# 1AC

## 1AC

### Innovation---1AC

#### Advantage 1 is Innovation:

#### Anticompetitive conduct in the pharmaceutical industry undermines effective and efficient innovation.

Robin Feldman 21. Stanford University (BA), Stanford Law School (JD). Arthur J. Goldberg Distinguished Professor of Law at the University of California, Hastings College of Law. “Drug companies keep merging. Why that’s bad for consumers and innovation.” <https://www.washingtonpost.com/outlook/2021/04/06/drug-companies-keep-merging-why-thats-bad-consumers-innovation/>.

This dramatic consolidation has remade the pharmaceutical industry. Before 1988, a robust cohort of drug manufacturers often competed across multiple therapeutic areas. This competition encouraged exploring different possible approaches for treating the same disease state as well as treatments for a wider range of health concerns, increasing the potential for innovations that might improve lives.

Although this marketplace was better for innovation, drug companies were drawn to merging because of the lure of increased market power, improved synergies, larger economies of scale and more diverse product portfolios.

Abrupt changes to the environment surrounding the pharmaceutical industry also encouraged consolidation. In the late 1980s, widespread deregulation at both the state and federal level may have facilitated an uptick in mergers, particularly as companies with expiring drug patents sought to make up for their revenue losses by acquiring other profitable drugs.

The second merger wave beginning around 1996 can be traced in part to another external shock, as globalization spurred firms to join forces to reach more potential markets. Similar to the first merger wave, “patent cliffs,” in which many of a company’s drugs were set to lose their lucrative patent monopoly around the same time, also helped push firms to combine forces.

But the newly consolidated pharmaceutical industry actually stifled innovation. In the period following merger waves one and two, the industry generated fewer new molecular entities each year compared to pre-merger levels. Merged drug companies also spent proportionally less on research than their non-merged competitors.

Consolidation also enabled drugmakers to directly quell competition through what were known as “killer acquisitions,” in which they acquired innovative peers solely to stop potential competition. Moreover, with the assistance of pharmacy benefits managers, newly giant pharmaceutical firms could leverage their dominant position with one type of drug to suppress competitors for another one of their drugs, or they could use the combined power of multiple drugs to shore up a waning monopoly position. Both of these practices could block cheaper drug competitors from reaching patients, inhibiting access and affordability.

In short, consumers were the losers from the two waves of drug company mergers. They confronted higher prices and fewer choices — and saw companies exploring fewer paths that might produce breakthroughs. To make matters worse, around 2010, another wave of mergers began.

#### Automatic substitution of bioequivalents is key---the anticompetitive costs of “product hopping” outweigh the procompetitive benefits.

Daniel Burke 18. Cleveland-Marshall College of Law. “An Examination of Product Hopping by Brand-Name Prescription Drug Manufacturers: The Problem and a Proposed Solution” Cleveland State Law Review. Volume 66; Issue 2; Article 8. 04-01-18. <https://engagedscholarship.csuohio.edu/cgi/viewcontent.cgi?article=3995&context=clevstlrev>

Another way that courts determine whether the second prong of the test (in an analysis of a potential monopoly) is satisfied is by applying the rule of reason test.131 The rule of reason test requires that courts examine the totality of the circumstances, rather than treat the potential violation of the Sherman Act as a per se violation, to determine whether the practice promotes competition in the relevant market.132 The rule of reason test requires that once the plaintiff has established the defendant’s monopoly power, the monopolist may offer justifications for maintaining that power.133 The plaintiff then may argue that “the anticompetitive harm outweighs the procompetitive benefit.”134 Relevant factors in determining whether a particular case of product hopping is a violation of the Sherman Act include looking at whether the conduct is anticompetitive, coerces consumers, and impedes competition.135 Generic drug manufacturers are inhibited from entering the prescription drug market when name-brand drug manufacturers are granted extended exclusivity protection, particularly due to automatic substitution laws.136 Automatic substitution laws allow pharmacists to substitute a generic bioequivalent drug for the more expensive name-brand prescription drug.137 Bioequivalence is defined as: the absence of a significant difference in the rate and extent to which the active ingredient or active moiety in pharmaceutical equivalents or pharmaceutical alternatives becomes available at the site of drug action when administered at the same molar dose under similar conditions in an appropriately designed study. Where there is an intentional difference in rate (e.g., in certain extended-release dosage forms), certain pharmaceutical equivalents or alternatives may be considered bioequivalent if there is no significant difference in the extent to which the active ingredient or moiety from each product becomes available at the site of drug action.138 This definition allows pharmacists to substitute generic prescription drugs, which are cheaper, for brand-name prescription drugs when filling the prescription.139 Prior to a pharmacist’s ability to make this substitution, the FDA must first determine that the generic drug is “interchangeable.”140 The goal of permitting this type of substitution is clear; allowing an equivalent, cheaper prescription benefits consumers because they receive the treatment needed at a lower cost. However, brand-name prescription drug manufacturers change the composition of the drug such that the new brand-name drug is no longer bioequivalent with the generic drug.141 The intention of the new drug is still to treat the same disease or disorder as before, but the new drug is no longer seen as “equivalent” in the eyes of the FDA.142 When brand-name prescription drug manufacturers do this, pharmacists cannot substitute the cheaper generic that would have been appropriate prior to changes to the brand-name drug. As a result, the generic drug manufacturer cannot enter the market due to state laws.143 The consumer must spend more money on a brand-name drug despite the existence of a generic prescription drug that would provide the same treatment if the consumer had access to it. For example, in the case of Forest Pharmaceuticals (the subsidiary of Actavis against whom the State of New York brought an action for engaging in allegedly monopolistic activity), a new version of their memantine drug, Namenda, is now available as Namenda XR (which stands for “extended relief”).144 However, as a result of the Second Circuit’s ruling in that case, generic memantine is available to consumers for half the price of branded Namenda.145 Had Forest (and by corollary, Actavis) been successful in its pursuit to maintain exclusivity in the memantine drug market, consumers would not be able to access generic memantine until the Namenda XR patent expires in 2025 or even later if the manufacturer altered the formula once more.146 Another example that illustrates the potential harm to consumers if the generic drug manufacturer had not been able to enter the market is the case of the brand-name Aricept, another Alzheimer’s and dementia treatment.147 When the generic version, Donepezil, entered the market, prices dropped from $230 for a thirty-day supply to less than $10.148 That amounts to potential savings of more than $2,600 per year for one drug. Most individuals with Alzheimer’s disease are aged sixty-five or older,149 a population that relies heavily on income from Social Security.150 Being able to save potentially thousands of dollars per year on the cost of medication greatly benefits consumers who are most likely to be on fixed income. Against this significant burden weighs the benefit of maintaining a brand-name drug manufacturer’s exclusivity, the expiration of which results in companies losing potentially billions of dollars in revenue.151 This loss in revenue could result in lost jobs if the drug companies fail to find new revenue sources.152 But other methods can help companies facing a patent cliff avoid such extensive losses, maintain their positions in the industry, and protect their future earnings and revenue stream.153 One way is to develop a generic version of the brand-name drug that the company developed, marketed, and sold for years before their patent expired.154 This is a way that a company can continue to explore the market in which they have enjoyed exclusivity for so long if courts adopt the approach recommended in this Note. Although companies will not be able to engage in the same activities that they engaged in before, particularly those extending their patent protection beyond their initial exclusivity period, they will be able to create a generic drug that they could continue to market and sell, albeit at a lower price than their previous brand-name prescription drug. This would create an environment where brand-name drug manufacturers become another actor in the generic market. The brand-name drug manufacturer may, in fact, have an advantage if they utilized their incumbent position in the market to position themselves in a manner to better effectuate marketing for a generic version of the brand-name drug. This approach may discourage a potential generic competitor from entering the market,155 even though this is not the type of competition that courts seek to curb.156 That is, as Judge Learned Hand warned, “[t]he successful competitor, having been urged to compete, must not be turned upon when he wins.”157 It is not in the interest of courts to insert themselves into a scenario where that company successfully enters into the generic prescription drug market after formerly competing exclusively in the brand-name prescription drug market.158 Such a scenario would provide a roadmap for other companies facing similar difficulties, vis-à-vis, patent cliffs. Ultimately, the harm at issue is the detrimental effect of a patent cliff on a corporation’s future revenue stream. While this harm is a significant event in the life- cycle of a corporation, it pales in comparison to the harm consumers suffer when brand-name prescription drug manufacturers extend their market exclusivity. The harm brand-name drug manufacturers cause when they engage in activities that prevent the triggering of automatic drug substitution invariably results in higher industry costs and decreased opportunity for innovation. The anticompetitive harm, in this case, therefore cannot justify the procompetitive benefit.

#### Antitrust regulation is key to innovation---the alternative is non-innovative patent extensions.

Tyler J. Klein 16. Lawyer. “Antitrust Enforcement Against Pharmaceutical Product Hopping: Protecting Consumers or Reaching Too Far?” Saint Louis University Journal of Health Law & Policy. Volume 10; Issue 1; Article 12. 2016. https://scholarship.law.slu.edu/cgi/viewcontent.cgi?article=1058&context=jhlp

In response to these arguments, opponents assert that antitrust enforcement impedes innovation in the pharmaceutical industry.147 The idea of chilling innovation and deterring the development of new, potentially life-saving drugs is certainly concerning. However, this argument is less concerning than it sounds. When submitting its Amicus Brief in support of Plaintiff-Appellee State of New York in the Second Circuit Actavis case, the AAI addressed this argument. First, the AAI asserted that no empirical evidence existed showing that antitrust scrutiny of product hopping deters innovation.148 Moreover, the AAI further asserted that antitrust scrutiny of product hopping actually increases innovation.149 Without antitrust scrutiny of product hopping, brand- name companies will invest in making minor alterations to products to extend the patent, rather than investing in research for new, innovative drugs.150 Indeed, one study found that “[b]rand-name firms have sought increasing recourse to ancillary patents on chemical variants, alternative formulations, methods of use, and relatively minor aspects of the drug.”151 Essentially, immunizing brand-name pharmaceutical companies from antitrust liability encourages them to spend time and resources in order to find ways to make insignificant changes to current drugs in order to preserve the patent, instead of using time and resources to develop the next innovative drug. In its Brief as Amicus Curiae filed with the district court in Mylan, the FTC bolstered this argument by asserting: “The threat posed to existing brand drugs by generic competition can incentivize the brand company facing dramatic loss of sales to develop new and innovative drugs that benefit consumers.”152 Notably, the FTC recently filed a Brief for Amicus Curiae in support of Mylan in its appeal to the Third Circuit.153 In sum, there is no evidence that antitrust regulation of product hopping slows down innovation by brand-name pharmaceutical companies. Rather, regulation actually encourages innovation, as the competition from generics causes brand-name manufactures to innovate new products and prevents them from spending resources on insignificant changes to extend patents.

#### The US is key.

Ernest Kawka 21. PhRMA’s deputy vice president for international intellectual property. Previously, he worked for industry’s international trade association in Geneva, Switzerland focusing on intellectual property and trade policies. He received a law degree from University of New Hampshire School of Law. “American leadership on innovation policy is essential to global health progress.” <https://catalyst.phrma.org/u.s.-government-reaffirms-commitment-to-american-innovators>.

Over the last year, the world has witnessed the importance of strong innovation policies as intellectual property protection and market access policies facilitated the research, development and distribution of COVID-19 diagnostics, treatments and vaccines. Innovative medicines are now making their way to patients around the world, demonstrating remarkable progress and collaboration at a scale that was unimaginable at the start of the pandemic, including more than 200 manufacturing and other partnerships to date. Underscoring the critical need for and value of American innovation, the Office of the United States Trade Representative (USTR) released last week the 2021 Special 301 Report. The report showcases how effective intellectual property protection and enforcement and related market access issues are essential to tackling current and future global health challenges. The report reaffirms the U.S. government’s continued commitment to promoting fair market access around the world for American inventions, including biopharmaceuticals. Promoting an equitable trading environment helps to deliver innovation worldwide and drives economic growth and job creation. In the United States alone, biopharmaceutical innovators contribute more than $1.1 trillion annually to the U.S. economy and create more than 4 million jobs across all 50 states. The 2021 Special 301 Report identifies how key U.S. trading partners can further increase the economic and innovation potential of open markets and implement effective intellectual property protection and enforcement regimes, including by addressing discriminatory, nontransparent and trade-restrictive measures and unreasonable regulatory approval and reimbursement delays. The progress made over the last year is nothing short of incredible. Intellectual property protection has been essential not only to speed the research and development of new treatments and vaccines, but also to facilitate the sharing of technologies and information across borders to scale up vaccine manufacturing to meet global needs. Working together, we can continue to bring the benefits of biopharmaceutical innovation to patients around the world.

#### Pharmaceutical innovation solves disease, bioterror, and ABR.

Sonja Marjanovic and Carolina Feijao 20. \*Sonja Marjanovic; Director, Healthcare Innovation, Industry and Policy, RAND Europe. \*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” RAND Corporation. 2020. https://www.rand.org/content/dam/rand/pubs/perspectives/PEA400/PEA407-1/RAND\_PEA407-1.pdf

As key actors in the healthcare innovation landscape, pharmaceutical and life sciences 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 context. 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 competition 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 pharmaceutical 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 sector. It is therefore unsurprising that we are seeing industry-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 compounds to assess their utility in the fight against COVID19; screening existing compound libraries in-house or with partners to see if they can be repurposed; accelerating trials 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. 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 accelerate 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. 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 relatively few companies that are ‘commercial’ winners. Those who might gain substantial revenues will be under pressure 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. Similarly, in the United States AbbVie has waived intellectual property rights for an existing combination product that is being tested for therapeutic potential against COVID-19, which would support affordability and allow for a supply of generics. 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. 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, bioterrorism 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 immediate term. The pharmaceutical industry has responded to previous public health emergencies associated with infectious disease in recent times – for example those associated with Ebola and Zika outbreaks. However, it has done so to a lesser scale than for COVID-19 and with contributions from fewer companies. Similarly, levels of activity in response to the threat of antimicrobial resistance are still low. 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 innovation conditions.

#### Innovation is key to preparedness.

Tahir Amin and Rohit Malpani 20. Tahir Amin is the co-executive director of the Initiative for Medicines, Access & Knowledge (I-MAK) a global nonprofit organization working on systemic changes to intellectual property and the political economy of pharmaceutical innovation. \*\*Rohit Malpani is a public health consultant and former policy director of the Medecins Sans Frontieres/Doctors Without Borders Access Campaign. “Covid-19 has exposed the limits of the pharmaceutical market model” STAT News. 05-19-20. https://www.statnews.com/2020/05/19/covid-19-exposed-limits-drug-development-model/

That so much hope is being pinned on remdesivir, the drug Gilead is testing for Covid-19, reflects the failure of our system for new drug development rather than the unqualified success some commentators are making it out to be. If anything, remdesivir is the poster child for why we need a new model of drug development for pandemics and neglected diseases that isn’t restricted by the current market-based model. The Covid-19 pandemic has provided the pharmaceutical industry with a chance at bolstering its heavily tarnished image. Abbott Laboratories is winning effusive praise for its introduction of a rapid Covid-19 test. After decades of profiteering from the opioid crisis, Johnson & Johnson has ramped-up its advertising on Twitter to promote the company’s research into a vaccine for Covid-19. It is even airing an eight-episode reality television series showcasing its efforts. The marketing offensive appears to be working. Recent polling shows that public perception of pharmaceutical companies is on the upswing after years of historical lows. The narrative emerging from the Covid-19 pandemic is that the market is responding to rescue us from global catastrophe, a public relations coup for an industry that has long known about the potential for another pandemic but hasn’t meaningfully invested in research until now. Related: With remdesivir, Gilead finds itself at strategic crossroads, with its reputation (and far more) at stake Since 2002, epidemics caused by severe acute respiratory syndrome (SARS), swine flu (H1N1), Middle East respiratory syndrome (MERS), Zika, Ebola, and other viral diseases have killed nearly 600,000 people worldwide. Yet, in the aftermath of these outbreaks, and despite clear warnings that another viral pandemic could emerge, the pharmaceutical industry failed to sustain investment into new treatments and vaccines. That may surprise the public, but it doesn’t surprise those working on public health issues. In today’s capital-driven market, investments in pandemic preparedness and in neglected diseases like tuberculosis and malaria are not, and never have been, a priority for pharmaceutical company drug development even though neglected diseases cause more than 2 million deaths per year, almost seven times the number of deaths caused so far by Covid-19. There are several reasons for this disconnect between need and action. One is that outbreaks are unpredictable and may not last long enough to generate a sufficient market for a new therapy. Another is that diseases like malaria and trachoma predominantly affect poor people living in low-income countries that don’t constitute a sufficiently profitable market. A company executive deciding between investing in a novel treatment to address a potential pandemic threat or buying back company shares to boost a company’s stock price will probably choose the latter. The practice of boosting shareholder profits and executive pay instead of investing in new products and services or employees has become the market norm, as the airline industry has shown. In 2018, global funding for basic research and product development for neglected diseases was just $4 billion. Of this funding, 64% came from public tax dollars. Another 19% came from philanthropic organizations. The private pharmaceutical sector contributed just 17% —$650 million — a drop in the ocean considering that the revenue of the top 20 pharmaceutical companies was more than $661 billion in 2019. The lack of investment by the pharmaceutical industry is not limited to neglected diseases and pandemic preparedness. Many of the largest pharmaceutical companies have stopped investing in the development of new antibiotics to treat drug-resistant infections, which is already a global health crisis that is costing lives and threatening modern medicine, including routine surgery and chemotherapy. Rather than conducting research and developing genuinely new drugs that could help solve some of the biggest public health issues now and in the future, companies spend more time finding ways to keep existing drug franchises profitable. This includes filing hundreds of patents on a single drug under the guise of medical innovation, as detailed in a report published by I-MAK, an organization one of us (T.A.) co-directs.

