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#### Counterplan: At least three-quarters of WTO member nations, excluding the United States, should reduce intellectual property protections for medicines.

#### Entirely solves while avoiding politics

Siripurapu 21 Anshu Siripurapu covers economics, energy, and geopolitics, BA in political economy from the University of Southern California. "The Debate Over a Patent Waiver for COVID-19 Vaccines: What to Know." Council on Foreign Relations, May 26, 2021, [www.cfr.org/in-brief/debate-over-patent-waiver-covid-19-vaccines-what-know](http://www.cfr.org/in-brief/debate-over-patent-waiver-covid-19-vaccines-what-know).

WTO negotiations are notoriously slow, and it could take months before countries reach an agreement, particularly over the scope and duration of a waiver. Decisions are normally made unanimously, and though a TRIPS waiver could be granted by a three-quarters vote of WTO members, it is unlikely that members would break precedent.

#### Drug price reform coming now – fight is ramping up but Biden has the opportunity

Cancryn 9/9 Cancryn, Adam. Adam Cancryn is a health care reporter for POLITICO Pro, graduate of Washington & Lee University."Biden admin backs direct government drug price negotiations." POLITICO, 9 Sept. 2021, www.politico.com/news/2021/09/09/biden-drug-price-negotiations-510828.

A new Biden administration plan aimed at lowering prescription drug prices endorses giving the government sweeping power to directly negotiate the cost of medicines, calling it one of the key steps Congress could take to make drugs “more affordable and equitable” for all Americans.

The plan — developed by the Department of Health and Human Services and released on Thursday — largely backs Democrats’ ongoing efforts to lower drug prices as part of a $3.5 trillion reconciliation proposal, and mirrors a range of legislative options that both House and Senate lawmakers have floated in recent years.

Those include capping out-of-pocket costs in Medicare Part D, limiting how quickly pharmaceutical companies can hike prices on existing drugs and banning so-called pay-for-delay agreements aimed at blocking generic competition to brand-name drugs.

But the HHS report’s embrace of broad price negotiation is the administration’s latest signal that it’s siding with progressives who have pushed for a far more aggressive approach to slashing pharmaceutical costs.

Under the HHS plan, the government would directly negotiate prices for drugs in Medicare parts B and D, with those prices also being available to private insurance plans and any employers who want to participate.

House Democrats passed a similar provision as part of a major drug pricing bill in 2019. But it never made it into law, and some in the party’s centrist wing have since vowed to oppose drug price negotiation.

Notably, the plan stops short of supporting the use of “march-in rights” that progressives argue empower the government to pull patent rights from a drug that is deemed too expensive. Sen. Elizabeth Warren has long advocated for the approach, and urged HHS to utilize it in an August letter with Sen. Amy Klobuchar and Rep. Lloyd Doggett.

“The Biden Administration has the opportunity to lower the prices of key drugs using these authorities,” the lawmakers wrote to HHS Secretary Xavier Becerra.

The department in its report acknowledged that it has been petitioned to use march-in rights, saying only that it would give them “due consideration.”

The HHS plan also lays out a series of administration actions that the department could take to fulfill what it identified as three “guiding principles:” making drugs more affordable, improving competition within the industry and encouraging innovation.

Those options included testing value-based payment models and boosting cost-sharing support to certain low-income Medicare beneficiaries. It also suggests that improved data collection from insurers and pharmacy benefit managers could give the government better insight into drug pricing, as well as rebates and out-of-pocket spending on prescription medications.

HHS developed the report in response to an executive order that President Joe Biden issued earlier this year aimed at improving competition across a range of industries, including the drug sector.

#### Biden’s PC is key to wrangle democrats and counter pharma lobbying

Johnson 8/12 Johnson, Jake, writer for Alternet . "Joe Biden throws support behind bold reforms to slash drug prices." Alternet, August 12, 2021, www.alternet.org/2021/08/biden-medicare-negotiate-prices.

The powerful industry's public and behind-closed-doors lobbying push is likely to grow more aggressive as congressional Democrats' reconciliation package begins to take shape.

On Wednesday, the Senate approved a $3.5 trillion budget resolution setting the boundaries for the package, and the House is expected to take up and pass the resolution later this month. Once both chambers have passed an identical resolution, congressional committees will begin crafting legislative text.

"We will save taxpayers hundreds of billions by requiring that Medicare negotiate prescription drug prices with the pharmaceutical industry and we will use those savings to expand Medicare by covering the dental care, hearing aids, and eyeglasses that seniors desperately need," Sen. Bernie Sanders (I-Vt.), the chief architect of the budget resolution, said in a statement earlier this week.

But it's far from certain that a Medicare negotiation provision will survive the process of developing the final reconciliation bill, particularly given that a number of Big Pharma-backed House Democrats—including Reps. Scott Peters (D-Calif.) and Jake Auchincloss (D-Mass.)—have recently voiced skepticism about the proposal.

With Republicans unanimously opposed to the reconciliation package, Democrats can afford just a handful of defections in the House and none in the Senate.

Larry Levitt, executive vice president for health policy at the Kaiser Family Foundation, told HuffPost on Thursday that "it's not yet clear how the Democratic leadership will corral the necessary votes for a drug pricing plan, but there's no sign they're backing off."

"An epic battle with the pharmaceutical industry is coming," said Levitt.

In a series of tweets responding to Biden's prescription drug agenda, Levitt wrote that while the president's "proposal doesn't break new policy ground," it "is significant in that he is now using his political capital to push for congressional action at a pivotal moment in the debate."

#### 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.

#### 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**.

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#### The member nations of the WTO should impose a mandatory lockdown until there is no more than one new case per day per 100,000 people after which local officials will modulate lockdown levels based on local case numbers. Governments should compensate both individual workers and small businesses that suffer substantial or irreparable economic loss as a result of lockdowns.

