars in economic costs, and massive suffering and dislocation to people around the world. This is a global security imperative, as it can avoid the migration and destabilization of entire societies and countries and reduce the likelihood of environmentally driven civil wars and other conflicts.

Staying well under 2°C will require a concerted global effort. We must address everything from our energy systems to our personal choices to reduce emissions to the greatest extent possible. We must redouble our efforts to invent, test, and perfect systems of governance so that the large measure of international cooperation needed to achieve these goals can be realized in practice. The health of people for generations to come and the health of ecosystems crucially depend on an energy revolution beginning now that will take us away from fossil fuels and toward the clean renewable energy sources of the future. It will be nearly impossible to obtain other critical social goals, including for example the UN agenda 2030 with the Sustainable Development Goals, if we do not make immediate and profound progress stabilizing climate, as we are outlining here.

1. The Building Blocks Approach The 2015 Paris Agreement, which went into effect November 2016, is a remarkable, historic achievement. For the frst time, essentially all nations have committed to limit their greenhouse gas emissions and take other actions to limit global temperature and adapt to unavoidable climate change. Nations agreed to hold “the increase in the global average temperature to well below 2°C above pre-industrial levels and pursue efforts to limit the temperature increase to 1.5°C above pre-industrial levels” and “achieve a balance between anthropogenic emissions by sources and removals by sinks of greenhouse gases in the second half of this century” (UNFCCC, 2015). Nevertheless, the initial Paris Agreement has to be strengthened substantially within fve years if we are to prevent catastrophic warming; **current pledges place the world on track for up to 3.4°C by 2100 (UNEP, 2016b). Until now, no specifc policy roadmap exists that provides a realistic and reasonable chance of limiting global temperatures to safe levels and preventing unmanageable climate change**. This report is our attempt to provide such a plan— an outline of specifc solutions that serve as the building blocks for a comprehensive strategy for limiting the warming to well under 2°C and avoiding dangerous climate change (Figure 1). The frst building block is the full implementation of the nationally determined mitigation pledges under the Paris Agreement of the UN Framework Convention on Climate Change (UNFCCC) and strengthening global sister agreements, such as the Kigali Amendment to the Montreal Protocol to phase down HFCs, which can provide additional targeted, fast action mitigation at scale. For the second building block, numerous sub-national and city scale climate action plans have to be scaled up such as California’s Under 2 Coalition signed by 177 jurisdictions from 37 countries on six continents. The third building block is targeted measures to reduce emissions of shortlived climate pollutants (SLCPs), beginning now and fully implemented by 2030, along with major measures to fully decarbonize the global economy, causing the overall emissions growth rate to stop in 2020-2030 and reach carbon neutrality by 2050. Such a deep decarbonization would require an energy revolution similar to the Industrial Revolution that was based on fossil fuels. The fnal building block includes scalable and reversible carbon dioxide (CO2 ) removal measures, which can begin removing CO2 already emitted into the atmosphere. Such a plan is urgently needed. Climate change is not a linear problem. Instead, climate tipping points can lead to self-reinforcing, cascading climate change impacts (Lenton et al., 2008). Tipping points are more likely with increased temperatures, and many of the potential abrupt climate shifts could happen as warming goes from 1.5°C to 2°C, with the potential to push us well beyond the Paris Agreement goals (Drijfhout et al., 2015). In order to avoid dangerous climate change, we must address these concerns. **We must act now, and we must act fast. Reduction of SLCPs will result in fast, near-term reductions in warming, while present-day reductions of CO2 will result in long-term climate benefts**. This two-lever approach—aggressively cutting both SLCPs and CO2 –-will slow warming in the coming decades when it is most crucial to avoid impacts from climate change as well as maintain a safe climate many decades from now. To achieve the nearterm goals, we have outlined solutions to be implemented immediately. These solutions to bend down the rising emissions curve and thus bend the warming trajectory curve follow a 2015 assessment by the University of California under its Carbon Neutrality Initiative (Ramanathan et al., 2016). The solutions are clustered into categories of social transformation, governance improvement, market- and regulation-based solutions, technological innovation and transformation, and natural and ecosystem management. Additionally, we need to intensely investigate and pursue a third lever—ACE (Atmospheric Carbon Extraction). While many potential technologies exist, we do not know the extent to which they could be scaled up to remove the requisite amount of carbon from the atmosphere in order to achieve the Paris Agreement goals, and any delay in mitigation will demand increasing reliance on these technologies. Yet, there is still hope. Humanity can come together, as we have done in the past, to collaborate towards a common goal. We have no choice but to tackle the challenge of climate change. We only have the choice of when and how: **either now, through the ambitious plan outlined here, or later, through radical adaptation and societal transformations in response to an ever-deteriorating climate system that will unleash devastating impacts—some of which may be beyond our capacity to fully adapt to or reverse for thousands of years.**