#### Disease causes extinction---the risk is categorically underestimated.

Dennis Pamlin & Stuart Armstrong 15. \*Executive Project Manager Global Risks, Global Challenges Foundation. \*\*James Martin Research Fellow, Future of Humanity Institute, Oxford Martin School, University of Oxford. February 2015, “Global Challenges: 12 Risks that threaten human civilization: The case for a new risk category,” Global Challenges Foundation, p.30-93. https://api.globalchallenges.org/static/wp-content/uploads/12-Risks-with-infinite-impact.pdf

A pandemic (from Greek πᾶν, pan, “all”, and δῆμος demos, “people”) is an epidemic of infectious disease that has spread through human populations across a large region; for instance several continents, or even worldwide. Here only worldwide events are included. A widespread endemic disease that is stable in terms of how many people become sick from it is not a pandemic. 260 84 Global Challenges – Twelve risks that threaten human civilisation – The case for a new category of risks 3.1 Current risks 3.1.4.1 Expected impact disaggregation 3.1.4.2 Probability Influenza subtypes266 Infectious diseases have been one of the greatest causes of mortality in history. Unlike many other global challenges pandemics have happened recently, as we can see where reasonably good data exist. Plotting historic epidemic fatalities on a log scale reveals that these tend to follow a power law with a small exponent: many plagues have been found to follow a power law with exponent 0.26.261 These kinds of power laws are heavy-tailed262 to a significant degree.263 In consequence most of the fatalities are accounted for by the top few events.264 If this law holds for future pandemics as well,265 then the majority of people who will die from epidemics will likely die from the single largest pandemic. Most epidemic fatalities follow a power law, with some extreme events – such as the Black Death and Spanish Flu – being even more deadly.267 There are other grounds for suspecting that such a highimpact epidemic will have a greater probability than usually assumed. All the features of an extremely devastating disease already exist in nature: essentially incurable (Ebola268), nearly always fatal (rabies269), extremely infectious (common cold270), and long incubation periods (HIV271). If a pathogen were to emerge that somehow combined these features (and influenza has demonstrated antigenic shift, the ability to combine features from different viruses272), its death toll would be extreme. Many relevant features of the world have changed considerably, making past comparisons problematic. The modern world has better sanitation and medical research, as well as national and supra-national institutions dedicated to combating diseases. Private insurers are also interested in modelling pandemic risks.273 Set against this is the fact that modern transport and dense human population allow infections to spread much more rapidly274, and there is the potential for urban slums to serve as breeding grounds for disease.275 Unlike events such as nuclear wars, pandemics would not damage the world’s infrastructure, and initial survivors would likely be resistant to the infection. And there would probably be survivors, if only in isolated locations. Hence the risk of a civilisation collapse would come from the ripple effect of the fatalities and the policy responses. These would include political and agricultural disruption as well as economic dislocation and damage to the world’s trade network (including the food trade). Extinction risk is only possible if the aftermath of the epidemic fragments and diminishes human society to the extent that recovery becomes impossible277 before humanity succumbs to other risks (such as climate change or further pandemics). Five important factors in estimating the probabilities and impacts of the challenge: 1. What the true probability distribution for pandemics is, especially at the tail. 2. The capacity of modern international health systems to deal with an extreme pandemic. 3. How fast medical research can proceed in an emergency. 4. How mobility of goods and people, as well as population density, will affect pandemic transmission. 5. Whether humans can develop novel and effective anti-pandemic solutions.

#### The next pandemic will be worse---action now is key.

Andy Plump 21. President for research and development at Takeda Pharmaceuticals and a cofounder of the Covid R&D Alliance. “Luck is not a strategy: The world needs to start preparing now for the next pandemic” 05-18-21. https://www.statnews.com/2021/05/18/luck-is-not-a-strategy-the-world-needs-to-start-preparing-now-for-the-next-pandemic/

As countries grapple with the worst global pandemic in a century, it’s hard to think about preparing for the next one. But if we don’t, it could be worse than Covid-19. Over the last 30 years, infectious disease outbreaks have emerged with alarming regularity. The World Health Organization lists an influenza pandemic and other high-threat viral diseases such as Ebola and dengue among the top 10 biggest threats to public health. The rate of animal-to-human transmission of viruses has been increasing, with the U.S. Centers for Disease Control and Prevention estimating that 75% of new infectious diseases in humans come from animals. These zoonotic infections can have profound effects on human life. The overall infection fatality rate is around 10% for severe acute respiratory syndrome (SARS), between 40% and 75% for Nipah virus, and as high as 88% for Ebola. While the infection fatality rate for Covid-19 is lower — likely less than 1% — the overall burden of death has been significantly higher since it has affected so many people, more than 160 million people as I write this. Luck is not a pandemic strategy Although the Covid-19 pandemic has been a human and health care disaster, by scientific measures the world was lucky this time. Covid-19 was far less lethal than its predecessors, less contagious than previous pandemic viruses, and we were able to quickly develop a cadre of effective vaccines. But luck is not a strategy. The same way the U.S. invests in and prepares for national defense, it must also prepare for another pandemic. Though the next viral outbreak cannot be prevented, the next pandemic can — but only with better preparation.

#### Bioterror causes extinction.

Piers Millett 17. \*\*Senior Research Fellow, University of Oxford’s Future of Humanity Institute (FHI). \*\*Andrew Snyder-Beattie, MS, is Director of Research, FHI. “Existential Risk and Cost-Effective Biosecurity.” Health Security 15(4): 373-83.

How worthwhile is it spending resources to study and mitigate the chance of human extinction from biological risks? The risks of such a catastrophe are presumably low, so a skeptic might argue that addressing such risks would be a waste of scarce resources. In this article, we investigate this position using a cost-effectiveness approach and ultimately conclude that the expected value of reducing these risks is large, especially since such risks jeopardize the existence of all future human lives. Historically, disease events have been responsible for the greatest death tolls on humanity. The 1918 flu was responsible for more than 50 million deaths,1 while smallpox killed perhaps 10 times that many in the 20th century alone.2 The Black Death was responsible for killing over 25% of the European population,3 while other pandemics, such as the plague of Justinian, are thought to have killed 25 million in the 6th century—constituting over 10% of the world's population at the time.4 It is an open question whether a future pandemic could result in outright human extinction or the irreversible collapse of civilization. A skeptic would have many good reasons to think that existential risk from disease is unlikely. Such a disease would need to spread worldwide to remote populations, overcome rare genetic resistances, and evade detection, cures, and countermeasures. Even evolution itself may work in humanity's favor: Virulence and transmission is often a trade-off, and so evolutionary pressures could push against maximally lethal wild-type pathogens.5,6 While these arguments point to a very small risk of human extinction, they do not rule the possibility out entirely. Although rare, there are recorded instances of species going extinct due to disease—primarily in amphibians, but also in 1 mammalian species of rat on Christmas Island.7,8 There are also historical examples of large human populations being almost entirely wiped out by disease, especially when multiple diseases were simultaneously introduced into a population without immunity. The most striking examples of total population collapse include native American tribes exposed to European diseases, such as the Massachusett (86% loss of population), Quiripi-Unquachog (95% loss of population), and the Western Abenaki (which suffered a staggering 98% loss of population).9 In the modern context, no single disease currently exists that combines the worst-case levels of transmissibility, lethality, resistance to countermeasures, and global reach. But many diseases are proof of principle that each worst-case attribute can be realized independently. For example, some diseases exhibit nearly a 100% case fatality ratio in the absence of treatment, such as rabies or septicemic plague. Other diseases have a track record of spreading to virtually every human community worldwide, such as the 1918 flu,10 and seroprevalence studies indicate that other pathogens, such as chickenpox and HSV-1, can successfully reach over 95% of a population.11,12 Under optimal virulence theory, natural evolution would be an unlikely source for pathogens with the highest possible levels of transmissibility, virulence, and global reach. But advances in biotechnology might allow the creation of diseases that combine such traits. Recent controversy has already emerged over a number of scientific experiments that resulted in viruses with enhanced transmissibility, lethality, and/or the ability to overcome therapeutics.13-17 Other experiments demonstrated that mousepox could be modified to have a 100% case fatality rate and render a vaccine ineffective.18 In addition to transmissibility and lethality, studies have shown that other disease traits, such as incubation time, environmental survival, and available vectors, could be modified as well.19-21 Although these experiments had scientific merit and were not conducted with malicious intent, their implications are still worrying. This is especially true given that there is also a long historical track record of state-run bioweapon research applying cutting-edge science and technology to design agents not previously seen in nature. The Soviet bioweapons program developed agents with traits such as enhanced virulence, resistance to therapies, greater environmental resilience, increased difficulty to diagnose or treat, and which caused unexpected disease presentations and outcomes.22 Delivery capabilities have also been subject to the cutting edge of technical development, with Canadian, US, and UK bioweapon efforts playing a critical role in developing the discipline of aerobiology.23,24 While there is no evidence of state-run bioweapons programs directly attempting to develop or deploy bioweapons that would pose an existential risk, the logic of deterrence and mutually assured destruction could create such incentives in more unstable political environments or following a breakdown of the Biological Weapons Convention.25 The possibility of a war between great powers could also increase the pressure to use such weapons—during the World Wars, bioweapons were used across multiple continents, with Germany targeting animals in WWI,26 and Japan using plague to cause an epidemic in China during WWII.27

#### Horizontal gene transfer overwhelms defenses.

Meredith Schroeder 17. \*PhD candidate, Department of Microbiological Sciences, North Dakota State University. \*\*Benjamin D. Brooks, PhD, Department of Electrical and Computer Engineering, North Dakota State University. \*\*\*Amanda E. Brooks, PhD, Department of Pharmaceutical Sciences, North Dakota State University. “The Complex Relationship between Virulence and Antibiotic Resistance.” Genes, Vol. 8, No. 1, page 39. January 2017. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5295033/

Antibiotic resistance, prompted by the overuse of antimicrobial agents, may arise from a variety of mechanisms, particularly horizontal gene transfer of virulence and antibiotic resistance genes, which is often facilitated by biofilm formation. The importance of phenotypic changes seen in a biofilm, which lead to genotypic alterations, cannot be overstated. Irrespective of if the biofilm is single microbe or polymicrobial, bacteria, protected within a biofilm from the external environment, communicate through signal transduction pathways (e.g., quorum sensing or two-component systems), leading to global changes in gene expression, enhancing virulence, and expediting the acquisition of antibiotic resistance. Thus, one must examine a genetic change in virulence and resistance not only in the context of the biofilm but also as inextricably linked pathologies. Observationally, it is clear that increased virulence and the advent of antibiotic resistance often arise almost simultaneously; however, their genetic connection has been relatively ignored. Although the complexities of genetic regulation in a multispecies community may obscure a causative relationship, uncovering key genetic interactions between virulence and resistance in biofilm bacteria is essential to identifying new druggable targets, ultimately providing a drug discovery and development pathway to improve treatment options for chronic and recurring infection.

1. Introduction

Until recently, conventional “antibiotic wisdom” suggesting the presence of a fitness cost associated with the development of antibiotic resistance that would eventually allow susceptible species to overtake resistant species was the predominating dogma in infectious diseases [1]. However, the ever-increasing threat of antibiotic resistant bacteria contradicts dogma and insinuates that the evolution of resistance may be associated with a fitness advantage, including enhanced virulence [2,3]. Although virulence has now been directly related to multidrug resistance in several animal infection models [2], the mechanism of virulence regulation in this climate of antibiotic resistance remains elusive. This review will explore the relationship between the mechanisms of acquired antibiotic resistance and enhanced virulence, a critical link in our war on the emergence of multidrug resistant bacteria.

### Costs---1AC

#### Advantage 2 is Costs:

#### Drug prices are skyrocketing---product hopping is key.

Michael A. Carrier & Steve Shadowen 17. \*\*Michael A. Carrier is a Distinguished Professor at Rutgers Law School and has testified to Congress on drug-pricing issues. \*\*Steve Shadowen is regularly recognized as a top national antitrust lawyer, a result of his dedicated work on cases where intellectual property and antitrust law intersect, including several groundbreaking cases in the pharmaceutical industry. “Pharmaceutical Product Hopping: A Proposed Framework For Antitrust Analysis” Health Affairs. 06-01-17. https://www.healthaffairs.org/do/10.1377/hblog20170601.060360/full/

Skyrocketing drug prices are in the news. Overnight price increases have riveted the attention of the public, media, and politicians of all stripes. But one reason for high prices has flown under the radar. When drug companies reformulate their product, switching from one version of a drug to another, the price doesn’t dramatically increase. Instead, it stays at a high level for longer than it otherwise would have without the switch. Although more difficult to discern than a price spike, this practice, when undertaken to prevent generic market entry, can result in the unjustified continuation of monopoly pricing, burdening patients, the government, and the health care system as a whole. Not all reformulations pose competitive concerns. Empirical studies have shown that more than 80 percent can be explained by improvements that are not temporally connected to impending generic entry. But a dangerous subset of such reformulations is undertaken for one, and only one, reason: to delay generic entry. In such cases, reformulation is called “product hopping.” When generics enter the market, the price can fall dramatically overnight, by as much as 85 percent. For that reason, brand firms have every incentive to delay this moment of reckoning as long as possible. Sure enough, making trivial changes to their drugs has that effect. Every state has a substitution law that requires or allows pharmacists to offer a generic drug when the patient presents a prescription for a brand drug. But such substitution is thwarted if the drug is not the same—in particular, if it is not bioequivalent (able to be absorbed into the body at the same rate) and therapeutically equivalent (having the same active ingredient, form, dosage, strength, and safety and efficacy profile). A minor change to a drug’s formulation can prevent the pharmacist from substituting the generic. Product hopping raises nuanced issues arising at the intersection of patent law, antitrust law, the federal Hatch-Waxman Act, and state drug product substitution laws. It is even more complex given the uniquely complicated pharmaceutical market, in which the buyer (patient, insurance company) is different from the decision maker (doctor). Courts applying US antitrust law have struggled to create a robust and defensible legal framework for separating anticompetitive product hops from competitively benign, legitimate product development. In this post, we propose a framework that would help courts defer to legitimate reformulations while targeting anticompetitive switches.

#### Each instance of product hopping costs one billion dollars annually.

CAPD 20. “New Report Quantifies the Harm of Product Hopping to Patients and the U.S. Health Care System” Coalition for Affordable Prescription Drugs. 09-14-20. <https://www.affordableprescriptiondrugs.org/new-report-quantifies-the-harm-of-product-hopping-to-patients-and-the-u-s-health-care-system/>

\*The study evaluates the costs of 5 instances of product hopping/evergreening which cost 4.7 billion dollars annually

Product hopping is a practice commonly used by pharmaceutical companies to extend the life of their patents, and as a result, the period of time they can charge high prices for their drugs. Normally, after an initial, patent-protected monopoly period, new drugs face competition from identical drugs manufactured and sold by other companies as a generic. This competition drives down drug prices for patients as a result. But with product hopping, when the drug is supposed to go generic, the drug company instead makes a minor tweak to the drug and rebrands it. Drug companies market this practice as “innovation,” but don’t be fooled. This practice really just allows the manufacturer to put what is essentially the same drug back on the market as a “new” drug, push patients onto that materially same drug at a higher price and take advantage of charging patients high monopoly prices a second time. A new report from Matrix Global Advisors (MGA) helps illustrate the impact these harmful tactics have on patients seeking access to affordable medicines. According to the findings, just five instances of product hopping – for the brand drugs Prilosec, TriCor, Suboxone, Doryx, and Namenda – cost patients and the U.S. health care system $4.7 billion annually. However, it’s not just the billions of additional dollars that patients have to pay for their drugs—it’s also the cost shouldered by employers, unions, and government programs that help pay for health coverage. These higher costs push premiums higher, limit wage growth for working Americans, and force higher spending on U.S. taxpayers—all so pharmaceutical companies can get a second bite at the apple.

#### That financially strains consumers, providers, and insurers.

Amaka Vanni 21. PhD and LLM degrees in International Economic Law from the University of Warwick. “On Intellectual Property Rights, Access to Medicines and Vaccine Imperialism.” <https://twailr.com/on-intellectual-property-rights-access-to-medicines-and-vaccine-imperialism/>.

Third, patent practices in recent decades have seen pharmaceutical companies engaging in trivial and cosmetic tweaking of a drug whilst still reaping the benefit of 20 years of patent protection. This tweaking sometimes involves making minor changes to patented drugs, such as changes in mode of administration, new dosages, extended release, or change in color of the drug. These changes normally do not offer any significant therapeutic advantage even though pharmaceutical companies argue they provide improved health outcomes to patients. These additional patents on small changes to existing drugs, known as evergreening or patent thickets, block the early entry of competitive, generic medicines that drive medicine prices down. For example, while not mandated by TRIPS, many US led TRIPS-plus free trade agreements have expanded the scope for evergreening. These include the US-Jordan FTA (2000), US-Australia FTA (2004) as well as the US-Korea FTA (2007), which allow for the patenting of new forms, uses, or methods of using existing products.

The cancer drug Gleevec®, owned by Novartis, is another example of how pharmaceutical companies often secure patents on new, more convenient versions with marginal therapeutic benefit to patients whilst blocking the entry of generic medicines. In 2013, Novartis’ patent application for Gleevec®– the β crystalline form of the salt imatinib mesylate – was rejected by the Indian Supreme Court because it lacked novelty. However, the company has secured patents for this product in other jurisdictions such as the US and has maintained a high price of Gleevec there. But in India the price of Gleevec® was reduced from approximately USD 2,200 to USD 88 for one month’s treatment in the generic drugs market as a result of the 2013 Indian Supreme Court judgement. Novartis is not the only culprit. The depression drug Effexor® by Pfizer was granted an evergreen patent when the company introduced an extended-release version, Efexor-XR®, even though there was no additional benefit to patients. Eventually, the patent was declared invalid, but by then it had already cost an estimated USD 209 million to Australian taxpayers and kept generic competition off the market for two and a half years. In another instance, Pfizer went on to secure an additional patent for the Pristiq®, which contained identical chemical compound as Efexor-XR®,and again with no added therapeutic benefit.