#### Only the lockdown solves- it curbs COVID spread until the vaccine

Osterholm, 20 -- Regents Professor and Director of the Center for Infectious Disease Research and Policy at the University of Minnesota

[Michael T. and Mark Olshaker, writer and documentary filmmaker, "America Needs to Lock Down Again," Foreign Affairs, 9-16-20, https://www.foreignaffairs.com/articles/united-states/2020-09-16/coronavirus-america-needs-lock-down-again, accessed 10-29-20]

In our essay “Chronicle of a Pandemic Foretold,” for the July/August issue of Foreign Affairs, we described the struggle against COVID-19 in terms of a baseball game and estimated that the United States was in about the third inning of a nine-inning contest. At this point, however, it may be more helpful to shift to an altogether different analogy. The unfolding story of the pandemic is a three-act play, in which the country is now midway through the second act.

The first act saw the disease spread from China to the rest of the world and to a woefully unprepared United States. The second witnessed Americans tire of restrictions and effectively surrender to the pandemic. Infection rates across the country soared during the summer and will likely rise again in the autumn as schools and universities reopen. To truly get the novel coronavirus under control, the United States must do what it has not done so far: impose real and stringent lockdowns across the country for roughly two months. Controlling the spread of the disease in this way will save lives ahead of the eventual end of this drama in the pandemic’s final act—the arrival of a safe, effective vaccine.

THE CURTAIN RISES

Act I opened in late 2019 with the emergence in China of a novel coronavirus that spread throughout much of the world with breathtaking speed and effect. Nations and regions faced the challenge in different ways and with varying levels of success. After a horrendous start, for example, Italy managed to get transmission substantially under control by imposing a near-complete shutdown of the northern part of the country. In the United States, both New York City and New York State saw catastrophic levels of infection that overwhelmed the entire health-care system. It is difficult to forget the images of refrigerated trailers sitting outside hospital emergency rooms to accommodate the dead. But under the leadership of Governor Andrew Cuomo—and thanks to a coordinated state public health response—New York locked down to get the number of cases to a manageable level and then maintain the low numbers, turning a disaster into a model for the rest of the United States.

The issue of testing loomed over Act I. Some Asian nations that had experience with SARS began widespread testing of possible cases early and therefore were able to do contact tracing and largely control viral transmission. The United States did not do that. The White House denied the potential seriousness of the coronavirus (allegedly in a bid to prevent “panic”), while the Centers for Disease Control and Prevention (CDC) developed a test for national use that was faulty, leaving the virus difficult to track and making case isolation and contact tracing ineffective as a means to control transmission. That forced the country onto a much more disruptive path: an attempt to control and mitigate the virus’s effects through a national lockdown of all nonessential personnel.

The price was steep, with millions of jobs lost, schools closed, and all public events and gatherings officially canceled. In mid-April, the United States was seeing 32,000 new cases a day. But a month later, that figure had dropped to 22,000 and Americans felt they had turned a corner, that the pandemic was subsiding and the battle was won.

THE DISTANT PEAK

Act II of this drama began around Memorial Day weekend in late May. Pandemic fatigue had set in. Americans seemed to collectively declare, “We’re done,” taking any decrease in daily case counts or deaths as a sign that the virus had been curtailed. The warm-weather months drew people into social settings, and the White House and a host of pundits encouraged this natural yearning to get back to business—and leisure—as usual. The administration and its allies posited a zero-sum choice between continuing to slow transmission of the disease and saving the economy. In fact, the country had the fire only under limited control, and if you stop fighting a fire at that point, it will naturally flare up again and continue to burn.

By July 20, with people resuming socializing in large groups, the country’s daily new case count shot up to more than 66,000. It should be noted that the many protests that followed the death of George Floyd in late May did not contribute much to the spread since the demonstrations occurred outdoors, where the virus rapidly dissipates in the air. The spring weekend beach gatherings of young people, by contrast, led to more serious transmissions because revelers often ended up indoors, particularly in close and crowded confines such as bars and houses.

The rate of daily new cases dipped to a little over 42,000 by the end of August, largely because of major containment efforts in California, Florida, Georgia, and Texas. As encouraging as that was on the face of it, the United States was still seeing about 1,000 COVID-19-related deaths per day, hardly a victory by any standard. Americans can expect these crests and troughs in new infections to continue, with each successive peak higher than the one before, until either an effective vaccine becomes widely available or herd immunity is established in the population through person-to-person transmission.

Herd immunity is often discussed but widely misunderstood. Each infectious disease has a different threshold for what percentage of a given population must be immune before the rate of transmission begins to drop. For a highly infectious agent transmitted through the air, such as measles, that percentage can be as high as 95 percent. For COVID-19, most public health infectious disease experts estimate it to be between 50 and 70 percent. One theory holds that the best way to approach the virus is to try to achieve herd immunity as quickly as possible through natural infection so everything can get back to normal, while protecting the older and most vulnerable people. This is the method seemingly employed by Sweden. Its transmission and mortality rates were significantly higher than those of neighboring Denmark and Norway, but the country does not appear to be substantially closer to reaching herd immunity than its Scandinavian neighbors, all of which are still far short of the threshold. Moreover, there is emerging evidence that exposure to the virus may confer only temporary immunity, possibly as brief as several months. And achieving herd immunity—if that is even possible—would only slow transmission, not halt it.

By the most liberal estimates, only about ten to 12 percent of the U.S. population has been infected thus far and, as Sweden’s experience has shown, reaching the threshold will be a long-drawn-out process that could result in the deaths of more than two million Americans. As it is, with about four percent of the world’s population, the United States has racked up about a quarter of all confirmed COVID-19 fatalities. The country failed to protect vulnerable populations, as witnessed in the many outbreaks in nursing homes and extended-care facilities. The virus has also taken a toll on young and healthy individuals; even some with mild or asymptomatic variants of the disease have become “long haulers,” who experience a range of symptoms, including chronic fatigue and cardiac and respiratory issues, weeks or months after getting infected.

SHUT IT DOWN

Herd immunity is a distant and unrealistic prospect, but Americans still have the opportunity to mitigate the suffering and death caused by the disease. The reality is that the only way for the United States to get through Act II with low levels of morbidity and mortality is through more complete lockdowns than were previously implemented in areas with high incidence of infection. Currently, the upper Midwest is the “hottest” area in the country for community-wide transmission, but other areas will see increasing case totals deeper into the fall. The aim at this point, quite simply, should be to cut transmission of the virus as much as possible until the creation and distribution of an effective vaccine.