2. Major Climate Disruptions: How Soon and How Fast? “Without adequate mitigation and adaptation, climate change poses unacceptable risks to global public health.” (WHO, 2016)

The planet has already witnessed nearly 1°C of warming, and another 0.6°C of additional warming is currently stored in the ocean to be released over the next two to four decades, if climate warming emissions are not radically reduced during that time (IPCC, 2013). The impacts of this warming on extreme weather, droughts, and foods are being felt by society worldwide to the extent that many think of this no longer as climate change but as climate disruption. Consider the business as usual scenario:

15 years from now: In 15 years, planetary warming will reach 1.5°C above pre-industrial global mean temperature (Ramanathan and Xu, 2010; Shindell et al., 2012). This exceeds the 0.5°C to 1°C of warming during the Eemian period, 115,000– 130,000 years ago, when sea-levels reached 6-9 meters (20-30 feet) higher than today (Hansen et al., 2016b). The impacts of this warming will affect us all yet will disproportionately affect the Earth’s poorest three billion people, who are primarily subsistence farmers that still rely on 18th century technologies and have the least capacity to adapt (IPCC, 2014a; Dasgupta et al., 2015). They thus may be forced to resort to mass migration into city slums and push across international borders (U.S. DOD, 2015). The existential fate of lowlying small islands and coastal communities will also need to be addressed, as they are primarily vulnerable to sea-level rise, diminishing freshwater resources, and more intense storms. In addition, many depend on fsheries for protein, and these are likely to be affected by ocean acidifcation and climate change. Climate injustice could start causing visible regional and international conficts. All of this will be exacerbated as the risk of passing tipping points increases (Lenton et al., 2008).

30 years from now: By mid-century, warming is expected to exceed 2°C, which would be unprecedented with respect to historical records of at least the last one million years (IPCC, 2014c). Such a warming through this century could result in sea-level rise of as much as 2 meters by 2100, with greater sea-level rise to follow. A group of tipping points are clustered between 1.5°C and 2°C (Figure 2) (Drijfhout et al., 2015). The melting of most mountain glaciers, including those in the Tibetan-Himalayas, combined with mega-droughts, heat waves, storms, and foods, would adversely affect nearly everyone on the planet.

80 years from now: In 80 years, warming is expected to exceed 4°C, increasing the likelihood of irreversible and catastrophic change (World Bank, 2013b). 4ºC warming is likely to expose as much as 75% of the global population to deadly heat (Mora et al., 2017). The 2°C and 4°C values quoted above and in other reports, however, are merely the central values with a 50% probability of occurrence (Ramanathan and Feng, 2008). There is a 5% probability the warming could be as high as 6°C due to uncertainties in the magnitude of amplifying feedbacks (see Section 4). This in turn could lead to major disruptions to natural and social systems, threatening food security, water security, and national security and fundamentally affecting the great majority of the projected 11.2 billion inhabitants of the planet in 2100 (UN DESA, 2015).

3. What Are the Wild Cards for Climate Disruption? Increasing the concentrations of greenhouse gases in the atmosphere increases radiative forcing (the difference between the amount of energy entering the atmosphere and leaving) and thus increases the global temperature (IPCC, 2013). However, climate wild cards exist that can alter the linear connection with warming and anthropogenic emissions by triggering abrupt changes in the climate (Lenton et al., 2008). Some of these wild cards have not been thoroughly captured by the models that policymakers rely on the most. These abrupt shifts are irreversible on a human time scale (<100 years) and will create a notable disruption to the climate system, condemning the world to warming beyond that which we have previously projected. These climate disruptions would divert resources from needed mitigation and upset mitigation strategies that we have already put in place.