These evergreening practices, of course, have material effects. Apart from delaying the entry of generic versions, they give brand-name pharmaceutical companies free reign in the market, which allows them to set the market price. Recent years have seen monopoly prices rise exorbitantly causing significant financial strain to patients, domestic healthcare services and even insurance companies in developed countries. A notorious example is Martin Shkreli, who in 2015 bought the rights to an anti-malarial drug, then raised the price by 5,000 per cent from a cost of USD 13.50 to USD 750. Similarly, a white paper by I-MAK shows how excessive patenting and related strategies are driving families to overspend on lifesaving medicines. Celgene, the makers of Revlimid® raised the price of the drug by more than 50 per cent since 2012 to over USD 125,000 per year of treatment. Using the example of Solvadi® by Gilead, which costs USD 84,000 per treatment, Feldman notes the drug would cost the US Department of Defense more than USD 12 billion to treat all hepatitis-infected patients in US Veterans Affairs. But the US is not alone. In Europe, expensive drugs have prompted a growing backlash against pharmaceutical corporations. Reacting to these price hikes, Dutch pharmacies are bypassing these exorbitant prices by preparing medicines in-house for individual patients. The broken IP system ranging from an extraordinarily low standard for granting patents to permissions of patent thickets around a single molecule has not only severely distorted the system of innovation, but they have also skewed access to life-saving drugs. As a result, prices for new and existing medicines are constantly rising, making essential medicines inaccessible for millions of people around the world.

#### Pharmaceuticals are the largest driver of healthcare costs.

Hannah Brennan et al 16. Law Clerk to the Honorable Theodore McKee, Chief Judge, Third Circuit. \*\*Amy Kapczynski; Professor of Law, Yale Law School. \*\*Christine H. Monahan; Yale Law School Class of 2016. \*\*Zain Rizv; Yale Law School Class of 2017. “A Prescription for Excessive Drug Pricing: Leveraging Government Patent Use for Health” 18 YALE J.L. & TECH. 275 (2016). https://digitalcommons.law.yale.edu/cgi/viewcontent.cgi?article=1124&context=yjolt

The soaring cost of pharmaceuticals is one of the most pressing domestic policy issues in the United States today. Nearly one-fifth of the U.S. Gross Domestic Product (GDP) is spent on healthcare, and pharmaceuticals are a key expenditure.**1** In 2014, the United States spent a record $297.7 billion on pharmaceuticals, over 12% more than the previous 2 year. The 2014 increase in prescription drug spending can be attributed almost entirely to recently approved drugs that treat the Hepatitis C virus (HCV). 3 With list prices that approach $100,000 for a twelve-week regimen, 4 these new medicines have brought the issue of drug pricing roaring to the fore in policy debates. High drug prices are of enormous concern to voters, 5 policymakers, and politicians across the political 6 spectrum. High drug prices also have a significant impact on health. The new HCV drugs offer an excellent example. Potentially deadly if untreated, HCV is one of the most pressing health problems facing the United States. 7 The new drugs are far superior to previous treatments and could potentially enable elimination of the disease.8 But treating all of the approximately 5.2 million people who currently have HCV in the United States at the best reported prices offered by Gilead, the sole supplier of the most important new drugs, would cost at least $234 billion.9 Given the budget impact of these new medicines, most payors have sharply restricted their availability-covering them only for the very sickest, or refusing to cover them at all 0-instead of rapidly rolling them out. Medicaid, for example, treated only 2.4% of enrollees estimated to have HCV in 2014, despite spending more than a billion dollars on the new medicines1.1 Even with the small number treated, Gilead's earnings have been stratospheric: the company earned $36 billion from its new HCV medicines in their first twenty-seven months on the market. 12

#### Rising healthcare costs compromise 17% of GDP---the current trajectory is unsustainable and makes collapse inevitable.

Ron Howrigon 16. President and CEO of Fulcrum Strategies, Masters in Economics from North Carolina State University, has held Senior Management level positions with three of the largest Managed Care Companies in the country, including Kaiser Permanente, CIGNA HealthCare and BlueCross BlueShield, former Director of Community Medical Services with Kaiser Permanente. “Flatlining: How Healthcare Could Kill the US Economy.”

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 of its portion of the US. 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 US. economy by the year 2060. Every economist worth their salt will tell you that healthcare 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 for healthcare—so much so that in 2016, healthcare 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 doubled 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, that simply can’t happen without causing signiﬁcant issues for the ﬁnancial wellbeing of our 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 healthcare is the next industry to suffer a major failure and collapse?

It’s safe to say that a healthcare meltdown would make both the automotive 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% 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. Healthcare 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% of our country’s GDP and employs 6.1 million people. Again, the healthcare market dwarfs this industry. It’s three times larger in terms of GDP production and, with 18 million people employed in the healthcare sector, it’s three times larger than construction in this area, too.

These comparisons give you an idea of just how signiﬁcant a portion healthcare comprises of the U.S. economy. It also begins to help us understand the impact it would have on the economy if healthcare 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 healthcare 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 healthcare 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 healthcare 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 healthcare 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 healthcare market, we come up with a truly frightening scenario. If healthcare lost 40% 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%. That means we could easily top the all-time high unemployment rate for our country. In November of 1982, the U.S. unemployment rate was 10.8%. A failure in the healthcare sector could push unemployment to those levels or higher. The only time in our country’s history when unemployment was higher was during the Great Depression. It should also be noted that in 1982, home mortgage interest rates were close to 20%! The U.S. Federal Funds Rate, or the interest rate the government pays on our national debt, was also close to 20% in 1982.

Economists fear that a large increase in unemployment could cause interest rates to escalate to levels approaching those of the early 1980s. If that were to happen today, with a $19 trillion national debt, it would mean that our annual debt service would be $3.8 trillion. Keep in mind that the federal government only takes in $3.4 trillion in total revenue. That’s right, in our nightmare scenario where healthcare fails and eliminates 7.2 million jobs, which pushes unemployment above 10% and causes interest rates to climb to almost 20%, we would be in a situation where the interest payments on our current debt would be more than our entire federal tax revenue. Basically, we would be Greece, but on a much larger scale.

Ok, now it’s time to take a deep breath. I’m not convinced that healthcare 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 healthcare collapse would still be devastating. Healthcare can’t be allowed to continue its current inﬂationary trending. I believe we are on the verge of some major changes in healthcare, 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 healthcare 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 healthcare market crashes and millions of people end up with no healthcare, the resulting fallout could be much worse than even the housing crisis.

#### COVID creates an economic brink---recovery is strong now because of effective monetary policy, but we’ve hit the zero-lower bound.

Christopher Rugaber 21. Associated Press. “Federal Reserve keeps key interest rate near zero, signals COVID-19 economic risks receding.” https://www.chicagotribune.com/business/ct-biz-fed-interest-rates-economy-20210428-bumyc3ynpza6ri4ygsntmdsmya-story.html.

WASHINGTON — The Federal Reserve is keeping its ultra-low interest rate policies in place, a sign that it wants to see more evidence of a strengthening economic recovery before it would consider easing its support.

In a statement Wednesday, the Fed expressed a brighter outlook, saying the economy has improved along with the job market. And while the policymakers noted that inflation has risen, they ascribed the increase to temporary factors.

The Fed also signaled its belief that the pandemic’s threat to the economy has diminished, a significant point given Chair Jerome Powell’s long-stated view that the recovery depends on the virus being brought under control. Last month, the Fed had cautioned that the virus posed “considerable risks to the economic outlook.” On Wednesday, it said only that “risks to the economic outlook remain” because of the pandemic.

The central bank left its benchmark short-term rate near zero, where it’s been since the pandemic erupted nearly a year ago, to help keep loan rates down to encourage borrowing and spending. It also said in a statement after its latest policy meeting that it would keep buying $120 billion in bonds each month to try to keep longer-term borrowing rates low.

The U.S. economy has been posting unexpectedly strong gains in recent weeks, with barometers of hiring, spending and manufacturing all surging. Most economists say they detect the early stages of what could be a robust and sustained recovery, with coronavirus case counts declining, vaccinations rising and Americans spending their stimulus-boosted savings.

#### Eroding financial resilience causes war---that overcomes traditional barriers to conflict.

Jomo Kwame Sundaram & Vladimir Popov 19. Former economics professor, was United Nations Assistant Secretary-General for Economic Development, and received the Wassily Leontief Prize for Advancing the Frontiers of Economic Thought in 2007. Former senior economics researcher in the Soviet Union, Russia and the United Nations Secretariat, is now Research Director at the Dialogue of Civilizations Research Institute in Berlin “Economic Crisis Can Trigger World War.” <http://www.ipsnews.net/2019/02/economic-crisis-can-trigger-world-war/>.

Economic recovery efforts since the 2008-2009 global financial crisis have mainly depended on unconventional monetary policies. As fears rise of yet another international financial crisis, there are growing concerns about the increased possibility of large-scale military conflict.

More worryingly, in the current political landscape, prolonged economic crisis, combined with rising economic inequality, chauvinistic ethno-populism as well as aggressive jingoist rhetoric, including threats, could easily spin out of control and ‘morph’ into military conflict, and worse, world war.

Crisis responses limited

The 2008-2009 global financial crisis almost ‘bankrupted’ governments and caused systemic collapse. Policymakers managed to pull the world economy from the brink, but soon switched from counter-cyclical fiscal efforts to unconventional monetary measures, primarily ‘quantitative easing’ and very low, if not negative real interest rates.

But while these monetary interventions averted realization of the worst fears at the time by turning the US economy around, they did little to address underlying economic weaknesses, largely due to the ascendance of finance in recent decades at the expense of the real economy. Since then, despite promising to do so, policymakers have not seriously pursued, let alone achieved, such needed reforms.

Instead, ostensible structural reformers have taken advantage of the crisis to pursue largely irrelevant efforts to further ‘casualize’ labour markets. This lack of structural reform has meant that the unprecedented liquidity central banks injected into economies has not been well allocated to stimulate resurgence of the real economy.

From bust to bubble

Instead, easy credit raised asset prices to levels even higher than those prevailing before 2008. US house prices are now 8% more than at the peak of the property bubble in 2006, while its price-to-earnings ratio in late 2018 was even higher than in 2008 and in 1929, when the Wall Street Crash precipitated the Great Depression.

As monetary tightening checks asset price bubbles, another economic crisis — possibly more severe than the last, as the economy has become less responsive to such blunt monetary interventions — is considered likely. A decade of such unconventional monetary policies, with very low interest rates, has greatly depleted their ability to revive the economy.

The implications beyond the economy of such developments and policy responses are already being seen. Prolonged economic distress has worsened public antipathy towards the culturally alien — not only abroad, but also within. Thus, another round of economic stress is deemed likely to foment unrest, conflict, even war as it is blamed on the foreign.

International trade shrank by two-thirds within half a decade after the US passed the Smoot-Hawley Tariff Act in 1930, at the start of the Great Depression, ostensibly to protect American workers and farmers from foreign competition!

Liberalization’s discontents

Rising economic insecurity, inequalities and deprivation are expected to strengthen ethno-populist and jingoistic nationalist sentiments, and increase social tensions and turmoil, especially among the growing precariat and others who feel vulnerable or threatened.

Thus, ethno-populist inspired chauvinistic nationalism may exacerbate tensions, leading to conflicts and tensions among countries, as in the 1930s. Opportunistic leaders have been blaming such misfortunes on outsiders and may seek to reverse policies associated with the perceived causes, such as ‘globalist’ economic liberalization.

Policies which successfully check such problems may reduce social tensions, as well as the likelihood of social turmoil and conflict, including among countries. However, these may also inadvertently exacerbate problems. The recent spread of anti-globalization sentiment appears correlated to slow, if not negative per capita income growth and increased economic inequality.

To be sure, globalization and liberalization are statistically associated with growing economic inequality and rising ethno-populism. Declining real incomes and growing economic insecurity have apparently strengthened ethno-populism and nationalistic chauvinism, threatening economic liberalization itself, both within and among countries.

Insecurity, populism, conflict

Thomas Piketty has argued that a sudden increase in income inequality is often followed by a great crisis. Although causality is difficult to prove, with wealth and income inequality now at historical highs, this should give cause for concern.

Of course, other factors also contribute to or exacerbate civil and international tensions, with some due to policies intended for other purposes. Nevertheless, even if unintended, such developments could inadvertently catalyse future crises and conflicts.

Publics often have good reason to be restless, if not angry, but the emotional appeals of ethno-populism and jingoistic nationalism are leading to chauvinistic policy measures which only make things worse.

At the international level, despite the world’s unprecedented and still growing interconnectedness, multilateralism is increasingly being eschewed as the US increasingly resorts to unilateral, sovereigntist policies without bothering to even build coalitions with its usual allies.

Avoiding Thucydides’ iceberg

Thus, protracted economic distress, economic conflicts or another financial crisis could lead to military confrontation by the protagonists, even if unintended. Less than a decade after the Great Depression started, the Second World War had begun as the Axis powers challenged the earlier entrenched colonial powers.

They patently ignored Thucydides’ warning, in chronicling the Peloponnesian wars over two millennia before, when the rise of Athens threatened the established dominance of Sparta!

Anticipating and addressing such possibilities may well serve to help avoid otherwise imminent disasters by undertaking pre-emptive collective action, as difficult as that may be.

#### And go nuclear.

Stein Tønnesson 15. Research Professor, Peace Research Institute Oslo; Leader of East Asia Peace program, Uppsala University, 2015. “Deterrence, interdependence and Sino–US peace.” International Area Studies Review, Vol. 18, No. 3, p. 297-311.

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.

### Solvency---1AC

#### Plan: The United States federal government should prohibit anticompetitive practices that artificially extend medical patents.

#### Solvency:

#### Antitrust is key to certainty---resolving inconsistent circuit splits is the only way to prevent over and underenforcement.

Tyler J. Klein 16. Lawyer. “Antitrust Enforcement Against Pharmaceutical Product Hopping: Protecting Consumers or Reaching Too Far?” Saint Louis University Journal of Health Law & Policy. Volume 10; Issue 1; Article 12. 2016. <https://scholarship.law.slu.edu/cgi/viewcontent.cgi?article=1058&context=jhlp>

C. Future Litigation and Supreme Court Intervention Without question, pharmaceutical product hopping is far from resolution. With so much at stake, it is unlikely that brand-name pharmaceutical companies will cease efforts to avoid generic competition in the near future. Moreover, Mylan, one of the most prominent product-hopping cases, may just be getting started. Considering the extreme profits, coupled with the need for a balance between innovation in the pharmaceutical industry and access to drugs, it seems that Supreme Court intervention is looming. As previously discussed, the Supreme Court almost had the opportunity to decide whether or not to weigh in on product hopping, but it dismissed Allergan’s Petition for Writ of Certiorari because the parties settled the case.168 Although the Supreme Court never heard arguments, Allergan’s Petition for Certiorari outlines the potential questions that the Court will face should it decide to take up a product-hopping case. The Petition presented the Court with two salient issues: the first, “Whether exercising rights granted by the Patent Act—in particular, not selling one patented product and selling a different patented product instead—can violate the Sherman Antitrust Act?”169 The second issue was: “Whether drug manufacturers have a federal antitrust duty to facilitate the operation of state drug substitution laws to maximize competitor’s sales?”170 Although it was dismissed, examining the Petition provides insight into possible arguments the Supreme Court could hear in the future. Unsurprisingly, the Petition begins by describing the unprecedented injunction that forced Allergan to continue producing and selling a drug they considered retired.171 The Second Circuit’s holding and injunction creates a duty that a brand drug manufacturer must produce and sell an outdated product to maximize the sales of generics.172 In making a case to the Supreme Court, Allergan expands on the common argument that antitrust regulation stifles innovation by asserting that the innovation process occurs through small, “incremental improvement[s]” and that brand-name companies must be allowed to make these small improvements in order to progress.173 While this explanation of the innovation process may certainly provide a basis for arguments by brand-name developers in future litigation, Allergan’s petition also foreshadows future issues that may result from product-hopping litigation. Allergan contends that the Second Circuit’s decision holding it liable for a violation of antitrust law “[p]recipitates a [c]ircuit [s]plit.”174 Allergan notes that the Seventh Circuit, Fourth Circuit, and Eleventh Circuit have all recognized that “[p]reventing competitors from free-riding on a monopolist’s advertising or other investments is a legitimate business purpose that enhances rather than impedes competition.”175 Allergan contends that the Second Circuit found antitrust liability where other circuits have not.176 However, the powerful implications of product hopping paired with the unique nature of the pharmaceutical market make it difficult to analogize a product-hopping case to a typical antitrust case. Although the U.S. Supreme Court did not issue a ruling there, the wait may not be long for a second opportunity. The Mylan case presents a new opportunity for the Court to weigh in on pharmaceutical product hopping. The Mylan case seems to fall somewhere in between the hard switching done in Actavis and the legal soft switching in Walgreen. If the Third Circuit affirms the Eastern District of Pennsylvania and does not follow the Actavis decision, it will create a direct circuit split on the issue of antitrust liability for pharmaceutical product hopping. The Third Circuit’s ruling on whether or not there is antitrust liability in this case could begin to either solidify a stance against product-hopping or further muddle the issue. Interestingly, and perhaps as a result of the Actavis litigation, Mylan, the generic drug, has gained the support of the FTC as it prepares its appeal. In the Mylan District Court case, the FTC filed a brief as Amicus Curiae.177 However, the FTC did not state in its brief whether or not it supported holding product-hopping companies liable for violating antitrust law.178 This amicus brief merely discussed competition in the pharmaceutical industry and noted the potential for brand-name manufacturers to exploit the market with product hopping.179 However, since Mylan appealed, the FTC made its stance clear by filing a Brief for Amicus Curiae supporting Mylan and explaining that companies who exploit monopoly power should face antitrust liability.180 The FTC contended that the district court erred in its judgment and misunderstood the unique characteristics of the pharmaceutical market.181 Additionally, the FTC relied on the Second Circuit Actavis decision to support its contention that Warner Chilcott had monopoly power and should face antitrust liability.182 The FTC maintained a neutral position when product-hopping litigation first began, but it now seems to favor holding product-hopping companies liable for antitrust violations. The shift in the FTC’s stance illustrates the magnitude of these cases, which further complicates the decision facing the Third Circuit. Adding to the need for Supreme Court intervention is the potential of a circuit split on the issue of antitrust liability for pharmaceutical product hopping. If a circuit split occurs, it could incentivize forum shopping, as companies will likely try to litigate in a more favorable forum. Perhaps more compelling is the increase in pharmaceutical startups, which magnifies the issue of forum shopping. For instance, “investments in biotechnology start-ups rose 26 percent in the first half of 2014.”183 Continuing this trend, “[t]he first half of 2015 has already seen more than $6 [billion] invested, putting it on track to beat 2014’s total of $11.2 [billion] invested.”184 With this kind of funding, it is likely that the number of startup pharmaceutical companies will continue to rise. Additionally, many brand-name pharmaceutical companies rely on smaller startup pharmaceutical companies to innovate new products.185 The drug development process is expensive, but startup pharmaceutical companies have streamlined operating costs and lower overhead, allowing these startups to develop drugs more efficiently.186 If startup pharmaceutical companies want to preserve their patents, they may be incentivized to operate in a circuit with a lenient stance on product hopping. Depending on how the Third Circuit decides the Mylan appeal, a circuit split and its accompanying forum-shopping incentives may be the catalyst that prompts the Supreme Court to grant a writ and issue a decisive ruling on antitrust liability for pharmaceutical product hopping. Even if the Third Circuit follows Actavis, it remains to be seen whether it will follow the Second Circuit’s remedy, use a different option, or create a new one. Perhaps this issue of finding the appropriate remedy will attract the Court’s attention. Regardless, Supreme Court intervention in the issue of product hopping seems likely, if not imminent. V. CONCLUSION In the end, many questions remain surrounding the use of antitrust law to prevent brand-name pharmaceutical companies from product hopping. Certainly, enforcing antitrust laws against product-hopping companies is essential to ensure that consumers can access the drugs they need. Permitting brand-name manufacturers to skirt liability severely inhibits the ability of generics to enter the market, thus upsetting the delicate balance of competition in the unique pharmaceutical market. This scenario paints a grim picture for the millions of Americans who depend on generic drugs to drive prices down to accessible and affordable amounts. However, zealous antitrust advocates must remain aware of the fact that restricting brand-name pharmaceutical companies has a price, and pushing too far threatens to stifle innovation of new drugs and treatments. Even more perturbing is the potential for injunctive relief to impose potentially unfair and overreaching remedies in these types of cases, as happened in Actavis. Remembering that the goal of the Sherman Act is to foster competition,187 courts hearing these cases must take care not to impose burdensome remedies that reach too far and stifle the exact thing antitrust laws are trying to foster— innovation and competition. Although Actavis’s soft versus hard switching distinction gives brand-name pharmaceutical companies a bright-line rule to follow, much is left unknown for companies trying to avoid liability in these types of suits. It seems that the high stakes surrounding the pharmaceutical market, the potential circuit split, and the fear of unconscionable remedies may prompt the Supreme Court to intervene. Issuing a definitive ruling explaining where the line between permissible competitive strategies and impermissible exclusionary conduct lies would provide much needed guidance to an industry that survives by pushing the envelope of science and competition. Until such a ruling happens, brand-name pharmaceutical companies and generics are left to explore competitive advantages and battle over where the boundaries are drawn. While this promises to provide some interesting litigation, the uncertainty and potential consequences for the pharmaceutical industry that the nation is so dependent upon is an unsettling notion for us all.