Such lockdowns should last six to eight weeks with a goal of reaching no more than one new case per day per 100,000 people. This low rate is necessary for testing and contact tracing to have any meaningful effect. Once that rate is achieved, however, local officials will be able to adjust lockdown measures more accurately and with the flexibility the pandemic demands. If the White House and federal government will not lead, which is unfortunately likely under the current administration, the governors of each state, in coordination with their neighboring states, must take the initiative themselves. Some might think this is unrealistic, but New York has been able to maintain this low rate of new infections for the past three months.

Stringent lockdowns, of course, would depend on the continued labor of essential workers, a category we estimate to be no more than 35 percent of the workforce and possibly less. What about other workers? As part of its broader anti-COVID-19 strategy, the federal and state governments should compensate both individual workers and small businesses that suffer substantial or irreparable economic loss as a result of lockdowns. Such support negates the false choice between public and economic health. If carried out successfully, the near-complete shutdowns would be not open-ended but limited in time. And the government has the means to prop up adversely affected workers and businesses. As Minneapolis Federal Reserve Bank President Neel Kashkari outlined in an op-ed in The New York Times cowritten with one of us (Osterholm), this fiscal obligation could be covered by the money most Americans who have not lost income are saving by not spending as much during the pandemic—the personal savings rate of Americans has grown from eight percent in January to 20 percent in August. Domestic savings can fund investment in the national economy, a concept that should work equally well in other developed nations. Banks, whose holdings have been boosted by the additional savings, could loan the money necessary for protecting jobs and businesses; Americans would essentially be repaying themselves rather than taking the more traditional route of incurring foreign debt. We believe many people would support a more robust lockdown if they understood that they would not suffer financially. Such a subsidy will actually save money in the long term by preserving jobs and small businesses.

The alternatives to serious lockdowns are insufficient. In areas where the disease is still rampant, masks and physical distancing alone will not get the job done. Business as usual for another six to eight months—until an effective vaccine is widely available—will send current rates of transmission even higher, especially as schools and colleges reopen. By the middle of September, some universities had already canceled in-person classes owing to widespread transmission on campus. Consider how much pain, suffering, and death Americans have endured so far, with no more than ten to 12 percent of the population infected. The next phase could be overwhelming and make Americans look back with nostalgia at the time when new infection rates were still under 100,000 per day.

A DIFFICULT DENOUEMENT

The final act will begin when—and if—one vaccine or more becomes broadly available. A vaccine will eventually bring this long drama to an end, but it will raise a whole new set of questions. Will enough Americans be willing to take it, given our national schizophrenic view of vaccines and science in general? How effective will a vaccine be, and how long will it confer immunity? What will the rules be for approving the vaccine, in the United States and the rest of the world? Who should, or will, get it first? There has been little official or public discussion about answers to these important questions.

It would be dangerous if a possible vaccine became politicized, either to achieve power, prestige, and influence for the country that produces it or to gain partisan advantage within the United States. Many in the public health sphere are afraid that a vaccine will be made available for use before it has been demonstrated to be safe and effective. Never before has the authority and confidence in U.S. government scientific institutions been so undermined by real or perceived political pressure from the White House. At the beginning of September, the CDC directed localities to prepare for the distribution of a vaccine in two months, at the beginning of November, right around the time of the presidential election. One possible mechanism for this expedited rollout would require the president to direct the Food and Drug Administration or the secretary of the Department of Health and Human Services to grant Emergency Use Authorization for a vaccine candidate that looks promising but has not been through the entire validating process.

There is indeed an inescapable tension between wanting a vaccine as soon as possible to prevent further transmission of the disease (and the resulting illnesses and deaths) and taking the necessary time to produce a safe vaccine, whose efficacy and effects on people of various ages and health situations are well understood. But public health and political officials should be extremely wary of any attempt to grant Emergency Use Authorization to a vaccine that hasn’t completed phase three trials, the final and most rigorous stage in which the product is tested over a broad range of thousands of subjects. In most instances in which such authorization is granted, it is for extremely sick or even dying patients. In this case, it would be granted to administer a vaccine to healthy people before the formula is perfected and before any potential negative effects have been documented. In 1955, one company’s production of the original Salk polio vaccine turned out to be defective, causing 40,000 cases of polio. Ten children died. In 1976, a rush to produce a vaccine against a perceived threat of swine flu left approximately 450 recipients with Guillain-Barré Syndrome paralysis.

One of the key reasons for a full phase three review, which includes at least 30,000 test subjects in a double-blind administration (meaning neither the subject nor the administrator knows who has been given the vaccine and who has been given a placebo), is to determine the vaccine’s impact and effects, positive and negative, on a range of different risk groups. What might be safe and effective for young adults, for example, might be ineffective or even harmful for seniors or those with certain underlying conditions. It is also possible that the effect on children could be different or unpredictable. These results will probably take months to sort out. Even more troubling, present plans do not call for either children or the elderly to be included in the phase three test group. Moreover, the first vaccines for this virus probably won’t be home runs (to go back to baseball analogies for a moment) like the smallpox, polio, and measles vaccines. They are more likely to be singles and doubles like the annual influenza vaccine, which in a good year is about 50 percent effective. Americans won’t be going back to the “old normal” anytime soon.

The best outcome in Act III will be the development and distribution of the vaccine as quickly and widely as possible, without shortcuts on safety or testing for effectiveness. The U.S. government should establish and publicize the criteria by which a vaccine will be considered ready for wide-scale public use as well as make clear which groups of people will receive the vaccine first. A proven safe and effective vaccine should first be given to physicians, hospital personnel, and first responders; then to essential workers with underlying risks for serious disease; and after that, to children so that they can stay in school.

But right now, the United States should just be trying to get through the rest of Act II—the coronavirus winter—and hold out until the arrival of a vaccine-enabled spring. It must impose severe lockdowns to truly curb the spread of the disease. New York has shown it can be done. It remains to be seen whether the rest of the country possesses the collective grit and determination to follow suit. A happy ending to this drama will very much be determined by how Americans decide to craft the rest of this current act.