1. Unmasking Aerosol Cooling: The frst such wild card is the unmasking of an estimated 0.7°C (with an uncertainty range of 0.3°C to 1.2°C) of the warming in addition to mitigating other aerosol effects such as disrupting rainfall patterns, by reducing emissions of aerosols such as sulfates and nitrates as part of air pollution regulations (Wigley, 1991; Ramanathan and Feng, 2008). Aerosol air pollution is a major health hazard with massive costs to public health and society, including contributing to about 7 million deaths (from household and ambient exposure) each year (WHO, 2014). While some aerosols, such as black carbon and brown carbon, strongly absorb sunlight and warm the climate, others refect sunlight back into space, which cools the climate (Ramanathan and Carmichael, 2008). The net impact of all manmade aerosols is negative, meaning that about 30% of the warming from greenhouse gases is being masked by co-emitted air pollution particles (Ramanathan and Carmichael, 2008). As we reduce greenhouse gas emissions and implement policies to eliminate air pollution, we are also reducing the concentration of aerosols in the air. Aerosols last in the atmosphere for about a week, so if we eliminate air pollution without reducing emissions of the greenhouse gases, the unmasking alone would lead to an estimated 0.7°C of warming within a matter of decades (Ramanathan and Feng, 2008). We must eliminate all aerosol emissions due to their health effects, but we must simultaneously mitigate emissions of CO2 , other greenhouse gases, and black carbon and co-pollutants to avoid an abrupt and very large jump in the near-term warming beyond 2°C (Brasseur and Roeckner, 2005).

2. Tipping Points**: It is likely that as we cross the 1.5°C to 2°C thresholds we will trigger so called “tipping points” for abrupt and nonlinear changes in the climate system with catastrophic consequences** for humanity and the environment (Lenton, 2008; Drijfhout et al., 2015). Once the tipping points are passed, the resulting impacts will range in timescales from: disruption of monsoon systems (transition in a year), loss of sea ice (approximately a decade for transition), dieback of major forests (nearly half a century for transition), reorganization of ocean circulation (approximately a century for transition), to loss of ice sheets and subsequent sea-level rise (transition over hundreds of years) (Lenton et al., 2008). Regardless of timescale, once underway many of these changes would be irreversible (Lontzek et al., 2015). There is also a likelihood of crossing over multiple tipping points simultaneously. Warming of close to 3°C would subject the system to a 46% probability of crossing multiple tipping points, while warming of close to 5°C would increase the risk to 87% (Cai et al., 2016). Recent modeling work shows a “cluster” of these tipping points could be triggered between 1.5°C and 2°C warming (Figure 2), including melting of land and sea ice and changes in highlatitude ocean circulation (deep convection) (Drijfhout et al., 2015). This is consistent with existing observations and understanding that the polar regions are particularly sensitive to global warming and have several potentially imminent tipping points. The Arctic is warming nearly twice as quickly as the global average, which makes the abrupt changes in the Arctic more likely at a lower level of global warming (IPCC, 2013). Similarly, the Himalayas are warming at roughly the same rate as the Arctic and are thus also more susceptible to incremental changes in temperature (UNEP-WMO, 2011). This gives further justifcation for limiting warming to no more than 1.5°C.

While all climate tipping points have the potential to rapidly destabilize climate, social, and economic systems, some are also **self-amplifying feedbacks that once set in motion increase warming in such a way that they perpetuate yet even more warming. Declining Arctic sea ice, thawing permafrost, and the poleward migration of cloud systems are all examples of self-amplifying feedback mechanisms, where initial warming feeds upon itself to cause still more warming acting as a force multiplier (Schuur et al., 2015).**

#### Solves war

#### Disease pandemics decrease the likelihood of war

Walt 20 (Stephen M. Walt is the Robert and Renée Belfer professor of international relations at Harvard University; “Will a Global Depression Trigger Another World War?”; Foreign Policy; May 13, 2020; https://foreignpolicy.com/2020/05/13/coronavirus-pandemic-depression-economy-world-war/; ERB)