#### The aff expands the Sherman Act to consider a third prong of analysis in monopolistic conduct pertaining to the pharmaceutical industry. That allows true competition in the market.

Daniel Burke 18. Cleveland-Marshall College of Law. “An Examination of Product Hopping by Brand-Name Prescription Drug Manufacturers: The Problem and a Proposed Solution” Cleveland State Law Review. Volume 66; Issue 2; Article 8. 04-01-18. <https://engagedscholarship.csuohio.edu/cgi/viewcontent.cgi?article=3995&context=clevstlrev>

E. Monopoly Analysis Related to a Potential Case of Product Hopping Must Take the Abnormalities of the Pharmaceutical Market into Consideration The analysis of suspected product hopping in violation of § 2 of the Sherman Act should consist of a traditional monopoly analysis with the addition of a consideration of the relevant market. Specifically, courts should consider, as a third prong to the analysis of potentially monopolistic conduct, whether the relevant market under review is typical or is one that has unique competitive (i.e., pricing) concerns lending that market to a more skeptical judicial inquiry. In effect, this new prong would be a sub-issue of the first prong of the analysis concerning whether the market actor in question has market monopoly power.193 Courts have stated that monopoly power exists in a market when one product comprises two-thirds of the relevant market,194 ninety percent of the relevant market,195 and eighty-seven percent of the relevant market.196 A presentation detailing company performance from 2013 indicated that Mayne Pharma Group, Ltd. (Warner Chilcott’s partner in the production and distribution of Doryx) reported a sixty percent market share for Doryx.197 This substantial control of the market that treats severe acne puts the drug’s manufacturer in position to continue to drive up prices and harm consumers. The prescription drug market is not like other markets. Pharmaceutical companies invest tremendous sums of money into research and development.198 This investment is superseded, however, by investment in marketing the fruits of research and development’s labors.199 For example, Johnson & Johnson spent twice as much on marketing than it did on research and development in 2013 ($17.5 billion and $8.2 billion, respectively).200 The even more interesting part of this breakdown is determining the target of that marketing. In 2012, pharmaceutical companies spent $24 billion marketing toward physicians as compared to a relatively modest $3 billion marketing toward consumers.201 This discrepancy highlights a point previously made and articulated in the Federal Trade Commission’s (“FTC”) Amicus Brief in support of Mylan: “the consumer who pays does not choose, and the physician who chooses does not pay.”202 Physicians, through no fault of their own, are the ones who limit consumers’ market by the very nature of the system of prescriptions. If courts refuse to accept the characteristics of the pharmaceutical market as being unique, and thus requiring bespoke analysis, rising prescription drug prices will continue to harm those same consumers who are powerless to affect change. The FTC’s amicus brief filed after the Mylan decision urged the court to understand the differences in the pharmaceutical market. The FTC specifically argued that, given market differences, consumers will be harmed if this practice is permitted to continue.203 The brief stressed that automatic substitution laws are “vital means to a successful competition since [they are] aimed to address the ‘disconnect between prescribing physicians and payors.’”204 Drug substitution laws, discussed supra, allow pharmacists to substitute cheaper, bioequivalent drugs for patients.205 This lowers costs and allows true competition from actors other than brand-name prescription drug manufacturers.206 The FTC’s concern that consumers would be harmed absent these laws is warranted and should be heeded by courts when addressing this issue. Additionally, a legislative solution to the issue of product hopping may prove efficacious. Congress should enact a statute that treats the reformulation of an existing drug as a monopolistic practice per se. Such a statute would have the effect of placing the burden on the brand-name manufacturer to show that the new drug has a meaningfully different characteristic. The bar for “meaningfully different” should be established with the goal of preventing the practice of product hopping in the future. That is, the test should be fairly difficult to meet if the brand-name manufacturer has submitted a new drug to treat the same illness that its previous drug treated. The prescription drug manufacturer should have to demonstrate clinically relevant improvements with regard to the new drug’s formulation, method in which it is administered, effectiveness, or potential side effects before a patent may be granted on a drug. While this requirement may seem unfair to brand-name drug manufacturers, it is a feasible way to dissuade product hopping, which has been shown to drive the increase in healthcare costs and ultimately harm consumers.207 The FDA is the proper agency to deal with this determination given its current position of being the regulator tasked with approving pharmaceutical drugs. Enacting a statute to effectuate this result should have the effect of minimizing product hopping issues. If litigated, because the presumption is that the new drug is equivalent to the former drug, the brand-name manufacturer would have to demonstrate to the court that that presumption is erroneous to avoid a finding of a violation of the Sherman Act.

#### Only antitrust can solve---an effect-based analysis is key. Otherwise, drug companies will adapt to any other system.

Michael A. Carrier 21. Rutgers Law School. “Pharmaceutical Antitrust: What the Biden Administration Can Do” Rutgers Law School Research Paper No. Forthcoming. 01-27-21. <https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3771055>

19. Every drug company profiting from a patented drug faces a moment of reckoning: the time its patent expires and it is subject to generic competition. Not surprisingly, the companies do everything they can to delay that moment as long as possible. The variety of conduct in which drug companies have engaged is wide-ranging and always changing. The FTC needs to be on its toes. 20. For example, who could have imagined in 2017 that the industry would reach into its bag of anticompetitive tricks to pull out. . .tribal immunity? Yes, Allergan transferred patents covering its dry-eye medicine Restasis to the Saint Regis Mohawk Tribe in an attempt to avoid re- view at the Patent Office.26 Such a shameless attempt to exploit immunity developed for a different purpose was not successful, as the Federal Circuit held that tribal im- munity did not apply to the proceedings at issue.27 But it is a reminder of drug firms’ creativity in avoiding competition.21. The latest ruse involves convincing courts to jettison a vital pathway by which generics have reached the market. In settings in which a drug can be used to treat multiple conditions, a generic can “carve out” the patented indications from its label.28 The resulting “skinny label” allows the generic to launch its product for uses not covered by the patent. 22. In October 2020, a Federal Circuit panel found that this long-recognized practice could form the basis for induced infringement, even though, as Chief Judge Prost explained in a 33-page dissent, generic company Teva “did everything right.”29 The dissent worried that the ruling rendered the “‘content’ of Teva’s skinny label alone (. . .) sufficient to prove induced infringement—even though Teva’s skinny label did not encourage, promote, recommend, or even suggest the patented method.”30 Such a “nullification”31 of the Hatch-Waxman Act “invites a claim of inducement for almost any generic that legally enters the market with a skinny label.”32 As shown by a lawsuit filed shortly after the decision, brand companies have wasted no time in doing this.33 23. One thing is for certain. The FTC needs to be nimble in assessing all the ever-changing ways the pharmaceutical industry can delay generics. V. Conclusion 24. The pharmaceutical industry often raises the argument that high drug prices are an inevitable result of innovation and that their conduct should avoid scrutiny because of the importance of drugs. But antitrust law allows us to have our cake and eat it too, ferreting out the “bad apples” while not harming innovation. The Biden administration can achieve these positive—in fact, life-altering—results by targeting conduct like pay-for-delay settlements, product hopping, biosimilar blockades, and the next frontier of anticompetitive conduct.

#### Product hopping is key.

Daniel Burke 18. Cleveland-Marshall College of Law. “An Examination of Product Hopping by Brand-Name Prescription Drug Manufacturers: The Problem and a Proposed Solution” Cleveland State Law Review. Volume 66; Issue 2; Article 8. 04-01-18. <https://engagedscholarship.csuohio.edu/cgi/viewcontent.cgi?article=3995&context=clevstlrev>

The practice of product hopping constitutes a violation of § 2 of the Sherman Act, vis-à-vis a monopolistic practice. Exclusivity necessarily allows a company to control market prices, as characterized by the Supreme Court.103 Under the Sherman Act, two factors must be met to establish a monopoly offense.104 The first is “the possession of monopoly power in the relevant market,” and the second is “the willful acquisition or maintenance of that power as distinguished from growth or development as a consequence of a superior product, business acumen, or historic accident.”105 In effect, a patent is the predicate for a legal monopoly granted to its holder by the United States Patent and Trademark Office. Brand-name drug companies control, if not the entire market, a highly significant portion of it, as previously discussed.106 While competitors could compete with a different formulation of a prescription drug, in practice this rarely occurs because of the cost of drug development.107 The first prong of the test, therefore, is satisfied. The company that has patent protection on a product has the power to create a monopoly in the relevant market, albeit a “legal” one for a limited duration. The second prong of the test, which requires the defendant company to maintain its monopoly without growth or development of its product, is more difficult to establish and highly fact specific.108 The patent holder may assert that the alterations result in a superior product, qualifying the holder for the right to a new patent (i.e. continued monopoly power in the same market). However, the nature of product hopping is that the patent holder maintains that monopoly power “as distinguished from growth or development as a consequence of a superior product . . . .”109 Companies can do this by changing the frequency of administration of the drug, changing the potency of the drug, or changing the chemical composition of the drug without altering the drug’s efficacy or limiting potential side effects.110 The lack of meaningful, clinical improvement after a change in the drug sufficient to warrant the grant of a new patent constitutes product hopping per se.111 As a result, the second prong of the test is met absent any significant, clinically-relevant improvement in the particular prescription drug. Addressing the Supreme Court’s characterization of the three requirements, which most appellate courts have adopted to demonstrate monopolistic activity,112 reinforces this conclusion. The first test, requiring that the plaintiff show “predatory or anticompetitive conduct,”113 is met because patents are inherently anticompetitive. A patent, as previously described, is a right to exclude others from using the protected process or technology.114 Exclusion by statutory right, although legal and endorsed by the Constitution and jurisprudence, purposefully prevents competition for a limited time as a means of fostering and furthering innovation. The second test, requiring the plaintiff to show intent to monopolize,115 is met by the pharmaceutical company’s act of filing and obtaining patent protection. When a company files a patent application, the company’s goal, or intent, is to obtain a patent for that technology. As previously mentioned, a patent essentially grants a legal monopoly for a set period of time to its holder.116 Therefore, inherent in every patent application is the applicant’s intent ultimately to obtain the right to exclude others from engaging in the process or using the technology described in his application. Furthermore, predatory intent is, in part, established by examining the barriers to entry in a relevant market.117 If a market has high barriers to entry, the company engaging in the questionable conduct will more likely be able to benefit from predatory prices.118 Conversely, in a market with relatively low barriers to entry, such tactics will not prove as fruitful.119 The barriers to entry in the prescription drug manufacturing market are high. As mentioned, entering the market requires a significant amount of research and development cost (totaling in the billions for some drugs), a massive amount of marketing investment, and technical expertise.120 One can easily see how the market’s characteristics may discourage competitors from entry into this market. Coupled with high drug prices, the conduct discussed here easily meets this second test. Finally, the third question, which requires a showing of a likelihood of obtaining monopoly power,121 is met based on whether a patent for a similar drug is actually obtained. If obtained, a patent is not only a “dangerous probability of achieving monopoly power,”122 but in fact is a conclusion of monopoly power for the duration of the patent.123 In the United States, the duration of a patent is generally twenty years after the date the inventor filed the patent application.124 Both the Second and Third Circuits emphasized, correctly, the importance of determining the relevant market for analysis of potentially monopolistic conduct. The relevant market can be demonstrated either directly “through evidence of control over prices or the exclusion of competition” or indirectly by showing one company’s market share.125 Thus, a company’s claim that it does not control a majority or even close to a majority of the relevant market (as measured by overall sales) is not dispositive.126 Instead, how a company’s conduct affects prices can demonstrate whether or not that company possesses monopoly power in the relevant market.127 Keeping this in mind, courts should consider not only explicit evidence of a particular drug’s control of a market (i.e., sales), but also that company’s effect on prices, which is ultimately the consumers’ greatest concern, and, intrinsically, the governmental agencies that regulate this area of the law and commerce.128 Although the Third Circuit found Doryx to be interchangeable with other similar medications,129 the determination of similarity should occur earlier in the process. For example, the United States Patent and Trademark Office is better equipped to determine the issue of whether a particular drug is equivalent or essentially equivalent to other existing prescription drugs based on the Office’s employment of a huge number of subject matter experts in a myriad of industries.130

# 2AC

## Innovation Advantage

#### No link---the aff only reduces coercive product hopping, which isn’t innovative.

Vikram Iyengar 16. Ph.D., 2002, Duke University; J.D., 2015, Stanford Law School. This article is based on research conducted while Dr. Vikram Iyengar was a J.D. candidate at Stanford Law School. “Should Pharmaceutical Product Hopping Be Subject to Antitrust Scrutiny?” 2016. https://assets.fenwick.com/legacy/FenwickDocuments/Pharmaceutical-Product-Hopping.pdf

But making cosmetic changes to a drug’s physical form is **hardly innovation**. Moreover, courts have stated that a monopolist’s products that gain acceptance in the market are free of antitrust liability only as long as “that success was not based on any form of coercion.”9 When a monopolist coercively reduces consumer choice, it can cause **harm to social welfare and should be subject to antitrust scrutiny.** For example, in New York v. Actavis, Actavis restricted patient access to its existing Namenda IR drug to **force patients to switch** to its newer, but virtually identical drug Namenda XR.10 Once patients switched to Namenda XR, the market for generic Namenda IR **would be destroyed** because pharmacists would be unable to substitute generic Namenda IR when presented with a prescription for Namenda XR. Moreover, there would be a significant burden on doctors, patients, and generic manufacturers to switch to the much-cheaper generic of Namenda IR. Doctors’ freedom to choose the right drug for their patients would therefore be curtailed.11 Patients would **pay much higher prices** for their medicine and would be forced to undergo an unnecessary change in medication and dosage.12 Under such coercive circum- stances, product hopping can have **negative consequences** for consumers and healthcare plans.13 Product hopping merits **antitrust scrutiny** when combined with coercive and predatory conduct because these circumstances reduce com- petition and social welfare. In other words, “[i]t is not the product introduction itself, but [the] associated conduct, that supplies the [antitrust violation.”14

#### The link is empirically denied---pharma companies have said any legislation in the past decade will destroy innovation and they’ve been wrong every time. Their authors are paid off.

Michael A. Carrier & Genevieve Tung 19. Professor of law at Rutgers Law School and an associate director of the Rutgers Law Library. “The industry that cries wolf: pharma and innovation.” <https://www.statnews.com/2019/09/26/innovation-boy-cried-wolf-pharma-industry/>.

But we write to raise a different point: Claims by big pharmaceutical companies (and the organizations they fund) that legislation addressing product hopping (or pay-for-delay settlements or sample denials) would harm innovation should be taken with a grain of salt. As HHS Secretary Alex Azar lamented, the industry incessantly claims that “if one penny disappears” from its profit margins, “American innovation will grind to a halt.” These “tired talking points,” he said, emerge each time Congress considers legislation affecting the industry.