## OFF

### NC – DA [Long]

#### Pharmaceutical innovation is accelerating now – new medicines are substantially better than existing treatments.

Wills, MBA, and Lipkus, PhD, 20 – Todd J. Wills [Managing Director @ Chemical Abstracts Service, MBA from THE Ohio State University] and Alan H. Lipkus [Senior Data Analyst @ Chemical Abstracts Service, PhD Physical Chemistry from the University of Rochester], “Structural Approach to Assessing the Innovativeness of New Drugs Finds Accelerating Rate of Innovation,” ACS Medicinal Chemistry Letters, Vol. 11, 2020, <https://pubs.acs.org/doi/pdf/10.1021/acsmedchemlett.0c00319> C.VC

Despite recent concerns over an innovation crisis, this analysis shows pharmaceutical innovation has actually increased over the last several decades based on the structural novelty of approved NMEs. The higher proportion of Pioneers over the most recent decade is a sign that innovation within the industry is accelerating rather than slowing. It is also an encouraging sign for the state of innovation in drug discovery that these Pioneers are significantly more likely to be the source of promising new therapies that are expected to provide substantial clinical advantages over existing treatments. Drug hunters are discovering Pioneers in newer and less explored regions of chemical space as they are increasingly found on scaffolds first reported in the CAS REGISTRY five or less years prior to their IND year or on scaffolds populated with 50 or less other compounds at the time of IND.

As scale becomes less of a strategic advantage, Big Pharma’s share of Pioneers has decreased even though the number of Big Pharma originated Pioneers has increased. This has created a structural innovation gap between Big Pharma and the Rest of Ecosystem which has widened over the last two decades as the Rest of Ecosystem is now responsible for originating almost 3 out of every 4 Pioneers. Pioneers originated by the Rest of Ecosystem are increasingly on new scaffolds, while a majority of Big Pharma originated Pioneers have historically been on new scaffolds.

The work presented here was intended as a study of drug innovation at a macro level. As a result, it included substances of various sizes with different degrees of complexity belonging to a range of functional and drug classes. Even though it was outside the scope of the present work to study specific subsets, such focused studies could yield additional insights into how innovation at a more micro level has changed over time. Other interesting subsets of our data set are the shapes and scaffolds of the Settlers and Colonists. Many of these shapes and scaffolds are privileged in the sense that they are seemingly capable of serving as ligands for a diverse array of target proteins. A separate study of the Settlers and Colonists as well as their side chains could provide insights into possible target-specific innovation trends.

As it often takes more than 10 years after initial discovery for an experimental drug to gain FDA approval, any measure of drug innovation that relies on the time of approval incorporates a significant time lag between initial discovery and ultimate approval. However, characterizing drug innovation based on structural novelty provides a means to assess the forward-looking innovation potential of an experimental drug at the time of initial discovery by comparing its framework information (at the scaffold and shape level) with prior FDA-approved drugs. Therefore, a separate study of drug candidates with publically disclosed structures currently in clinical development could provide additional insights into innovation trends at an FDA regulatory review level and serve as a leading indicator of innovation trends at an FDA approval level.

Given the tremendous opportunity represented by the vast amount of chemical space yet to be explored, drug-hunters of all types will continue pushing the boundaries to find promising new therapies in previously unexplored areas of chemical space. The race to discover these new drugs will be fueled by further advancements in screening approaches and in-silico methods (including innovations related to machine learning algorithms and molecular representations). However, comprehensive data on known shapes and scaffolds can fast track the identification of meaningful open areas of chemical space (shapes or scaffolds that are potentially important but have never been used as the basis for a molecule) to further explore.

#### The biopharmaceutical industry is uniquely reliant on IP protections – undermining them would kill innovation by making an already expensive process completely unfeasible.

Kristina M. Lybecker, PhD, 17 [PhD Economics, Associate Professor of Economics @ Colorado College], “Intellectual Property Rights Protection and the Biopharmaceutical Industry: How Canada Measures Up,” Fraser Institute, January 2017, <https://www.fraserinstitute.org/sites/default/files/intellectual-property-rights-protection-and-the%20biopharmaceutical-industry.pdf> C.VC

The unique structure of the innovative biopharmaceutical industry necessitates a variety of intellectual property protection mechanisms. In particular, the industry is characterized by a research and development (R&D) process that is lengthy, expensive, uncertain, and risky. According to DiMasi and colleagues, the estimated cost of developing a new medicine is US$2.6 billion (DiMasi, Grabowski, and Hansen, 2016).2 In addition, the time required to develop a new drug is also significant, averaging 10 to 15 years without any guarantee of success (PhRMA, n.d.). While these figures are highly controversial, biopharmaceutical innovation is unquestionably an expensive and lengthy undertaking.3 For the biopharmaceutical industry, innovation and its protection are essential and the source of both profits and growth. As such, patent protection is disproportionally more important for ensuring that the innovator appropriates the returns to R&D for the biopharmaceutical industry than virtually any other. Extending the findings of the 1987 “Yale Survey” (Levin, Klevorick, Nelson, and Winter, 1987), the “Carnegie Mellon Survey” established that while patents are again considered “unambiguously the least effective appropriability mechanisms,” the drug industry and other scholars regard them as strictly more effective than alternative mechanisms (Cohen, Nelson, and Walsh, 1996). The industry’s disproportionate reliance on patents and other forms of intellectual property protection is confirmed in numerous other studies.4

In essence, IPR protections provide innovative biopharmaceutical firms with an assurance of some return on their investment, thus creating incentives for the development of new technologies that could otherwise be easily replicated and sold by competitors. Due to the tremendous fixed costs required to develop new treatments and cures, a significant potential exists for free riding by follower firms, a market failure that would prevent investment in innovation were it not for the patents and other forms of intellectual property protections that provide a limited period of market exclusivity or other such incentives. Fundamentally, patents amount to an efficiency tradeoff. Society provides innovators with a limited period of market exclusivity to encourage innovation in exchange for public access to this knowledge. In exchange for the temporary static loss from market exclusivity, society gains complete knowledge of the innovation through disclosure, a permanent dynamic gain. Through this tradeoff, the existing patent system corrects the market failure that would stymie innovation. In its Apotex Inc. v. Wellcome Foundation Ltd. finding, Justice Binnie wrote for the Supreme Court of Canada, “A patent, as has been said many times, is not intended as an accolade or civic award for ingenuity. It is a method by which inventive solutions to practical problems are coaxed into the public domain by the promise of a limited monopoly for a limited time. Disclosure is the quid pro quo for valuable proprietary rights to exclusivity which are entirely the statutory creature of the Patent Act” (para. 37).