By many measures, 2020 is looking to be the worst year that humankind has faced in many decades. We’re in the midst of a pandemic that has already claimed more than 280,000 lives, sickened millions of people, and is certain to afflict millions more before it ends. The world economy is in free fall, with unemployment rising dramatically, trade and output plummeting, and no hopeful end in sight. A plague of locusts is back for a second time in Africa, and last week we learned about murderous killer wasps threatening the bee population in the United States. Americans have a head-in-the-sand president who prescribes potentially lethal nostrums and ignores the advice of his scientific advisors. Even if all those things magically disappeared tomorrow—and they won’t—we still face the looming long-term danger from climate change. Given all that, what could possibly make things worse? Here’s one possibility: war. It is therefore worth asking whether the combination of a pandemic and a major economic depression is making war more or less likely. What does history and theory tell us about that question? For starters, we know neither plague nor depression make war impossible. World War I ended just as the 1918-1919 influenza was beginning to devastate the world, but that pandemic didn’t stop the Russian Civil War, the Russo-Polish War, or several other serious conflicts. The Great Depression that began in 1929 didn’t prevent Japan from invading Manchuria in 1931, and it helped fuel the rise of fascism in the 1930s and made World War II more likely. So if you think major war simply can’t happen during COVID-19 and the accompanying global recession, think again. But war could still be much less likely. The Massachusetts Institute of Technology’s Barry Posen has already considered the likely impact of the current pandemic on the probability of war, and he believes COVID-19 is more likely to promote peace instead. He argues that the current pandemic is affecting all the major powers adversely, which means it isn’t creating tempting windows of opportunity for unaffected states while leaving others weaker and therefore vulnerable. Instead, it is making all governments more pessimistic about their short- to medium-term prospects. Because states often go to war out of sense of overconfidence (however misplaced it sometimes turns out to be), pandemic-induced pessimism should be conducive to peace. Moreover, by its very nature war requires states to assemble lots of people in close proximity—at training camps, military bases, mobilization areas, ships at sea, etc.—and that’s not something you want to do in the middle of a pandemic. For the moment at least, beleaguered governments of all types are focusing on convincing their citizens they are doing everything in their power to protect the public from the disease. Taken together, these considerations might explain why even an impulsive and headstrong warmaker like Saudi Arabia’s Mohammed bin Salman has gotten more interested in winding down his brutal and unsuccessful military campaign in Yemen. Posen adds that COVID-19 is also likely to reduce international trade in the short to medium term. Those who believe economic interdependence is a powerful barrier to war might be alarmed by this development, but he points out that trade issues have been a source of considerable friction in recent years—especially between the United States and China—and a degree of decoupling might reduce tensions somewhat and cause the odds of war to recede. For these reasons, the pandemic itself may be conducive to peace. But what about the relationship between broader economic conditions and the likelihood of war? Might a few leaders still convince themselves that provoking a crisis and going to war could still advance either long-term national interests or their own political fortunes? Are the other paths by which a deep and sustained economic downturn might make serious global conflict more likely? One familiar argument is the so-called diversionary (or “scapegoat”) theory of war. It suggests that leaders who are worried about their popularity at home will try to divert attention from their failures by provoking a crisis with a foreign power and maybe even using force against it. Drawing on this logic, some Americans now worry that President Donald Trump will decide to attack a country like Iran or Venezuela in the run-up to the presidential election and especially if he thinks he’s likely to lose. This outcome strikes me as unlikely, even if one ignores the logical and empirical flaws in the theory itself. War is always a gamble, and should things go badly—even a little bit—it would hammer the last nail in the coffin of Trump’s declining fortunes. Moreover, none of the countries Trump might consider going after pose an imminent threat to U.S. security, and even his staunchest supporters may wonder why he is wasting time and money going after Iran or Venezuela at a moment when thousands of Americans are dying preventable deaths at home. Even a successful military action won’t put Americans back to work, create the sort of testing-and-tracing regime that competent governments around the world have been able to implement already, or hasten the development of a vaccine. The same logic is likely to guide the decisions of other world leaders too. Another familiar folk theory is “military Keynesianism.” War generates a lot of economic demand, and it can sometimes lift depressed economies out of the doldrums and back toward prosperity and full employment. The obvious case in point here is World War II, which did help the U.S economy finally escape the quicksand of the Great Depression. Those who are convinced that great powers go to war primarily to keep Big Business (or the arms industry) happy are naturally drawn to this sort of argument, and they might worry that governments looking at bleak economic forecasts will try to restart their economies through some sort of military adventure. I doubt it. It takes a really big war to generate a significant stimulus, and it is hard to imagine any country launching a large-scale war—with all its attendant risks—at a moment when debt levels are already soaring. More importantly, there are lots of easier and more direct ways to stimulate the economy—infrastructure spending, unemployment insurance, even “helicopter payments”—and launching a war has to be one of the least efficient methods available. The threat of war usually spooks investors too, which any politician with their eye on the stock market would be loath to do. Economic downturns can encourage war in some special circumstances, especially when a war would enable a country facing severe hardships to capture something of immediate and significant value. Saddam Hussein’s decision to seize Kuwait in 1990 fits this model perfectly: The Iraqi economy was in terrible shape after its long war with Iran; unemployment was threatening Saddam’s domestic position; Kuwait’s vast oil riches were a considerable prize; and seizing the lightly armed emirate was exceedingly easy to do. Iraq also owed Kuwait a lot of money, and a hostile takeover by Baghdad would wipe those debts off the books overnight. In this case, Iraq’s parlous economic condition clearly made war more likely. Yet I cannot think of any country in similar circumstances today. Now is hardly the time for Russia to try to grab more of Ukraine—if it even wanted to—or for China to make a play for Taiwan, because the costs of doing so would clearly outweigh the economic benefits. Even conquering an oil-rich country—the sort of greedy acquisitiveness that Trump occasionally hints at—doesn’t look attractive when there’s a vast glut on the market. I might be worried if some weak and defenseless country somehow came to possess the entire global stock of a successful coronavirus vaccine, but that scenario is not even remotely possible. If one takes a longer-term perspective, however, a sustained economic depression could make war more likely by strengthening fascist or xenophobic political movements, fueling protectionism and hypernationalism, and making it more difficult for countries to reach mutually acceptable bargains with each other. The history of the 1930s shows where such trends can lead, although the economic effects of the Depression are hardly the only reason world politics took such a deadly turn in the 1930s. Nationalism, xenophobia, and authoritarian rule were making a comeback well before COVID-19 struck, but the economic misery now occurring in every corner of the world could intensify these trends and leave us in a more war-prone condition when fear of the virus has diminished. On balance, however, I do not think that even the extraordinary economic conditions we are witnessing today are going to have much impact on the likelihood of war. Why? First of all, if depressions were a powerful cause of war, there would be a lot more of the latter. To take one example, the United States has suffered 40 or more recessions since the country was founded, yet it has fought perhaps 20 interstate wars, most of them unrelated to the state of the economy.