The outcries trace back at least to 1961, when Eugene N. Beesley, the president of Eli Lilly, responded to the Drug Industry Antitrust Act (which sought to rein in high prices and impose licensing on drug manufacturers) before a subcommittee of the U.S. Senate. Speaking on behalf of the Pharmaceutical Manufacturers Association, Beesley warned that deletion of patent protection would “increasingly dilute the intense competition for superiority in discovery and manufacturing,” which would be “a tragic result in an area so vital to the public health.”

Even the landmark legislation that became the Hatch-Waxman Act was subject to industry threats that “you get what you pay for” and that if “Congress and the American public are unwilling to make a substantial investment in new drugs, they will get very little in return [and] innovation will dry up.”

The ominous warnings have continued ever since. Of the countless examples that could be offered, here are eight from the past 15 years.

In 2004, PhRMA claimed that modifications to the Hatch-Waxman Act “would undermine the act’s few critical protections for innovator [IP] rights,” leading to “less innovation [and] fewer new drugs to enhance treatment.”

In 2013, PhRMA criticized the House’s passage of the Innovation Act, which sought to curb the misuse of patent enforcement, voicing “concerns that it would undermine the ability of patent holders to enforce their rights, … potentially decreasing the value of patents and weakening incentives for innovation.”

Also in 2013, the president and CEO of PhRMA testified that European cost-containment measures “raise serious concerns” about EU member states’ “commitment to adequately reward innovation.”

Yet again in 2013, a PhRMA representative criticized legislation targeting pay-for-delay settlements since a presumption of illegality “would significantly undermine the value of patents that are the cornerstone of pharmaceutical innovation.”

In 2015, PhRMA worried that state legislation capping drug prices would “have a devastating impact on medical innovation.”

The same year, the organization referred to post-grant proceedings that allow patents to be reviewed as a “death squad” that “would impact our ability to develop new medicines that treat some of the most devastating diseases.”

In 2016, PhRMA lamented that the president’s FY17 budget mandating information disclosure would “undermine our competitive … incentives for innovation.”

And in 2019, PhRMA warned that “march-in rights” allowing the government to compel the granting of patent licenses if it funded some of the research would “jeopardize U.S. innovation.”

In the classic Aesop fable, the first two times the young shepherd cried wolf, the villagers came to help him. But after that, they stopped coming.

Big Pharma has cried Innovation Wolf every time Congress seeks to address its shenanigans. And the legislators keep coming to defend it. That has to stop. It is past time for the industry to be called to account on using its get-out-of-jail-free innovation card to avoid reasonable legislation.

As we get closer to the finish line of passing legislation addressing product hopping and other games, the cries about threats to innovation will grow louder and more urgent. But the industry’s history needs to be remembered. Consumers’ lives depend on it.

## Costs Advantage

#### Growth is sustainable and solves a laundry list of threats.

Mark Budolfson 21. PhD in Philosophy. Assistant Professor in the Department of Environmental and Occupational Health and Justice at the Rutgers School of Public Health and Center for Population–Level Bioethics "Arguments for Well-Regulated Capitalism, and Implications for Global Ethics, Food, Environment, Climate Change, and Beyond". Cambridge Core. 5-7-2021. https://www-cambridge-org.proxy.library.emory.edu/core/journals/ethics-and-international-affairs/article/arguments-for-wellregulated-capitalism-and-implications-for-global-ethics-food-environment-climate-change-and-beyond/96F422D04E171EECDEF77312266AE9DD

Discourse on food ethics often advocates the anti-capitalist idea that we need less capitalism, less growth, and less globalization if we want to make the world a better and more equitable place, with arguments focused on applications to food, globalization, and a just society. For example, arguments for this anti-capitalist view are at the core of some chapters in nearly every handbook and edited volume in the rapidly expanding subdiscipline of food ethics. None of these volumes (or any article published in this subdiscipline broadly construed) focuses on a defense of globalized capitalism.1

More generally, discourse on global ethics, environment, and political theory in much of academia—and in society—increasingly features this anti-capitalist idea as well.2 The idea is especially prominent in discourse surrounding the environment, climate, and global poverty, where we face a nexus of problems of which capitalism is a key driver, including climate change, air and water pollution, the challenge of feeding the world, ensuring sustainable development for the world's poorest, and other interrelated challenges.

It is therefore important to ask whether this anti-capitalist idea is justified by reason and evidence that is as strong as the degree of confidence placed in it by activists and many commentators on food ethics, global ethics, and political theory, more generally.

In fact, many experts argue that this anti-capitalist idea is not supported by reason and argument and is actually wrong. The main contribution of this essay is to explain the structure of the leading arguments against the anti-capitalist idea, and in favor of the opposite conclusion. I begin by focusing on the general argument in favor of well-regulated globalized capitalism as the key to a just, flourishing, and environmentally healthy world. This is the most important of all of the arguments in terms of its consequences for health, wellbeing, and justice, and it is endorsed by experts in the empirically minded disciplines best placed to analyze the issue, including experts in long-run global development, human health, wellbeing, economics, law, public policy, and other related disciplines. On the basis of the arguments outlined below, well-regulated capitalism has been endorsed by recent Democratic presidents of the United States such as Barack Obama, and by progressive Nobel laureates who have devoted their lives to human development and more equitable societies, as well as by a wide range of experts in government and leading nongovernmental organizations.

The goal of this essay is to make the structure and importance of these arguments clear, and thereby highlight that discourse on global ethics and political theory should engage carefully with them. The goal is not to endorse them as necessarily sound and correct. The essay will begin by examining general arguments for and against capitalism, and then turn to implications for food, the environment, climate change, and beyond.

Arguments for and against Forms of Capitalism

The Argument against Capitalism

Capitalism is often argued to be a key driver of many of society's ills: inequalities, pollution, land use changes, and incentives that cause people to live differently than in their ideal dreams. Capitalism can sometimes deepen injustices. These negative consequences are easy to see—resting, as they do, at the center of many of society's greatest challenges.3

And at the same time, it is often difficult to see the positive consequences of capitalism.4 What are the positive consequences of allowing private interests to clear-cut forests and plant crops, especially if those private interests are rich multinational corporations and the forests are in poor, developing countries whose citizens do not receive the profits from deforestation? Why give private companies the right to exploit resources at all, since exploitation almost always has some negative consequences such as those listed above? These are the right questions to ask, and they highlight genuine challenges to capitalism. And in light of these challenges, it is reasonable to consider the possibility that perhaps a different economic system altogether would be more equitable and beneficial to the global population.

The Argument for Well-Regulated Capitalism

However, things are more complicated than the arguments above would suggest, and the benefits of capitalism, especially for the world's poorest and most vulnerable people, are in fact myriad and significant. In addition, as we will see in this section, many experts argue that capitalism is not the fundamental cause of the previously described problems but rather an essential component of the best solutions to them and of the best methods for promoting our goals of health, well-being, and justice.

To see where the defenders of capitalism are coming from, consider an analogy involving a response to a pandemic: if a country administered a rushed and untested vaccine to its population that ended up killing people, we would not say that vaccines were the problem. Instead, the problem would be the flawed and sloppy policies of vaccine implementation. Vaccines might easily remain absolutely essential to the correct response to such a pandemic and could also be essential to promoting health and flourishing, more generally.

The argument is similar with capitalism according to the leading mainstream arguments in favor of it: Capitalism is an essential part of the best society we could have, just like vaccines are an essential part of the best response to a pandemic such as COVID-19. But of course both capitalism and vaccines can be implemented poorly, and can even do harm, especially when combined with other incorrect policy decisions. But that does not mean that we should turn against them—quite the opposite. Instead, we should embrace them as essential to the best and most just outcomes for society, and educate ourselves and others on their importance and on how they must be properly designed and implemented with other policies in order to best help us all. In fact, the argument in favor of capitalism is even more dramatic because it claims that much more is at stake than even what is at stake in response to a global pandemic—what is at stake with capitalism is nothing less than whether the world's poorest and most vulnerable billion people will remain in conditions of poverty and oppression, or if they will instead finally gain access to what is minimally necessary for basic health and wellbeing and become increasingly affluent and empowered. The argument in favor of capitalism proceeds as follows:

Premise 1. Development and the past. Over the course of recorded human history, the majority of historical increases in health, wellbeing, and justice have occurred in the last two centuries, largely as a result of societies adopting or moving toward capitalism. Capitalism is a relevant cause of these improvements, in the sense that they could not have happened to such a degree if it were not for capitalism and would not have happened to the same degree under any alternative noncapitalist approach to structuring society. The argument in support of this premise relies on observed relationships across societies and centuries between indicators of degree of capitalism, wealth, investments in public goods, and outcomes for health, wellbeing, and justice, together with econometric analysis in support of the conclusion that the best explanation of these correlations and the underlying mechanism is that large increases in health, wellbeing, and justice are largely driven by increasing investments in public goods. The scale of increased wealth necessary to maximize these investments requires capitalism. Thus, as capitalist societies have become dramatically wealthier over the past hundred years (and wealthier than societies with alternative systems), this has allowed larger investments in public goods, which simply has not been possible in a sustained way in societies without the greater wealth that capitalism makes possible. Important investments in public goods include investments in basic medical knowledge, in health and nutrition programs, and in the institutional capacity and know-how to regulate society and capitalism itself. As a result, capitalism is a primary driver of positive outcomes in health and wellbeing (such as increased life expectancy, lowered child and maternal mortality, adequate calories per day, minimized infectious disease rates, a lower percentage and number of people in poverty, and more reported happiness);5 and in justice (such as reduced deaths from war and homicide; higher rankings in human rights indices; the reduced prevalence of racist, sexist, homophobic opinions in surveys; and higher literacy rates).6 These quantifiable positive consequences of global capitalism dramatically outweigh the negative consequences (such as deaths from pollution in the course of development), with the result that the net benefits from capitalism in terms of health, wellbeing, and justice have been greater than they would have been under any known noncapitalist approach to structuring society.7

Premise 2. Economics, ethics, and policy. Although capitalism has often been ill-regulated and therefore failed to maximize net benefits for health, wellbeing, and justice, it can become well-regulated so that it maximizes these societal goals, by including mechanisms identified by economists and other policy experts that do the following:

* optimally8 regulate negative effects such as pollution and monopoly power, and invest in public goods such as education, basic healthcare, and fundamental research including biomedical knowledge (more generally, policies that correct the failures of free markets that economists have long recognized will arise from “externalities” in the absence of regulation);9
* ensure equity and distributive justice (for example, via wealth redistribution);10
* ensure basic rights, justice, and the rule of law independent of the market (for example, by an independent judiciary, bill of rights, property rights, and redistribution and other legislation to correct historical injustices due to colonialism, racism, and correct current and historical distortions that have prevented markets from being fair);11 and
* ensure that there is no alternative way of structuring society that is more efficient or better promotes the equity, justice, and fairness goals outlined above (by allowing free exchange given the regulations mentioned).12

To summarize the implication of the first two premises, well-regulated capitalism is essential to best achieving our ethical goals—which is true even though capitalism has certainly not always been well regulated historically. Society can still do much better and remove the large deficits in terms of health, wellbeing, and justice that exist under the current inferior and imperfect versions of capitalism.

Premise 3. Development and the future. If the global spread of capitalism is allowed to continue, desperate poverty can be essentially eliminated in our lifetimes. Furthermore, this can be accomplished faster and in a more just way via well-regulated global capitalism than by any alternatives. If we instead opt for less capitalism, less growth, and less globalization, then desperate poverty will continue to exist for a significant portion of the world's population into the further future, and the world will be a worse and less equitable place than it would have been with more capitalism. For example, in a world with less capitalism, there would be more overpopulation, food insecurity, air pollution, ill health, injustice, and other problems. In part, this is because of the factors identified by premise 1, which connect a turn away from capitalism with a turn away from continuing improvements in health, wellbeing, and justice, especially for the developing world. In addition, fertility declines are also a consequence of increased wealth, and the size of the population is a primary determinant of food demand and other environmental stressors.13 Finally, as discussed at length in the next section of the essay, capitalism can be naturally combined with optimal environmental regulations.14 Even bracketing anything like optimal regulation, it remains true that sufficiently wealthy nations reduce environmental degradation as they become wealthier, whereas developing nations that are nearing peak degradation will remain stuck at the worst levels of degradation if we stall growth, rather than allowing them to transition to less and less degradation in the future via capitalism and economic growth.15 In contrast, well-regulated capitalism is a key part of the best way of coping with these problems, as well as a key part of dealing with climate change, global food production, and other specific challenges, as argued at length in the next section. Here it is important to stress that we should favor well-regulated capitalism that includes correct investments in public goods over other capitalist systems such as the neoliberalism of the recent past that promoted inadequately regulated capitalism with inadequate concern for externalities, equity, and background distortions and injustices.16

Conclusion. Therefore, we should be in favor of capitalism over noncapitalism, and we should especially favor well-regulated capitalism, which is the ethically optimal economic system and is essential to any just basic structure for society.

This argument is impressive because, as stated earlier in the essay, it is based on evidence that is so striking that it leads a bipartisan range of open-minded thinkers and activists to endorse well-regulated capitalism, including many of those who were not initially attracted to the view because of a reasonable concern for the societal ills with which we began. To better understand why such a range of thinkers could agree that well-regulated capitalism is best, it may help to clarify some things that are not assumed or implied by the argument for it, which could be invoked by other bad arguments for capitalism.

One thing the argument above does not assume is that health, wellbeing, or justice are the same thing as wealth, because, in fact, they are not. Instead, the argument above relies on well-accepted, measurable indicators of health and wellbeing, such as increased lifespan; decreased early childhood mortality; adequate nutrition; and other empirically measurable leading indicators of health, wellbeing, and justice.17 Similarly, the argument that capitalism promotes justice, peace, freedom, human rights, and tolerance relies on empirical metrics for each of these.18

Furthermore, the argument does not assume that because these indicators of health, wellbeing, and justice are highly correlated with high degrees of capitalism, that therefore capitalism is the direct cause of these good outcomes. Rather, the analyses suggest instead that something other than capitalism is the direct cause of societal improvements (such as improvements in knowledge and technology, public infrastructure, and good governance), and that capitalism is simply a necessary condition for these improvements to happen.19 In other words, the richer a society is, the more it is able to invest in all of these and other things that are the direct causes of health, wellbeing, and justice. But, to maximize investment in these things societies need well-regulated capitalism.

As part of these analyses, it is often stressed that current forms of capitalism around the world are highly defective and must be reformed in the direction of well-regulated capitalism because they lack investments in public goods, such as basic knowledge, healthcare, nutrition, other safety nets, and good governance.20 In this way, an argument for a particular kind of progressive reformism is an essential part of the analyses that lead many to endorse the more general argument for well-regulated capitalism.

Although these analyses are nuanced, and appropriately so, it remains the case that the things that directly lead to health, wellbeing, and justice require resources, and the best path toward generating those resources is well-regulated capitalism. And on the flip side, according to the analyses behind premise 1 described above, an anti-capitalist system would not produce the resources that are needed, and would thus be a disaster, especially for the poorest billion people who are most desperately in need of the resources that capitalism can create and direct, to escape from extreme poverty.21

### AT: Defense

#### Answered above.

## States CP

#### State courts cannot consider cases pertaining to federal patent law---federal courts have exclusive jurisdiction.

Paul D. Clement 21. Counsel of Record. WARSAW ORTHOPEDIC, INC., MEDTRONIC, INC., MEDTRONIC SOFAMOR DANEK, INC., Petitioners v. RICK C. SASSO, M.D., Respondent. On Petition for Writ of Certiorari to the United States Court of Appeals for the Federal Circuit. 03-12-21. https://www.supremecourt.gov/DocketPDF/20/20-1284/171750/20210312113145882\_2021-03-12%20Medtronic%20Petition%20Final.pdf

Pursuant to 28 U.S.C. §1338(a), federal courts have exclusive jurisdiction over all cases arising under federal patent law; that jurisdiction is exclusive of state courts, which are explicitly prohibited from adjudicating such cases. Petitioners brought this suit in federal court seeking a declaration that its products were not covered by valid patent claims and thus they did not owe respondent damages. The district court assumed it had exclusive jurisdiction to hear petitioners’ claims, but “abstain[ed]” from resolving them—deferring instead to a “mirror image” Indiana state-court proceeding respondent had brought against petitioners, in which the state trial court essentially held a patent infringement trial, addressing, inter alia, issues of claim construction and PTO cancellation of the same patent claims. On appeal, the Federal Circuit went even further than the district court: It explicitly held in a precedential opinion that the district court had exclusive jurisdiction, such that the Federal Circuit (and not the Seventh Circuit) had exclusive appellate jurisdiction. But despite holding that the federal courts had exclusive jurisdiction over this federal patent-law dispute, the Federal Circuit held the district court could properly “abstain” from resolving the parties’ federal patent-law dispute in deference to the ongoing state-court proceedings.

#### The counterplan causes jurisdictional grab---that makes state-court disputes inevitable and undermines business clarity.