The biopharmaceutical industry is characterized by a number of legal and economic issues that distinguish it from other research-intensive industries. Danzon (1999) describes three features that are particularly noteworthy. First, given that the biopharmaceutical industry is characterized by an unusually high rate of R&D, intellectual property protection provides for the potential for significant market power and monopoly pricing that raises numerous public health policy questions surrounding prices and profits. Second, virtually every aspect of the industry is heavily regulated, from safety and efficacy to promotion and advertising, to pricing and reimbursement. Danzon describes the impact of these regulations as “profound and multidimensional even within a single country, affecting consumption patterns, productivity, R&D and hence the supply of future technologies” (Danzon, 1999: 1056). Lastly, while research and development costs are borne solely by the innovator, the resulting product is a global public good. “Each country faces an incentive to adopt the regulatory policies that best control its pharmaceutical budget in the short run, free-riding on others to pay for the joint costs of R&D and ignoring cross-national spillovers of national regulatory policies through parallel trade and international price comparisons” (Danzon, 1999: 1056). The combination of these characteristics defines a set of unique economic and legal challenges for the innovation of new drugs and the public health policies that surround their production, marketing, and distribution.

Innovative companies make far greater investments in time, resources, and financial support than do generic firms. Notably, innovation-based companies spend more than 200 times that which generic companies spend on the development of a particular drug (CIPC, 2011: 10). In addition, the investment of time, from laboratory to market, is also close to double for innovative companies relative to generic producers. Table 1 highlights the differences in the drug development processes of innovative and generic companies. For innovative biopharmaceutical companies, the development process is expensive, risky, and time consuming, all of which points to the need for strong IP protection to encourage investment and ensure companies are able to recover their investments.

The risk involved in biopharmaceutical development is starkly illustrated in a recent report by Biotechnology Innovation Organization (BIO), which reports that less than one of every 10 drugs that enter clinical trials is ultimately approved by the Food and Drug Administration in the United States. The report finds a success rate of merely 9.6%, a calculation that is significantly smaller than the widely-cited 11.8% figure from a 2014 study by the Tufts University’s Center for the Study of Drug Development.5 The International Federation of Pharmaceutical Manufacturers and Associations (2012) estimates that more than 3,200 compounds were at different stages of development globally in 2011, but only 35 new medicines were launched (Dawson, 2015).

Fundamentally, research-based biopharmaceutical companies incur greater expenses and risk in the development of their products than do generic manufactures. These investments of time and financial resources should be recognized and the effective patent life should be sufficient to recoup these investments. Continued investment and innovation are contingent upon strong, effective intellectual property protection and the ability of innovative firms to recoup their investments. Patents and other forms of intellectual property protection are disproportionally important to the research-based biopharmaceutical industry. Consequently, the legal architecture necessary to foster a robust innovation-based industry is multifaceted and is a powerful force shaping the biopharmaceutical industry, its profitability, productivity, and innovative future.

**Pharmaceutical innovation is key to protecting against future pandemics, bioterrorism, and antibiotic resistance.**

**Marjanovic and Fejiao ‘20** Marjanovic, Sonja, and Carolina Feijao. Sonja Marjanovic, Ph.D., Judge Business School, University of Cambridge. Carolina Feijao, Ph.D. in biochemistry, University of Cambridge; M.Sc. in quantitive biology, Imperial College London; B.Sc. in biology, University of Lisbon. "Pharmaceutical Innovation for Infectious Disease Management: From Troubleshooting to Sustainable Models of Engagement." (2020). [Quality Control]

As key actors in the healthcare innovation landscape, pharmaceutical and life sci-ences companies have been called on to develop medicines, vaccines and diagnostics for pressing public health challenges. The COVID-19 crisis is one such challenge, but there are many others. For example, MERS, SARS, Ebola, Zika and avian and swine flu are also infectious diseases that represent public health threats. Infectious agents such as anthrax, smallpox and tularemia could present threats in a **bioterrorism con-text**.1 The general threat to public health that is posed by **antimicrobial resistance** is also **well-recognised** as an area **in need of pharmaceutical innovation**. Innovating in response to these challenges does not always align well with pharmaceutical industry commercial models, shareholder expectations and compe-tition within the industry. However, the expertise, networks and infrastructure that industry has within its reach, as well as public expectations and the moral imperative, make pharmaceutical companies and the wider life sciences sector an **indispensable** partner in the search for solutions that save lives. This perspective argues for the need to establish more sustainable and scalable ways of incentivising pharmaceu-tical innovation in response to infectious disease threats to public health. It considers both past and current examples of efforts to mobilise pharmaceutical innovation in high commercial risk areas, including in the context of current efforts to respond to the COVID-19 pandemic. In global pandemic crises like COVID-19, the urgency and scale of the crisis – as well as the spotlight placed on pharmaceutical companies – mean that contributing to the search for effective medicines, vaccines or diagnostics is **essential** for socially responsible companies in the sec-tor.2 It is therefore unsurprising that we are seeing indus-try-wide efforts unfold at unprecedented scale and pace. Whereas there is always scope for more activity, industry is currently contributing in a variety of ways. Examples include pharmaceutical companies donating existing com-pounds to assess their utility in the fight against COVID-19; screening existing compound libraries in-house or with partners to see if they can be repurposed; accelerating tri-als for potentially effective medicine or vaccine candidates; and in some cases rapidly accelerating in-house research and development to discover new treatments or vaccine agents and develop diagnostics tests.3,4 Pharmaceutical companies are collaborating with each other in some of these efforts and participating in global R&D partnerships (such as the Innovative Medicines Initiative effort to accel-erate the development of potential therapies for COVID-19) and supporting national efforts to expand diagnosis and testing capacity and ensure affordable and ready access to potential solutions.3,5,6 The primary purpose of such innovation is to **benefit patients** and wider **population health**. Although there are also reputational benefits from involvement that can be realised across the industry, there are likely to be rela-tively few companies that are ‘commercial’ winners. Those who might gain substantial revenues will be under pres-sure not to be seen as profiting from the pandemic. In the United Kingdom for example, GSK has stated that it does not expect to profit from its COVID-19 related activities and that any gains will be invested in supporting research and long-term pandemic preparedness, as well as in developing products that would be affordable in the world’s poorest countries.7 Similarly, in the United States AbbVie has waived intellectual property rights for an existing com-bination product that is being tested for therapeutic poten-tial against COVID-19, which would support affordability and allow for a supply of generics.8,9 Johnson & Johnson has stated that its potential vaccine – which is expected to begin trials – will be available on a not-for-profit basis during the pandemic.10 Pharma is mobilising substantial efforts to rise to the COVID-19 challenge at hand. However, we need to consider how pharmaceutical innovation for responding to emerging infectious diseases can best be enabled beyond the current crisis. Many public health threats (including those associated with other **infectious diseases**, **bioterror-ism** agents **and antimicrobial resistance**) are **urgently in need of pharmaceutical innovation**, **even if their impacts are not as visible** to society **as COVID**-19 is in the imme-diate term. The pharmaceutical industry has responded to previous public health emergencies associated with infec-tious disease in recent times – for example those associated with Ebola and Zika outbreaks.11 However, it has done so to a lesser scale than for COVID-19 and with contribu-tions from fewer companies. Similarly, levels of activity in response to the threat of antimicrobial resistance are still **low**.12 There are important policy questions as to whether – and how – industry could engage with such public health threats to an even greater extent under improved innova-tion conditions.