To paraphrase the economist Paul Samuelson’s famous quip about the stock market, if recessions were a powerful cause of war, they would have predicted “nine out of the last five (or fewer).” Second, states do not start wars unless they believe they will win a quick and relatively cheap victory. As John Mearsheimer showed in his classic book Conventional Deterrence, national leaders avoid war when they are convinced it will be long, bloody, costly, and uncertain. To choose war, political leaders have to convince themselves they can either win a quick, cheap, and decisive victory or achieve some limited objective at low cost. Europe went to war in 1914 with each side believing it would win a rapid and easy victory, and Nazi Germany developed the strategy of blitzkrieg in order to subdue its foes as quickly and cheaply as possible. Iraq attacked Iran in 1980 because Saddam believed the Islamic Republic was in disarray and would be easy to defeat, and George W. Bush invaded Iraq in 2003 convinced the war would be short, successful, and pay for itself. The fact that each of these leaders miscalculated badly does not alter the main point: No matter what a country’s economic condition might be, its leaders will not go to war unless they think they can do so quickly, cheaply, and with a reasonable probability of success. Third, and most important, the primary motivation for most wars is the desire for security, not economic gain. For this reason, the odds of war increase when states believe the long-term balance of power may be shifting against them, when they are convinced that adversaries are unalterably hostile and cannot be accommodated, and when they are confident they can reverse the unfavorable trends and establish a secure position if they act now. The historian A.J.P. Taylor once observed that “every war between Great Powers [between 1848 and 1918] … started as a preventive war, not as a war of conquest,” and that remains true of most wars fought since then. The bottom line: Economic conditions (i.e., a depression) may affect the broader political environment in which decisions for war or peace are made, but they are only one factor among many and rarely the most significant. Even if the COVID-19 pandemic has large, lasting, and negative effects on the world economy—as seems quite likely—it is not likely to affect the probability of war very much, especially in the short term.