Paul D. Clement 21. Counsel of Record. WARSAW ORTHOPEDIC, INC., MEDTRONIC, INC., MEDTRONIC SOFAMOR DANEK, INC., Petitioners v. RICK C. SASSO, M.D., Respondent. On Petition for Writ of Certiorari to the United States Court of Appeals for the Federal Circuit. 03-12-21. https://www.supremecourt.gov/DocketPDF/20/20-1284/171750/20210312113145882\_2021-03-12%20Medtronic%20Petition%20Final.pdf

Second, by condoning state-court adjudication of cases that Congress assigned to exclusive federal jurisdiction, the decision below simultaneously invites abdication and encroachment, both of which produce endless jurisdictional snarls. This case itself provides the perfect example: Once the Federal Circuit affirmed the district court’s decision to abstain, the state court of appeals was emboldened to treat that abstention ruling as support for the trial court’s jurisdictional grab, affirming a $112 million award in a case that the state courts should never have heard. Warsaw, 162 N.E.3d at 15-16. The Federal Circuit’s erroneous approach to abstention invites parties in future cases who (like the parties here) are denied access to an exclusive federal forum to “spend years litigating claims [in state court] only to learn that their efforts and expense were wasted in a court that lacked jurisdiction.” Christianson, 486 U.S. at 818. Last, but far from least, the decision below undermines Congress’ judgment to entrust cases arising under the patent laws to the federal courts (with appeal only to the Federal Circuit), destroying Congress’ design for ensuring uniformity in a complicated regime that involves the intersection of private disputes and public-agency action. Once again, this case provides the perfect example. The Indiana courts here adjudicated countless federal patent-law issues that fell well outside their jurisdiction—from hearing expert testimony and argument on claim construction, to construing Medtronic’s patent claims as a matter of law, to delivering jury instructions on patent coverage, to adjudicating the effect of the PTO’s reexamination and invalidation of relevant claims. See supra pp.7-11. By Congress’ express mandate, cases turning on such federal patent-law issues should be decided exclusively (and consistently) by the federal courts, not through scattershot adjudication in the courts of fifty different states subject to review only in this Court. This novel and illogical expansion of abstention not only invites but encourages state-court disputes that should have never been in state court in the first place. That is precisely the opposite of what Congress enacted in §1338 and §1295.

#### No follow-on---empirics.

Alex Weil 8. Executive director, National Academy for State Health Policy. “How Far Can States Take Health Reform?” *Health Affairs* 27(3): 736-47. Emory Libraries.

While states have accomplished a great deal with their reform efforts targeting access and quality, there is little about state health policy that resembles the conditions of a laboratory. Scientists in laboratories develop hypotheses, conduct experiments, collect and analyze data, and reach conclusions that are then applied to real-world conditions. State health policy development, by contrast, is episodic. Sometimes the spread of ideas is based on political trends that shift much more rapidly than the knowledge base that would support a policy shift. Examples can be found in state-level adoption of managed care regulation, regulation of the small-group insurance market, the wholesale adoption of managed care in Medicaid, and the growing application of cost sharing in public programs. Limited use of experiments. Very few state health policy changes are studied using experimental methods. Despite the fact that Medicaid Section 1115 waivers are for the purpose of “research and demonstration,” these waivers are often granted primarily to enable states to make program changes with a very small research component. Indeed, the Deficit Reduction Act (DRA) of 2006 converted options that once required a waiver into authority to act without a waiver, despite the fact that no experiments have ever been conducted regarding the likely effects of many of the changes the DRA anticipates. For example, no experiments have been conducted on the effects of providing very-low-income people with scaled-back benefit packages; carving out Early and Periodic Screening, Diagnosis, and Treatment (EPSDT) benefits from overall Medicaid coverage for children; or denial of services when enrollees fail to pay a copayment at the point of service. The state of health care experimentation stands in stark contrast to the experience prior to the adoption of national welfare reform in 1996. With much federal funding and guidance, states truly experimented with their welfare programs in the early 1990s. Starting with well-defined hypotheses about the possible effects of various changes in welfare policy—most notably, a shift away from supporting general skill development to requiring work upon enrollment—state policies were subject to random-assignment experiments in multiple locations with extensive data on outcomes collected over a period of years. These experiments led to a change in thinking about what made for effective welfare policies, and that new thinking was embodied in the new federal welfare law.10 There is no comparable story for state health policy. None of this is to minimize the tremendous contribution to our understanding of health policy made by the large volume of high-quality health services research—much of it supported by private foundations. However, researchers are constrained in the methods they can use when the research endeavor is not built into the program design. The continued extensive reliance upon the twenty-five-year-old RAND Health Insurance Experiment (HIE) for evidence regarding the effects of cost sharing is a sign of how infrequently critical health policy topics are subjected to formal evaluation.11 Limited knowledge transfer. The laboratory metaphor also implies the transfer of knowledge learned—either to shape national policy or to shape other states’ choices. Here again, the metaphor is more powerful than the reality. The diffusion of policy innovations is slow and sometimes does not occur at all. Federal health policy certainly learns from and follows state experiences. Medicare Part D, the prescription drug benefit, was enacted only after almost half of the states had developed pharmacy assistance programs.12 But the learning ended there. Two key features of the federal law—the doughnut hole benefit design and the instantaneous enrollment of 6.4 million dually eligible (Medicare and Medicaid) enrollees 1 January 2006—diverge sharply from the lessons states learned implementing their programs. The current impasse over the State Children’s Health Insurance Program (SCHIP) also demonstrates the limitations of federal learning from state experience. SCHIP has been evaluated through a congressionally mandated study and a number of privately funded initiatives.13 By every criterion set forth in the original statute, the program is a success. Yet reauthorization of the program has been held up because of major ideological disagreements regarding the program’s design. Thus, even in the best case, evidence from state experience does not necessarily pave the way for prompt federal action.

## Core PIC

#### 3. Antitrust is key---anything else causes jurisdictional side-stepping.

Matthew G. Sipe 17. J.D., Yale Law School; B.A., University of Virginia. “Patents v. Antitrust: Preempting Conflict” 66 Am. U. L. Rev. 415 (2016-2017). https://heinonline.org/HOL/LandingPage?handle=hein.journals/aulr66&div=15&id=&page=

Exacerbating the problem, this **jurisdictional side-stepping** can also happen in reverse: litigants may avoid the **otherwise controlling** regional circuit by **dressing up their antitrust claims with tacked-on patent claims,** thereby ending up before the Federal Circuit on appeal. Before 1998, this would not have been a problem because "the general jurisprudence of the Federal Circuit had been to apply its own substantive law to patent issues and the appropriate regional circuit law to non-patent issues," including antitrust issues.2'8 But over the past two decades, the Federal Circuit has created its own body of antitrust law that is distinct and separate from the bodies of antitrust law for each of the regional circuits.' This puts district courts in a **considerable bind when antitrust and patent claims overlap**: Should they apply the Federal Circuit's antitrust law or the law of their regional circuit?.so To the extent that different districts- across different types of cases-vary in their answer to that question,"' the overlap between patent and antitrust law will continue to **generate inconsistency and conflict.**

#### 4. Only antitrust solves it.

Harry First 19. Charles L. Denison Professor of Law, New York University School of Law. Fellow, Innovators Network Foundation. “EXCESSIVE DRUG PRICING AS AN ANTITRUST VIOLATION” Antitrust Law Journal. April 2019. <https://www.antitrustinstitute.org/wp-content/uploads/2019/04/First-ALJ-82-2-FINAL.pdf>

Finally, even if excessive pricing could be the subject of a Section 2 case, would antitrust law be a good vehicle for remedying excessive pricing of pharmaceutical drugs? There are some obvious institutional problems in using antitrust to deal with this issue. The case-by-case development of standards is a slow and expensive process, even when augmented by guidelines, and does not always produce clarity. Antitrust enforcement against excessive pricing of pharmaceutical drugs will necessarily be more sporadic and more ex post than a regulatory scheme would be, but **these may count as virtues**. Antitrust is less likely to be **captured by the pharmaceutical industry** and more consistent with **relying on market mechanisms**, indeed as we are trying to do in other, more regulatory schemes. But if antitrust enforcement works, it may allow us to **avoid more intrusive regulatory schemes**, such as more general pharmaceutical price regulation, schemes that may carry **larger risks to innovation** and entrepreneurial freedom. Every proposal advanced in this area has problems, and it is doubtful that any one proposal will be the solution. But the real mystery is why we have taken antitrust law off the table. At their core, the antitrust laws are directed against the harmful conduct of monopolists, and particularly the harmful conduct of monopolists that **leads to high prices**, misallocates resources, and ex- tracts money from consumers and gives it to producers for no other reason than they are in a position to take it. Unless we prefer to do nothing at all, we should **embrace the opportunity to use antitrust law** this way, making it truly a “consumer welfare prescription.”222

#### 7. Only the plan solves the incentive to produce bioequivalents.

Michael A. Carrier and Steve Shadowen 18. Michael A. Carrier; Rutgers Law School. Steve Shadowen; Hilliard & Shadowen LLP. “A Non-Coercive Approach to Product Hopping” Rutgers Law School Research Paper. 11-30-18. https://papers.ssrn.com/sol3/papers.cfm?abstract\_id=3310834

Prescription drug markets are **different**. Consumers are **not knowledgeable buyers** of prescription drugs. State drug-safety laws prevent consumers from buying the drugs without a permission slip—a prescription—from their doctors. But the doctor who chooses which product the consumer will buy does not herself have to pay for it. So the person who chooses does not pay, and the person who pays does not choose.13 No one makes the price/quality decision or trade-off that ensures that manufacturers sell products at competitive prices. In this context, pegging antitrust liability to a manufacturer’s “coercing” a sale is **misguided**. The **absence of the price/quality trade-off** inheres in the very structure of these markets, and the brand manufacturer takes advantage of that market defect by **engineering the product hop.** Perhaps traditional means of “coercion,” where they exist, would also justify subjecting product hops to antitrust scrutiny. But every product hop that occurs in a price-disconnected market, regardless of any traditional “coercion,” **justifies such scrutiny**. A price disconnect plus a product hop, without more, establishes that no one made the price/quality trade-off—the fundamental consumer choice that motivates manufacturers to make only those product redesigns that are likely to increase consumer welfare. Pace and Adam elide the economic reality of the price disconnect by invoking non-empirical generalities. They assert, for example, that every entity in the distribution chain “is price sensitive and works to ensure the lowest price possible for drugs” and that “price competition for formulary placement through rebates to PBMs [pharmacy benefit managers] is fierce.”14 But economic and structural hurdles prevent managed care organizations from defeating product-hopping schemes,15 and the three largest PBMs (which control 85 percent of the market16) have significant bargaining leverage with insurers and pharmacies and are aligned with brands, which, to have their drugs covered on PBM-run formularies, provide large rebates, which drives up price and discourages the use of generics.17 The economic reality is that until generic entry occurs, brand drugs—even those with many close therapeutic substitutes—are sold at gross margins of 70 percent or more.18 When multiple generics enter the market, prices drop by 85 percent on average.19 Federal and state governments have founded their **generic-drug-promotion statutory and regulatory regimes** on the fact that brand-to-brand competition **does not drive prices** to anywhere near c**ompetitive levels.** The price disconnect in these markets **makes product hopping a viable strategy** for brand firms and a serious problem for consumers. The empirical and historical records are clear and cannot be waved away by generalities about the existence of some price competition. The question is whether brand-to- brand competition drives prices to the competitive level, and the answer for almost all markets in this industry is “no.” **Ordinarily**, **antitrust law** has, at most, a limited role to play in policing manufacturers’ unilateral decisions related to product design. But **with no one making the price/quality tradeoff**, brand firms have the **incentive and opportunity** to reformulate products solely to **impair generic competition.** The price disconnect **justifies antitrust scrutiny of product reformulations in the pharmaceutical industry.** Pace and Adam’s apparent denial of the existence or implications of the price disconnect leads them into a muddle on the issue of “coercion.” They cite Berkey Photo, which concluded that courts should take a hands-off approach to product redesigns “so long as the free choice of consumers is pre- served.”20 The court noted that “any form of coercion” would negate this “free choice of consumers,”21 but it did not address whether a price disconnect would negate the requisite consumer choice (which was not a surprise, given that the market for instant-loading cameras and film did not suffer from such a disconnect). The court’s entire analysis of “free consumer choice” is premised on a market in which the **consumer who chooses also pays**. As the court explained, a product that “commends itself to many users because superior in certain respects may be rendered unsatisfactory to others by flaws they considered fatal”; “[m]illions of consumers . . . evidently found the [defendant’s] camera highly attractive”; and “[u]nless consumers desired to use the . . . camera for its own attractive qualities, they were not compelled to purchase [the defendant’s film].”22 In short, the court’s entire analysis assumes a market that functions because consumers who pay for the product vote with their feet. Of course, **none** **of that is true in pharmaceutical markets** where doctors **choose the product but consumers (or their insurers) pay**. Unlike in Berkey Photo, prescription drugs are responsive not to “the demands of customers,”23 but to the demands of doctors who do not pay. Neither Berkey Photo nor any other authority supports importing into the antitrust analysis any “coercion” element that ignores the price dis- connect.

#### 8. The CP leaves innovation directives to regulators---they’re uninformed and can’t keep up with the industry. Applying a clear legal standard is key.

Fiona Scott Morton and Lysle Boller 17. \*\*Fiona M. Scott Morton is the Theodore Nierenberg Professor of Economics at the Yale University School of Management, where she has been on the faculty since 1999. \*\*Lysle Boller is a Statistician at Yale's School of Management, where he works on research related to healthcare policy and competition in pharmaceutical markets. “Enabling competition in pharmaceutical markets” Brookings Institution. 05-02-17. <https://www.brookings.edu/research/enabling-competition-in-pharmaceutical-markets/>

Without a return to **competitive conditions** in this sector, expenditure will continue to grow. We are already hearing calls for regulation of pharmaceutical prices and seeing legislation that proposes price regulation.[1] It is very **difficult to devise regulation that encourages innovation** in a fast-changing industry. Regulators may be **uninformed** about valuable research, be **captured by the industry**, or **lack the resources** to keep up with changes in science or the cost of production.[2] Because **innovation is hugely valuable to consumers**, we are hesitant to recommend government regulation of pharmaceutical prices as a solution to the current problem of high and growing pharmaceutical expenditures. The regulatory system in the U.S. is designed, in principle, to enable vigorous and effective competition that will bring down drug prices, particularly of any drug that faces a competitor or substitute. Over the last 10-15 years, however, industry participants have managed to disable many of these competitive mechanisms and create niches in which drugs can be sold **with little to no competition**. We argue in this paper that the first step toward bringing down pharmaceutical prices would simply be to fully apply the existing rules we already have. For example, speedy and effective entry of generic products, and financial incentives for consumers to choose treatments that have offered significant discounts are both part of the existing regulatory framework and result in lower prices. Both forces, however, have been greatly attenuated or stymied by the actions of pharmaceutical manufacturers. Enforcement of existing regulations that make markets more competitive will reduce pharmaceutical expenditures. The one type of market we will not address in this paper is the case of the patented, valuable medication that has no therapeutic substitutes because it represents a breakthrough in treatment. We refer the reader to the companion piece by Frank and Zeckhauser for a discussion of pricing when a drug faces no competition. We note that industry participants who benefit from the status quo may work **against a return to competitive markets**. If pharmaceutical firms and other market participants block policies that restore competition, then calls for more stringent regulation will re-appear and may well be successful.

## Antitrust PIC

## Enforce Squo CP

#### Congressional legislation is key---otherwise, antitrust laws encourage anticompetitive activity.

Michael Kades 21. Director, Markets and Competition Policy, Washington Center for Equitable Growth. “A Canary in the Coal Mine for the Failure of U.S. Competition Law: Competition Problems in Prescription Drug Market” 07-13-21. Washington Center for Equitable Growth. <https://equitablegrowth.org/a-canary-in-the-coal-mine-for-the-failure-of-u-s-competition-law-competition-problems-in-prescription-drug-market/>

**Anticompetitive activity is prevalent** for two related reasons. First, the **economic dynamics of prescription drug markets** make anticompetitive conduct both **uniquely effective and profitable.** Second, the courts have increasingly stripped the antitrust laws of their potency. As a result, too often, anticompetitive conduct **escapes condemnation**. Rather than deterring anticompetitive conduct, the antitrust laws, as currently interpreted by the courts, **almost invite it.** It would be wrong, however, to think anticompetitive conduct and market power are uniquely a prescription drug market phenomenon. Rather, prescriptions drug markets, where these problems have existed for decades, were the canary in the coal mine. We are seeing similar problems across the economy, including in agricultural markets, digital markets, and labor markets. Although the competitive dynamics and potential anticompetitive conduct differs across industries, one common thread exists. The antitrust laws, **as enforced and interpreted**, do not sufficiently deter anticompetitive conduct. As the letter to the House Judiciary Committee that I signed with 11 other economists and lawyers explains: “current **antitrust doctrines are too limited** to protect competition adequately, making it needlessly difficult to stop anticompetitive conduct in digital markets.”2 The same judgment applies to prescription drug markets and many others. As Equitable Growth’s antitrust transition report explains, “Without **new legislation**, the agencies can still address these issues, but the task will **be more challenging and take far longer**.”3 The courts have made it clear that they believe the antitrust laws have, at most, a limited role in protecting competition because the market can fix itself. And, therefore, do no harm is the prevailing approach. **Unless Congress takes a different view by passing legislation, dominant firms will have little concern about the antitrust laws limiting their conduct.**

#### Perm do the counterplan---the FTC expands antitrust laws.

Michael Gleason et al 7-15-21. Gleason is a member of the American Bar Association's Section of Antitrust Law, serves as a vice chair of the ABA Section of Antitrust Law's Mergers & Acquisitions Committee, and is a partner at Jones Day. Lin Kahn is a partner at Jones Day and served as lead litigation and trial counsel at the FTC. J. Bruce McDonald is a partner at Jones Day, served as deputy assistant attorney general with the United States Department of Justice, served as chair of the State Bar of Texas' Antitrust & Business Litigation Section, as chair of the ABA Antitrust Section's Transportation & Energy Committee, and chair of the Houston Bar Association's Antitrust Section, and as adjunct professor at the University of Houston Law Center. Craig Waldman co-chairs Jones Day's global Antitrust & Competition Law Practice, served as an attorney in the Federal Trade Commission's Mergers I division, served as an adjunct professor at both Berkeley and Hastings Law Schools, has lectured at Stanford Business School, has served in numerous roles within ABA Antitrust Leadership, and has served on the board of directors of Global Strategies. “FTC Signals Aggressive Antitrust Policy as Part of Government Pro-Enforcement Agenda”. JD Supra. https://www.jdsupra.com/legalnews/ftc-signals-aggressive-antitrust-policy-7983021/

The Result: A majority of the Commission, along party lines, voted to expand its interpretation of the agency's power to combat anticompetitive conduct and, at the same time, contract procedural safeguards. Specifically, the FTC voted to rescind a policy that defined limits to challenge "unfair competition" violations under FTC Act Section 5. The FTC also voted to remove certain restrictions on its rulemaking and to empower individual Commissioners to serve subpoenas in certain industries, enabling a single Commissioner, rather than a majority of the Commission, to launch an industrywide investigation. Looking Ahead: The measures can be expected to result in increased FTC activity in the form of more rulemaking, investigations, and enforcement. The changes are consistent with recent proposals by the administration, legislators, and other policymakers to expand the U.S. antitrust laws to target perceived problems with industry concentration and dominant companies. Nevertheless, the goal of increased enforcement may be hindered by the well-established framework for antitrust analysis adopted by federal courts, the agency's current merger guidelines, and career staff.