#### Bioterrorism and future pandemics cause extinction.

Hamish De Bretton-Gordon, CBRN Expert @ British Army, 20 [Director @ DBG Defense, Consultant on CBRN and Biosecurity], “Biosecurity in the Wake of COVID-19: The Urgent Action Needed,” Combatting Terrorism Center Sentinel, November/December 2020, Volume 13, Issue 11, <https://ctc.usma.edu/biosecurity-in-the-wake-of-covid-19-the-urgent-action-needed/> C.VC

Policymakers around the world did not grasp just how large the impact of a bio threat could be. Beyond the enormous human and economic impact, the current pandemic has exposed the weakness, lack of preparedness, and poor responsiveness of healthcare systems of even highly developed countries like the United States and the United Kingdom. And the virus has inflicted carnage, even though SARS-CoV-2 (the virus that causes COVID-19) is not especially virulent. The world may be confronted with other viruses in the future whose combination of virulence (the harm a pathogen does to its host), transmissibility, and other characteristics pose much greater danger.

While overwhelming evidence points to SARS-CoV-2 spontaneously spreading to humans, the advances in synthetic biology and the growth in the number of Level 3 and 4 biocontainment facilities around the world storing deadly viruses1 mean there is also the very real possibility that in the future, bad actors will try to engineer or steal/obtain a highly transmissible and highly virulent virus and unleash it onto the world. Another risk is accidental releases from such biocontainment facilities.

COVID-19, a highly transmissible but not very virulent pathogen, has had a devastating global impact, a fact that will not have gone unnoticed by rogue states and terror organizations. Advances in synthetic biology have created tools that could be put to malevolent use. In the last two decades, scientists synthesized the poliovirus from its genetic sequence,2 recreated the 1918 Spanish flu virus,3 and succeeded in modifying the H5N1 avian flu virus so that it resulted (in a research laboratory) in airborne transmission among mammals.4 In the future, we should think of weaponized biology as no less of an existential threat to the planet than weaponized atomic science. It should also be noted that the fear and panic that even a medium-scale bioterror attack could create could have dangerous implications that may rival or even surpass the immediate loss of life.

The Need to Rethink Likelihood

Given the fact that in late 2019 when, as far as is known, COVID-19 cases first started emerging in China, it had been more than a century since the previous catastrophic outbreak (the 1918-1919 “Spanish flu” pandemic),d it was unsurprising that many thought of such pandemics as a one-in-a-100-year event. Such assumptions should no longer hold. The encroachment of human settlements into areas that had previously been sanctuaries for wildlife5 and the popularity in some parts of the world of markets where people and wild animals are brought into proximity have made it more likely viruses will make the species leap to human beings.e And when they do, as the COVID-19 pandemic illustrated, the interconnectedness of a world in which millions of people fly each day6 means they can spread very rapidly.

There is also growing concern about engineered viruses. Not only have advances in synthetic biology (SynBio) created growing capacity for extremely dangerous viruses to be engineered in a laboratory, but the number of people with access to potentially dangerous ‘dual use’ technology has greatly expanded and continues to expand, making malevolent use of such technology ever more likely.

In the August 2020 issue of this publication, scientists at the U.S. Military Academy at West Point warned that:

The wide availability of the protocols, procedures, and techniques necessary to produce and modify living organisms combined with an exponential increase in the availability of genetic data is leading to a revolution in science affecting the threat landscape that can be rivaled only by the development of the atomic bomb. As the technology improves, the level of education and skills necessary to engineer biological agents decreases. Whereas only state actors historically had the resources to develop and employ biological weapons, SynBio is changing the threat paradigm.

The cost threshold of engineering viruses is also lowering, with the West Point scientists warning that synthetic biology has “placed the ability to recreate some of the deadliest infectious diseases known well within the grasp of the state-sponsored terrorist and the talented non-state actor.”7

As already noted, another source of vulnerability is that deadly viruses could be stolen from or escape from a research laboratory. There are now around 50 Biosafety Level 4f facilities around the world, where the deadliest pathogens are stored and worked on, and this figure is set to increase in the next few years.g This is a large increase over the last 30 years, creating bigger risk of a breach. Of equal, if not greater concern are the thousands of Biosafety Level 3 labs globally,8 which handle deadly pathogens like COVID-19.9

Given what has been outlined above, the risk of a future destructive biological attack or another devastating global pandemic should no longer be seen as low. From this point forward, there should no higher priority for the international community than biosecurity.