## Drug Prices CP

#### Fails---must address the root cause of the crisis.

Tahir Amin 18. Co-founder of nonprofit I-MAK.org. “The problem with high drug prices isn't 'foreign freeloading,' it's the patent system” CNBC. 06-25-18. <https://www.cnbc.com/2018/06/25/high-drug-prices-caused-by-us-patent-system.html>

Americans continue to suffer the highest prescription drug costs of anyone in the world. **One in four** are unable to fill prescriptions **due to high prices**, according to a recent poll. And even though drug prices tripled over the last decade, analysts predict they will **double again** in the next ten years. We have a runaway problem on our hands, and while new proposals from Congress and the president seek to improve the drug pricing system, we **will fail to reach lasting solutions** unless we address a **root factor in this national crisis: patents**. Contrary to the Trump administration’s recent claims, the source of our prescription drug problems is not “foreign freeloading” governments creating unfair pricing schemes—it’s the unfair pricing systems **created right here** in the U.S. Today’s **drug patent monopolies are deeper, longer and stronger** than at any point in the last century—and it’s costing Americans and people around the world. Before a prescription drug even enters the market—before pricing negotiations occur between payers, government agencies, insurers, and so on—the U.S. patent office awards exclusivity to drug makers for intellectual property claims that have a huge impact on the market. And unfortunately, while patenting is an important mechanism for incentivizing and rewarding invention, pharmaceutical companies have figured out **how to game the system**—prolonging monopolies, **claiming newness where there often is none**, and taking patients on a ride they can barely afford. In a recent study of every drug on the market between 2005 and 2015, a University of California School of Law professor found a “**startling departure from the classic conceptualization** of intellectual property protection for pharmaceuticals.”

## Public Option CP

#### Public option pushes down compensation for innovation --- no incentive.

Glen Whitman and Raymond Raad, 1/6/2010. \*Associate professor of economics at California State University, Northridge. \*\*M.D., M.P.H., is a resident in psychiatry at New York Presbyterian Hospital / Weill Cornell Medical Center. “The Healing Power Of Innovation,” Forbes. https://www.forbes.com/2010/01/06/health-care-reform-congress-politics-opinions-contributors-whitman-raad.html

As congressional Democrats prepare to revamp America’s health care sector, few have addressed how their plans might affect medical innovation. The United States leads the world in such innovation, generating most of the medical discoveries, drugs, devices and procedures that improve health throughout the world. That’s one feature of American health care we should not throw out with the bath water.

In a new study for the Cato Institute, we compare the U.S. to other nations by their contributions to basic medical sciences, diagnostics, therapeutics, and business models. With the exception of business model innovation (which appears sluggish across nations), the U.S. has contributed more in these areas than any other country–and sometimes more than all other countries combined.

Take basic medical sciences, meaning advances in our understanding of disease and the human body. As measured by Nobel Prizes in medicine and physiology, the U.S. leads the world: 57 U.S.-based prize winners in the last four decades, compared with just 40 from other nations.

How about diagnostics and therapeutics, which help doctors identify and treat disease? Of the top 27 diagnostic and therapeutic innovations over the past four decades, work in the U.S. contributed significantly to 20, including nine of the top 10. By contrast, all European Union countries together with Switzerland had a hand in 14 of those advances, and just five of the top 10.

Important innovations developed solely in the U.S. include drugs like ACE inhibitors for heart failure and high blood pressure, selective serotonin reuptake inhibitors for depression, and treatments for cataracts.

Why does America outpace the rest of the world in medical innovation? It’s not our large population. The combined population of the E.U. and Switzerland exceeds the U.S. population by more than 50%.

Many characteristics of a country can affect innovation, including the patent system, tax code, medical culture, general business climate and quality of universities. But health care policy surely plays a major role. It seems likely that American medical innovation is driven largely by something often regarded as a defect: the fact that we spend so much money.

The NIH spends more than $30 billion annually on research in basic medical sciences, while its counterparts in Europe spend $3 billion to $4 billion annually.

Additionally, centrally organized health care systems, like those in much of Europe, are characterized by strong buyer power that pushes down compensation. As a result, they pay 35% to 55% less for prescription drugs.

Centralized systems also place limits on the use of new drugs, technologies and procedures. As a result, they tend to adopt new technologies later and use them less extensively.

Lower spending might seem like a good thing, until you consider the poor incentive it creates for innovation. Other things equal, people and firms tend to invest more in medical innovation when they expect a higher return, when the returns last longer and when the returns arrive sooner.

As Sidney Taurel, former CEO of the pharmaceutical giant Eli Lilly , once put it: America, “though hardly ‘free’ of government intervention … is the one market where global innovators find the incentive they need to keep pushing the boundaries.” Critics often describe America’s high level of per-capita medical spending as a problem–but when encouraging innovation, it’s a feature.

Unfortunately, the health care bills moving through Congress could curtail medical innovation. Imposing price controls on drugs and treatments–or indirectly forcing their prices down by means of a “public option” or expanded public insurance programs–would reduce the incentive for innovators to develop new treatments.

Proposed reforms could also ~~retard~~ slow business model innovation–an area where innovation is weak. Congress has already used its control of Medicare to limit the growth of specialty hospitals. A nationally mandated insurance package would severely curtail innovation in payment methods and insurance products, which have the potential to improve the coordination and delivery of health care services.

The health care debate should address more than just covering the uninsured and controlling costs. When the U.S. generates medical innovations, the whole world benefits. That is a virtue of the American system that is not reflected in comparative life expectancy and mortality statistics.

#### Focusing on price alone fails---wholesale law change is key.

Dhruv Khullar and Peter B. Bach 20. MD “3 Actions Congress Can Take to Reduce Drug Prices” Harvard Business Review. 02-21-20. <https://hbr.org/2020/02/3-actions-congress-can-take-to-reduce-drug-prices>

Some pharmaceutical companies use a technique known as “evergreening” or “product hopping” to **extend monopoly prices** and **prevent the use of generic drugs**. A company product hops when shortly before the expiration of monopoly protection, it introduces minor changes to a branded drug — tablet to film administration, for example, or twice-daily to once-a-day dosing — and removes the original product from the market, thereby delaying generic drug approvals and substitutions. The Federal Trade Commission could more **aggressively enforce antitrust laws** against such tactics, and the FDA should not grant cosmetically different products market exclusivity immediately before branded products are set to lose monopoly protection. In some drug classes like biologic drugs, where competitors are simply hard to make, lawmakers may ultimately have to regulate prices if they can’t make the market work. Today, the United States has a system that has **allowed the prices for drugs to skyrocket**, often outstripping the value they offer patients. But by reforming the whole system and **not just focusing on prices alone, lawmakers can bring down the cost of drugs and stimulate the development of new therapies.**

#### Doesn’t solves advantage 2.

Adam Gaffney, 7/19/2017. Physician whose work has appeared in Salon, Dissent, and In These Times. He blogs at theprogressivephysician.org. “The Case Against the Public Option,” Jacobin. <https://jacobinmag.com/2017/07/trumpcare-obamacare-repeal-public-option-single-payer>

as a solution to such troubles. “It’s enough to make a frazzled health care consumer in one of those feeble markets wish there were another option — perhaps even (dare one say it?) a public option,” he wrote.

But here again lies one of the public’s option’s cardinal flaws: whatever it does for those buying insurance on the Obamacare marketplaces (which I’ll return to in a minute), it does basically nothing for the large majority of the nation not insured through them. The so-called “Obamacare” plans cover some 12.2 million enrollees — a substantial number of people to be sure, but still a very small fraction of the population.

What would a public option do, for example, for the 28.6 million US residents who are uninsured? According to the Congressional Budget Office’s (CBO) 2013 scoring of a public option added to the ACA marketplaces, the answer is nothing: the public option, the CBO estimated, “would have minimal effects . . . on the number of people who would be uninsured.”

The goal of single-payer is to reduce that 28.6 million figure to zero; under the public option — at least according to this admittedly old CBO score of one particular variation of the public option — the number wouldn’t so much as budge. Perhaps a more ambitious public option could do a bit better. Nonetheless, it’s not clear that even a more robust plan would be a step toward universal coverage.

And how about for the underinsured? The roughly half of the nation currently covered through their employer saw a 2016 deductible that was 300 percent higher than a decade ago. Such cost-shifting of health care costs to workers is a major cause of financial suffering, as well as deferred medical care. Yet the public option would do nothing for the great majority of these families.

A longstanding aim of universal health care advocates — stretching back to the German Social Democrats’ 1891 Erfurt Program, which called for “[f]ree medical care, including midwifery and medicines” — has been to eliminate out-of-pocket payments (for example, copayments and deductibles) at the time of health care use. In Canada and the United Kingdom, this goal has largely been achieved: most health care remains free when patients use it. The public option, however, would do little to nothing to bring us closer to this goal.

Nor would the public option ameliorate existing deficiencies in the two big public insurance programs, Medicare and Medicaid. Medicare, like private insurance, often imposes high out-of-pocket payments on enrollees, and it excludes coverage for important health services like dentistry and long-term care. The partial privatization of the program (via Medicare Advantage plans, which are managed by private insurance companies) has yielded little but colossal waste over the years.” And while Medicaid has broader benefits and usually minimal out-of-pocket payments, as a result of its lower reimbursements, it sometimes provides inferior access to providers (a vestige of its heritage as a “poor person’s program).

The public option wouldn’t address the inadequacies of either public program.

Finally, in terms of global costs, the public option’s effect would again be quite minor, as single-payer advocates have long noted. Eliminating both uninsurance and underinsurance would cost money, and reduced administrative spending ($503 billion dollars a year, according to one estimate) and reduced drug costs ($113.2 billion a year) are typically cited as key sources of savings. But although a Medicare-like public option may have lower administrative costs, only a small fraction of the efficiency savings of single-payer would be achieved if the multi-payer framework persisted (and drug prices wouldn’t be controlled on a system-wide level).

Or as Physician for a National Health Program’s Don McCanne puts it, the “public option would be only one more player in our wasteful, administratively-complex, fragmented system of financing care.” The upshot? It wouldn’t generate anywhere near the savings needed to fund a truly universal expansion of health care.

Would there be benefits? Probably for some. According to the 2013 CBO estimates, if the public option brought provider reimbursements more in line with those paid by Medicare, its enrollees — which it estimates would account for about 35 percent of those insured through the ACA marketplaces — would enjoy approximately 7 to 8 percent lower premiums. (A 2009 CBO score that did not make this assumption, it should be noted, found that premiums might actually be somewhat higher.) Assuming — as the CBO did in 2013 — that about 2 million more individuals would be insured through the marketplaces, this would yield a relatively small reduction in premiums for perhaps some 5 million Americans.

Others in the marketplace could conceivably see a drop in premiums as private plans were forced to compete with the public option. However, given that insurers are currently exiting the marketplace due to what they view as insufficient profitability (even as they raise premiums), it’s hard to see how this would happen.

Of course, if the public option winded up taking on people who are “less healthy — and therefore more costly,” as the CBO assumes, the reform might succeed in “stabilizing” the marketplaces by functioning as a “high risk pool.” In other words, it would essentially subsidize the private insurance industry by socializing the larger health risks (and perhaps increase its profits).

Yet this would also lock into place all the dysfunctions of the health care status quo, perhaps lowering private insurance plan premiums for some but potentially driving up the cost of the public option. More generally, uninsurance would persist while underinsurance could continue to rise.

## FDA CP

## Con Con

#### 7---Counterplan causes a runaway convention---collapses democracy

Riestenberg 18 Jay Riestenberg, Deputy Communications Director @ Common Cause U.S. Constitution Threatened as Article V Convention Movement Nears Success https://www.commoncause.org/resource/u-s-constitution-threatened-as-article-v-convention-movement-nears-success/

A well-funded, highly coordinated national effort is underway to call a constitutional convention, under Article V of the U.S. Constitution, for the first time in history. The result of such a convention could be a complete overhaul of the Constitution and supporters of the convention are dangerously close to succeeding. With special interest groups gaining more momentum, conservative advocates are just six states short of reaching the constitutionally-required 34-state goal. They are targeting Republican-controlled legislatures in 2018 and are within striking distance. The unknowns surrounding a constitutional convention pose an unacceptable risk, particularly in the current polarized political climate. Given how close calling a new convention is, it’s time to spotlight that risk and sound an alarm for the preservation of our Constitution. Too few Americans are even aware that a constitutional convention can be called, let alone that there would be no checks on its scope and further that the process to call one is well underway and being underwritten by some of the nation’s richest individuals. Calls for a convention are coming from right and left, with more money, a stronger campaign structure, and national coordination on the right. A number of major conservative organizations and donors, including Mercer family and Koch-funded groups such as the American Legislative Exchange Council (ALEC), have renewed and intensified efforts to thrust this issue into the spotlight after years of inactivity. This memo that outlines the different campaigns calling for an Article V convention and why it is just a dangerous idea. These calls for a constitutional convention represent the most serious threat to our democracy flying almost completely under the radar.

## Court Politics DA

#### Antitrust enforcement against the pharmaceutical industry thumps.

Harry First 19. Charles L. Denison Professor of Law, New York University School of Law. Fellow, Innovators Network Foundation. “EXCESSIVE DRUG PRICING AS AN ANTITRUST VIOLATION” Antitrust Law Journal. April 2019. <https://www.antitrustinstitute.org/wp-content/uploads/2019/04/First-ALJ-82-2-FINAL.pdf>

One might think that antitrust would be on the list of public policy tools to wield against high pharmaceutical prices, but it’s not.12 Of course, there have been **antitrust enforcement efforts against various pharmaceutical practices that elevate price** above the competitive level. For almost 20 years the FTC has been challenging reverse payments (or pay-for-delay) made by branded pharmaceutical companies to generics in return for their promise to stay out of the market for some period of time, an enforcement effort that is ongoing.13 Product hopping has been **successfully attacked** by the New York State Attorney General.14 An investigation into collusion among generic drug manufacturers, underway at the Department of Justice, has resulted in **criminal charges against two executives**,15 along with a threat of a treble-damages action by the Justice Department to recover damages that the United States has sustained in overpaying for generic drugs.16 Forty-seven state attorneys general have filed a civil suit alleging damages to their governments and citizens arising out of generic company collusion.17

#### Senate antitrust bill thumps.

Benjamin Din, 8-12-2021, "Senators set stage for antitrust fight," POLITICO, https://www.politico.com/newsletters/morning-tech/2021/08/12/senators-set-stage-for-antitrust-fight-797122

SENATE SHARPENS ITS ANTITRUST FOCUS — The Senate is moving on its antitrust response, following the House Judiciary Committee’s approval of its own antitrust package. But senators are taking a more targeted approach that could make their bill easier to actually get to Biden’s desk.

Sen. Richard Blumenthal (D-Conn.) on Wednesday introduced the Open App Markets Act, as Leah reported for Pros. The new bill would target Apple and Google's "gatekeeper power" over the smartphone market, forcing the tech giants to allow developers to use alternative app stores and to tell consumers about where they can purchase software for a cheaper price online. Sens. Marsha Blackburn (R-Tenn.) and Klobuchar, who chairs the Senate Judiciary antitrust subcommittee, are cosponsors of the legislation.

— Not quite a companion bill: The Senate bill does have some overlap with a House bill introduced by Rep. David Cicilline (D-R.I.), who chairs the House Judiciary antitrust panel. However, Cicilline’s legislation is broader, applying to everything from app stores to advertising to logistics, and would ban companies from prioritizing their own products over their competitors’.

Companion legislation from the House is currently in the works. Senators are still working on companions for the House’s proposals, but those bills aren’t expected until later in the fall.

## FTC Tradeoff DA

#### The FTC is prioritizing resources to target pharmaceutical companies now.

FTC 21. “FTC Authorizes Investigations into Key Enforcement Priorities” Federal Trade Commission. 07-01-21. https://www.ftc.gov/news-events/press-releases/2021/07/ftc-authorizes-investigations-key-enforcement-priorities

The Federal Trade Commission voted to approve a series of resolutions **authorizing investigations into key law enforcement priorities** for the next decade. Specifically, the resolutions direct agency staff to use “compulsory process,” such as subpoenas, to investigate seven specific enforcement priorities. **Priority targets include** repeat offenders; technology companies and digital platforms; and healthcare businesses such as **pharmaceutical companies**, pharmacy benefits managers, and hospitals. The agency is also prioritizing investigations into harms against workers and small businesses, along with harms related to the COVID-19 pandemic. Finally, at a time when merger filings are surging, the agency is ramping up enforcement against illegal mergers, both proposed and consummated. In remarks delivered during the open meeting, Chair Lina M. Khan noted that the resolutions approved today represent an important step in rethinking the work of the FTC. Instituting new cross-agency, investigatory resolutions will promote a more holistic use of the FTC’s enforcement authorities to stop bad actors across markets. “The reforms are designed to ensure that our **staff can comprehensively investigate** unlawful business practices across the economy,” said Chair Khan. “They will help relieve unnecessary burdens on staff and cut back delays and ‘red tape’ bureaucracy when it comes to advancing our Commission’s law enforcement priorities. This is particularly important given that we are in the midst of a massive merger boom.”