## Case

### NC – AT 1AR Theory [:10]

#### They get 1AR theory but it’s not DTD- incentivizes reading 10 friv shells since they can win on any of them- AND, 1AR time advantage on 1AR theory since they get 2 speeches and 7 min, abuse is self-imposed b/c they could always better develop the shell in the 1ar; proportional- reading theory cancels out the abuse; and no reason short speech means drop the debater- just get more efficient or don’t read theory.

### COVID Advantage

#### WTO already did the AFF – Doha Declaration nullifies medical patents for developing countries struggling with pricing

World Trade Organization 17 (World Trade Organization – you should know who this is, “WTO IP rules amended to ease poor countries’ access to affordable medicines”, <https://www.wto.org/english/news_e/news17_e/trip_23jan17_e.htm>, 23 January 2017, EmmieeM)

An amendment to the agreement on intellectual property entered into force today (23 January) securing for developing countries a legal pathway to access affordable medicines under WTO rules.

The amendment to the WTO Trade Related Aspects of Intellectual Property Rights (TRIPS) Agreement marks the first time since the organization opened its doors in 1995 that WTO accords have been amended.

The WTO Secretariat has received in recent days notifications from five members that they have ratified the protocol amending the WTO TRIPS Agreement. These notifications — from Burkina Faso, Nigeria, Liechtenstein, the United Arab Emirates and Viet Nam — brought to two-thirds the number of WTO members which have now ratified the amendment. The two-thirds threshold was needed to formally bring the amendment into the TRIPS Agreement.

Members took the decision to amend the TRIPS Agreement specifically to adapt the rules of the global trading system to the public health needs of people in poor countries. This action follows repeated calls from the multilateral system for acceptance of the amendment, most recently by the United Nations General Assembly High-Level Meeting on Ending AIDS in June 2016.

“This is an extremely important amendment. It gives legal certainty that generic medicines can be exported at reasonable prices to satisfy the needs of countries with no pharmaceutical production capacity, or those with limited capacity. By doing so, it helps the most vulnerable access the drugs that meet their needs, helping to deal with diseases such as HIV/AIDS, tuberculosis or malaria, as well as other epidemics. I am delighted that WTO members have now followed through on their commitment and brought this important measure into force,” said WTO Director-General Roberto Azevêdo. In video statements available here, some of the key players share their thoughts on the TRIPS amendment.

Unanimously adopted by WTO members in 2005, the protocol amending the TRIPS Agreement makes permanent a mechanism to ease poorer WTO members’ access to affordable generic medicines produced in other countries. The amendment empowers importing developing and least-developed countries facing public health problems and lacking the capacity to produce drugs generically to seek such medicines from third country producers under "compulsory licensing" arrangements. Normally, most medicines produced under compulsory licences can only be provided to the domestic market in the country where they are produced. This amendment allows exporting countries to grant compulsory licences to generic suppliers exclusively for the purpose of manufacturing and exporting needed medicines to countries lacking production capacity.

“As important as trade policy is, health and well-being must take precedence,” said Amina Mohamed, Kenya’s Foreign Minister who chaired the WTO General Council at the time when the amendment was approved in December 2005. “WTO members recognise this and have proven how seriously they take health issues by ratifying and putting into force an amendment to WTO rules which will facilitate access to essential medicines in low income countries.”

The amendment provides a secure and sustained legal basis for both potential exporters and importers to adopt legislation and establish the means needed to allow countries with limited or no production capacity to import affordable generics from countries where pharmaceuticals are patented. More and more WTO members are taking practical steps to implement the system in their laws. The bulk of global medicine exports is covered by laws enabling exports under this system, opening up new options for potential beneficiaries to access a wider range of potential suppliers and enabling new, innovative procurement strategies.

#### No impact – just a question of whether poor countries buy vaccines from companies or domestically produce those vaccines, which takes too long.

#### Their own ev says that it should be” distributed globally, on a priority basis” – which proves the CP solves.

#### The mutations argument doesn’t mention future vaccines. Also, most developing countries are reducing case counts, like India.

#### Patents are key to adequate regulation and testing of drugs -- AFF leads to rampant counterfeiting and unsafe medication, which threatens public health, kills most vulnerable patients, and causes narcotic/human trafficking to surge. Especially true now due to public desperation over COVID, rise in e-commerce, and expansion of substandard medicine manufacturers targeting critical life-saving drugs

IPKey 21 (IP Key – Run by EUIPO and the European Commission to provide news coverage and scientific knowledge concerning intellectual property rights, “Intellectual Property and Keeping Medicines Safe”, https://ipkey.eu/en/south-east-asia/news/intellectual-property-and-keeping-medicines-safe, 2 February 2021, EmmieeM)

If you are what you eat, and bad diets lead to bad health, imagine what unsafe medicines can do.

We ask today, why the provenance of vaccines has attracted so much attention when the origin of medicines we take, in some cases, every day and without even thinking, is not questioned at all? How do we know we can trust medicines readily available on the market from seemingly legitimate sources? Where does intellectual property (IP) come into all of this and why is a proper IP application and registration process important?

The global race to develop vaccines to fight the spread of COVID-19 has understandably captured the attention of the public worldwide. People of all generations and with little or no expertise in clinical trials have followed the process keenly, wishing and willing together that science can provide the answer to stopping the pandemic so what was called ‘normal’ life can return. This public interest has also rightly scrutinised the testing that is designed to make sure that these vaccines are safe and this same focus is thankfully putting medicines under the spotlight more broadly.

When we talk about medicines, they are universally understood to mean a drug or other preparation for the treatment or prevention of a disease or illness. In essence, they serve to keep us feeling healthy, or make us feel better. But what about when they achieve the exact opposite, when they are in fact harmful, or even fatal? The cause is usually because of fake and counterfeit medicines. This is because something they both have in common is the lack of rigorous inspections by public authorities that seek to guarantee the safety of medicines for widespread use.

What’s more, the proliferation of both kinds of these illegal medicines is worsened by a critical fact. Previously, they used to mainly be related to ‘lifestyle’ medicines, but now, even innovative or critical life-saving medicines, such as medicines that tackle cardiovascular diseases, are being increasingly created and are entering the market without official IP application and registration processes.

But if they are both illegal and both cause harm, what’s the difference between fake and counterfeit medicines? Fake medicines pass themselves off as real, authorised medicines but they may actually contain ingredients that are of low quality or in the wrong dosage. Since they have not passed through the necessary evaluation of quality, safety and efficacy as required by authorisation procedures, they can be a major health threat. Counterfeit medicines, in contrast, are those medicines that do not comply with intellectual and industrial property rights, such as registered trade marks or patent rights. But it is important to stress, this is not just an IP issue. In the vast majority of cases (90%) they can also be harmful to a patient’s health, according to a study recently released by the European Union Intellectual Property Office (EUIPO) and the Organisation for Economic Cooperation and Development (OECD) on ‘Trade in Counterfeit Pharmaceutical Products’. The World Health Organization (WHO) also shared in the 2017 report, ‘WHO Global Surveillance and Monitoring System for Substandard and Falsified Medical Products’, that the estimated number of children who may die from pneumonia each year after consuming counterfeit medicines is between 72 000 and 169 000.

But counterfeit medicines are not just a public health concern. Innovation and creativity are the cornerstones of modern economies and counterfeit medicines siphon off revenue that should justly have been earned by the rightful owners of the medicines that counterfeit medicines seek to imitate. Not just legal pharmaceutical companies are hurt. The public lose out on better and more effective medicines because less revenue can be dedicated to further research and development.

Worryingly, experience shows that these products are finding their way into the legal supply chains more easily than ever, meaning the sale of counterfeit medicines is not limited to illegal trading channels, such as illegal retailers or online sales. Instead, innocent consumers and desperate patients with life-threatening conditions can unwittingly purchase them and be completely ignorant of the potentially harmful side effects.

But the problem does not stop there, either. As highlighted by the United Nations Office on Drugs and Crime report, organised crime is often behind the production of counterfeit medicines, meaning their profits can be used to fuel other illicit trades of, for example, narcotics or even human trafficking practices that help perpetuate more violent crimes, including kidnappings and extortion.

This process has been aided in part by the boom in e-commerce. Technological advancements and the growing tendency to buy online, especially during the pandemic, have made regulation more difficult and helped increase the prevalence of counterfeit goods. These conditions create the perfect environment for non-regulated sellers and, rather than big shipments, the European Commission’s report on the EU customs enforcement of intellectual property rights indicates that courier and postal traffic accounted for 84% of all detentions of counterfeit goods generally in the EU.

But citizens can play a part in combating counterfeit medicines. Basic steps such as checking the origin of products or looking for stamps of authorities help, as does greater awareness of their existence. We must come together to fight them because counterfeit medicines have existed in the market now for a long time, and without sufficient awareness, consumption of these substances can lead to unexpected symptoms, permanent disabilities, and even loss of life.

#### Their impact card is in the past tense – COVID has ALREADY done these things – slammed borders shut and changed foreign policy forever. The card is just describing long term changes that have happened as a result of a disease.

#### This is also not true – there are renewed calls for interventionist foreign policy following Afghanistan, and the amount of nuclear armed peer competitors has fallen with the Iran nuclear deal and the US’s accession to Paris increases multilat.

#### No disease can cause extinction

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

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

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

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

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

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

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

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

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

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

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

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

### Trade Advantage

#### WTO dispute settlement takes forever- undermines its power

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Nicely: In the first several years of the WTO’s existence, it was common to see large economies challenging one another ­– Japan v. US, US v. EU, India v. EU, Brazil v. US, and so on. Today, it is becoming more and more common to see developing countries challenging one another, such as ­Panama v. Colombia, Costa Rica v. Dominican Republic, as well as challenging developed countries, for instance Antigua and Barbuda v. US, and Vietnam v. US. Further, as mentioned, the most common disputes in the WTO context involve trade remedies. What has changed in recent years is that a greater number of countries are using their trade remedy laws more frequently – and not doing so very well. So, while the US continues to be the favourite target of disputes over its use of trade remedies – in part because of its stubborn use of the 'zeroing' methodology in dumping cases and its application of the countervailing duty laws to non-market economies – other countries like China are now also being challenged for their poorly administered trade remedy laws. Unfortunately, I think this reflects a view by many countries that they can apply these laws sloppily and not be forced to fix them until well after two or more years have passed. This is because there is no injunctive relief to stop the application of trade remedy measures; and, while the WTO’s dispute settlement system has teeth – allowing trade retaliation when a country does not comply – it takes a long time to reach the point where a country has to pay for its sins. In the meantime, import relief remains in place. The lack of a rule of law mentality among members to the WTO arguably undermines the important principles on which the organisation is based.

#### Free trade turns their war scenarios –

#### a. Asymmetric balances take out their free trade good arguments; in trade process, one country benefits more than another; this causes the disadvantaged country to increase tensions; benefits that go towards national defense cause countries to miscalculate and start wars

#### c. Even if they win both countries benefit in general, domestic actors that don’t benefit create instability and support violent foreign policy

Fordham and Kleinberg 11 (Fordham, Benjamin O. and Kleinberg, Katja B., professors of political science at Binghamton University, “International Trade and US Relations with China”, Foreign Policy Analysis)FS

The distributive effects of trade suggest one important modification to the liberal argument at the individual level. Although international trade provides aggregate

benefits to both states, it does not follow that all individuals within the two trading states also benefit. Trade creates domestic winners and losers. The implications of the liberal argument are reversed when one considers the effects of trade on the attitudes of the losers. Those who are harmed by international trade have reason to see trading partners as threats, and to support correspondingly hostile foreign policies. To the extent that hostile policies disrupt trade, they may be expected to produce results similar to a protective tariff. If economic interests indeed influence attitudes on security matters, the domestic political battle lines on these issues will resemble those in debates over trade protection.