#### The FTC is already overwhelmed with antitrust cases.

PYMNTS 7/28/21. “FTC Sees Most Merger Filings In 2 Decades, Chair Says.” https://www.pymnts.com/antitrust/2021/ftc-sees-most-merger-filings-2-decades/

The Federal Trade Commission (FTC) is dealing with a rise in mergers that has amounted to the highest number of filings in 20 years, Bloomberg reported.

“Although the FTC is working to review many of these deals, the sheer volume of transactions is significantly straining commission resources,” FTC Chair Lina Khan said, per Bloomberg. “I am deeply concerned that the current merger boom will further exacerbate deep asymmetries of power across our economy, further enabling abuses.”

Companies have thus far announced $2.8 trillion in deals in the first seven months of this year, Bloomberg reported, which amounts to 2021 likely being the most active ever.

The reason for the influx is the high level of corporate confidence and the free spending of private equity firms, which has been happening over several industries, including technology, media, healthcare, transportation and others, according to Bloomberg.

Over the first three quarters of the current fiscal year, antitrust agencies have processed more than 2,400 merger filings Khan said, per Bloomberg.

But she said the wave of mergers hasn’t been the only issue. There are two other big problems facing the FTC, including a recent Supreme Court decision making it harder to recover money for victims of scams or deceptive practices, and the general boost in fraud during the pandemic, which has been made even worse by digital platforms, Bloomberg reported.

Khan, nominated by President Joe Biden for her role at the FTC, was officially approved June 15 in a 69-28 Senate vote.

“The overwhelming support in the Senate for Lina Khan’s nomination to serve on the Federal Trade Commission is a big win for fair competition in our country,” FTC Commissioner Rohit Chopra said in a statement at the time. “There is a growing consensus that the FTC must turn the page on the failed policies spanning multiple administrations.”

Khan has been known for being a critic of the tech industry and has worked on anti-competition issues before. She wrote a paper when she was a student that looked into how antitrust legislation didn’t negatively affect Amazon.

#### Zero link uniqueness---aggressive antitrust enforcement is back.

E. Steele Clayton, IV, 8/10/21 – Bass, Berry & Sims PLC, “Be Prepared: Aggressive Antitrust Enforcement Is Back.” https://www.jdsupra.com/legalnews/be-prepared-aggressive-antitrust-8939761/

This summer has seen a flurry of bold antitrust announcements from the Biden administration. By issuing a sweeping executive order calling for numerous changes to antitrust enforcement and by naming progressive favorites and prominent Big Tech critics to head the Federal Trade Commission (FTC) and the Antitrust Division of the U.S. Department of Justice (DOJ), President Biden has signaled that federal antitrust policy is entering a new era.

The FTC has already begun carrying out its mandate to reshape antitrust policy. Under the leadership of new Chairwoman Lina Khan, the FTC has moved quickly to eliminate checks on its antitrust enforcement powers. A majority of the FTC’s commissioners have expressly disavowed the agency’s longstanding approaches to policing antitrust violations and have given the new chair unprecedented authority over investigations and rulemakings.

Collectively, the Biden administration and the FTC have sent a clear message to the business community: aggressive antitrust enforcement is back. Companies should expect to see an increase in antitrust investigations, stiffer penalties for violations, more burdensome merger reviews, and new rules targeting a range of industry practices. In this environment, effective antitrust counseling and compliance programs are more important than ever.

#### FTC COVID response ineffective now---lacks authority.

FTC 21. Media Contact Juliana Gruenwald Henderson, 4/20/21. “FTC Testifies Before Congress on its Work to Protect Consumers from COVID-19 Scams, and Threats to its Ability to Return Money to Victims of Illegal Conduct.” https://www.ftc.gov/news-events/press-releases/2021/04/ftc-testifies-congress-its-work-protect-consumers-covid-19-scams

In testimony before the Senate Commerce Committee, the Federal Trade Commission updated lawmakers on its efforts to combat scams and address other consumer issues related to the COVID-19 pandemic, while urging lawmakers to ensure the agency has the authority it needs to prohibit illegal conduct and return money to consumers who have been victims of illegal conduct.

Testifying on behalf of the Commission, Acting FTC Chairwoman Rebecca Kelly Slaughter along with Commissioners Noah Joshua Phillips, Rohit Chopra, and Christine S. Wilson detailed the FTC’s work to protect consumers through law enforcement actions and consumer and business education aimed at dispelling misinformation and warning about the latest COVID-19-related scams. The testimony noted that the FTC has brought law enforcement actions against those who have allegedly broken promises to quickly ship personal protective equipment and cleaning products, tricked consumers into paying for sanitizing products that were never delivered, falsely claimed that their products could treat and/or prevent COVID-19, and made deceptive claims regarding stimulus benefits. Most recently, the FTC deployed its new authority under the COVID-19 Consumer Protection Act to charge that a chiropractor and his company deceptively marketed products containing vitamin D and zinc as scientifically proven to treat or prevent COVID-19.

The testimony also noted that the FTC has issued hundreds of warning letters, many with other federal agencies, to sellers or marketers of products that claim to treat or prevent COVID-19; to those making misleading claims about pandemic relief loans; and to Voice over Internet Protocol service providers and others related to illegal telemarketing calls. The overwhelming majority of those who have received warning letters removed problematic claims, but the FTC reiterated its promise to take swift enforcement action against those recipients who fail to comply, according to the testimony.

In response to the eviction crisis, the testimony also detailed the FTC’s work with the Consumer Financial Protection Bureau to ensure renters are not subjected to unlawful practices. In addition, the FTC will continue its work to ensure that background screening companies comply with the Fair Credit Reporting Act and do not engage in actions that could unfairly deny housing to potential renters.

Many of the FTC’s efforts to help consumers during the pandemic are detailed in a new report released Monday describing the major challenges consumers face and the Commission’s efforts to help. These efforts include using reports from consumers to identify and respond to emerging unlawful practices in real time; filing more than a dozen law enforcement cases and directing the removal of deceptive claims related to COVID-19 made by more than 350 companies; and educating consumers and businesses through a multi-media campaign, including more than 100 alerts on COVID-related topics.

In its testimony, the Commission also reiterated its call for Congress to pass legislation reaffirming that the agency has authority to prohibit unlawful conduct and seek monetary relief for consumers who have lost money from illegal conduct. The FTC’s 13(b) authority to secure relief for consumers, including those harmed by scammers seeking to exploit the pandemic, has been put at risk by recent federal court rulings. While the issue is currently pending before the U.S. Supreme Court, the testimony noted that the uncertainty created by the recent court rulings has affected some pending enforcement cases. The FTC has used its authority under Section 13(b) of the FTC Act to return billions of dollars to consumers targeted by a wide variety of scams and anticompetitive practices.

#### Authorities already juggle competing goals.

Michelle Meagher 21. A competition lawyer and Senior Policy Fellow at the University College London Centre for Law, Economics and Society. This paper has been prepared for the ABA Spring Meeting 2021 session on the consumer welfare standard. “Adaptive Antitrust.” 03-24-21. https://papers.ssrn.com/sol3/papers.cfm?abstract\_id=3816662

(7) How will authorities juggle competing goals? – The application of an “excessive power” legal standard is not a question purely of “juggling” or “balancing”. Instead, authorities must **synthesise the evidence from a range of sources, as they already do.** And courts will be required to do the same, **as they already must.**

# 1AR

## FDA CP

#### AT BEST massive delay---courts will struggle to apply the FDA.

Bret Dickey et al 19. Bret Dickey and Kun Huang are economists with Compass Lexecon. Daniel L. Rubinfeld is Robert L. Bridges Professor of Law and Professor of Economics Emeritus, University of California, Berkeley, and Professor of Law, New York University. “Pharmaceutical Product Hopping: Is There a Role for Antitrust Scrutiny?” *Antitrust Law Journal.* 01-01-19.

Given the apparent failure of market participants to adequately combat product-hopping strategies and the **difficulty of designing an effective regulatory solution**, we view careful intervention by the courts as a potentially viable approach to **scrutinizing product hopping** issues.45 The potentially anticompetitive exclusion of generic competition through product hopping tactics is the **type of conduct antitrust law addresses**. Moreover, the existence of complex regulations in the pharmaceutical industry **does not** by itself **prevent an application of antitrust analysis** to this industry. Rather, it means that **antitrust analysis** **needs to be tailored** to account for the regulatory environment of the pharmaceutical industry (and that the inferences drawn from that analysis should not necessarily be applied to other industries). l. What Is the Appropriate Antitrust Standard? If an antitrust approach is to be used, how do we determine the appropriate standard? To begin, because product hopping based on trivial innovations can adversely affect generic competition and deprive consumers of large savings, per se legality for pharmaceutical innovation is not an appropriate standard for product hopping. If a per se standard is not appropriate, it follows that competition authorities and the courts will likely need to undertake a difficult evaluation of product hopping under a rule of reason standard.46 Identifying potentially anticompetitive product hops will, of course, raise challenging questions. **But so too** do many of the intellectual property-antitrust issues that the **competition agencies and the courts have faced.**47 Operating within the **confines of antitrust law would offer additional advantages.** The courts would be evaluating cases in light of **existing competition case law**, not regulatory case law, a task that several courts have **already undertaken**.48 In that context, it will be natural for the courts to decide whether a pure balancing test is appropriate or, as we discuss below, a clearer standard should be applied. In fact, courts have done it: the TriCor court embraced a rule of reason analysis,49 and the Namenda court raised the question whether the defendant's switch "makes economic sense in the absence of the benefit derived from eliminating generic competition."50

#### Antitrust intervention is key.

Tyler J. Klein 16. Lawyer. “Antitrust Enforcement Against Pharmaceutical Product Hopping: Protecting Consumers or Reaching Too Far?” Saint Louis University Journal of Health Law & Policy. Volume 10; Issue 1; Article 12. 2016. https://scholarship.law.slu.edu/cgi/viewcontent.cgi?article=1058&context=jhlp

Without question, the pharmaceutical market has a regulatory scheme and structure that is unlike any other, making it a difficult and expensive place to do business. But much to the chagrin of brand-name pharmaceutical companies competing with generics in this market, society cannot afford to allow them carte blanche in their marketing strategies. The ultimate goal of the Sherman Act is to **foster competition**.138 When a brand-name drug enters the market, it faces weak, and in some cases, virtually non-existent competition from other drugs.139 Therefore, **generics provide a source of competition** by offering a product that is extremely close to the brand-name drug but at only a fraction of the price.140 Without generic competition, brand-name pharmaceutical companies would **have the power to control market prices**—the exact definition of a monopoly.141 As such, in order to keep competition alive in the pharmaceutical market, **antitrust regulation is not only warranted, but it is also a necessity.** While **fostering competition on its face is a sufficient enough reason to warrant antitrust regulation**, the underlying reason of access further bolsters the argument. In the absence of competition, brand-name companies would **control the price of pharmaceutical drugs**. In a country where people depend on drugs for everything from pain management to treating chronic illnesses,142 **this reality could be truly disastrous.** Without affordably priced prescriptions, the **seventy percent** of U.S. citizens that take prescription drugs on a daily basis143 could face extreme financial hardship. To illustrate, take the Actavis IR case. Based on data provided to the court by Actavis, consumers would have to “pay almost $300 million more, and third-party payers would pay almost $1.4 billion more,” if Actavis were permitted to remove IR prior to generic entry.144 Additionally, the Department of Health and Human Services found that the withdrawal of IR before generic entry would cost Medicare a minimum of six billion dollars over ten years.145 While these numbers are large, they only represent one drug. If **courts do not enforce antitrust violations** against product- hopping companies, product hopping could become **more prevalent**, and these numbers could **increase by a large multiplier.** With drug-related spending already accounting for twelve percent of total personal health care expenditures,146 it is questionable whether **both the system and consumers could sustain** these potentially huge increases in price.

#### Absent antitrust, pharma companies will exploit the market.

Michael A. Carrier & Steve D. Shadowen 16. \*\*Michael A. Carrier; Distinguished Professor, Rutgers Law School. \*\*Steve D. Shadowen; Founding partner of Hilliard & Shadowen LLP. “Product Hopping: A New Framework” 2016. <https://poseidon01.ssrn.com/delivery.php?ID=774106069097102102029024030081011065099038066037028071088064097088127003089023118076007011027056020006042084024002100100113082048008059012061106007082016066027073073062037091110073003022005002117025115006089073105125026005090073006103074002087007103&EXT=pdf&INDEX=TRUE>

There is a **general misperception** that the high prices of prescription drugs in the United States are the natural (and earned) result of patents. The government grants a patent on an innovative product, so the argument goes, and high prices and profits are the inventor’s just reward for developing that product. **Antitrust scrutiny of prescription drug product hops is needed**, however, because high prices and profits might be the result not of valued innovations, but of the **exploitation of market failures**. The granting of a patent by the U.S. Patent and Trademark Office (PTO) certainly does not guarantee, or even suggest, that the reformulated product is superior in any way to existing products. The PTO requires only that the product be “novel[]”63 and “non- obvious,”64 not that it be an improvement. The Federal Circuit has explained that “[f]inding that an invention is an ‘improvement’ is not a pre- requisite to patentability,” as “[i]t is possible for an invention to be less effective than existing devices but nevertheless meet the statutory criteria for patentability.”65 Under this standard, the PTO routinely grants patents on minor differences in existing chemical entities, such as different crystalline forms of a chemical, or different formulations that do not necessarily improve the product in any meaningful way.66 Likewise, before approving a new product for marketing, the FDA requires that the product be superior only to a placebo, not to existing products.67 In competitive markets, patents do not always, or even usually, create the ability to charge supracompetitive prices.68 Patent law simply prevents others from using or making the exact same (or very similar) invention. Competitors can offer consumers similar products that perform the same function in an analogous way, and this competition is typically sufficient to keep market prices at or near the competitive level. This **competition point is crucial**. Society grants patents to inventors as an inducement for them to innovate and bring valuable new products to the market. But in an **otherwise competitive market**, a patent will allow the manufacturer to price the product **above the competitive level** only if and to the extent that the patented technology reflects a real, valuable innovation for which knowledgeable, price-sensitive consumers are willing to pay a premium.69

## FTC DA

#### 2. Lacks the requisite resources now.

Olive Morris 7/12/21. Policy analyst with The New Center. “Lina Khan Has Big Plans For Big Tech — But She Might Not Have the Tools.” https://www.realclearpolicy.com/articles/2021/07/12/lina\_khan\_has\_big\_plans\_for\_big\_tech\_\_but\_she\_might\_not\_have\_the\_tools\_785004.html

But the FTC may not be equipped for that fight. Cases taken up by the FTC cost the agency enormously in fees paid to outside consultants and economists, who can charge as much as $1,350 an hour. At the same time, corporate merger filing fees, which traditionally serve as a major cash flow for the agency, have fallen during the pandemic.

According to emails obtained by POLITICO, the lack of funding is also taking its toll on FTC staffing and resources. “[W]e will either need to bring fewer expert intensive cases or significantly decrease our litigation costs (e.g. experts, transcripts, litigation support contractors, etc.),” Executive Director David Robbins said in an October 29, 2020 email.

Robbins said in later emails that the agency would be freezing all hiring, promotions, and end-of-the-year bonuses indefinitely. The FTC may see more funding in 2021 if Congress passes bills like the U.S. Innovation and Competition Act, which would allow the agency to increase their merger filing fees. However, it’s still unclear how much these fees would be raised and when the new payment schedule could be applied.

#### 3. Mergers now.

Keith A. Reynolds 8/6/21 – writer for Medical Economics. “FTC overwhelmed with merger filings.” https://www.medicaleconomics.com/view/ftc-overwhelmed-with-merger-filings

FTC overwhelmed with merger filings

The glut of merger filings has led the Federal Trade Commission (FTC) to begin warning companies who seek to merge before their investigations are completed.

According to a news release, for mergers the FTC can’t fully investigate during the requested time frame the agency will send out a form letter warning the companies that the investigation is still ongoing and that the deal may still be ruled to be unlawful.

The agency notes that the issuance of such a letter should not be construed to mean that the deal is unlawful, and the failure to receive this letter should not be taken as an indication that the deal is lawful, according to the release.

According to the FTC website, the agency received 2,067 merger filings between January and July 2021. This is a huge increase from 2020 which saw 815 filings in the same period.

#### 4. if they can handle mergers, they can handle the plan. Emory = Yellow.

**FTC 21**. “FTC Authorizes Investigations into Key Enforcement Priorities” Federal Trade Commission. 07-01-21. https://www.ftc.gov/news-events/press-releases/2021/07/ftc-authorizes-investigations-key-enforcement-priorities

The Federal Trade Commission voted to approve a series of resolutions **authorizing investigations into key law enforcement priorities** for the next decade. Specifically, the resolutions direct agency staff to use “compulsory process,” such as subpoenas, to investigate seven specific enforcement priorities. **Priority targets include** repeat offenders; technology companies and digital platforms; and healthcare businesses such as **pharmaceutical companies**, pharmacy benefits managers, and hospitals. The agency is also prioritizing investigations into harms against workers and small businesses, along with harms related to the COVID-19 pandemic. Finally, at a time when merger filings are surging, the agency is ramping up enforcement against illegal mergers, both proposed and consummated. In remarks delivered during the open meeting, Chair Lina M. Khan noted that the resolutions approved today represent an important step in rethinking the work of the FTC. Instituting new cross-agency, investigatory resolutions will promote a more holistic use of the FTC’s enforcement authorities to stop bad actors across markets. “The reforms are designed to ensure that our **staff can comprehensively investigate** unlawful business practices across the economy,” said Chair Khan. “They will help relieve unnecessary burdens on staff and cut back delays and ‘red tape’ bureaucracy when it comes to advancing our Commission’s law enforcement priorities. This is particularly important given that we are in the midst of a massive merger boom.”

#### 2. FTC using antitrust to crack down on oil and gas.

Jeff Stein 8/30/21. White House economics reporter for The Washington Post. “Biden administration ramps up antitrust efforts amid worries about high prices.” https://www.washingtonpost.com/us-policy/2021/08/30/white-house-oil-gas-ftc/?outputType=amp

In response to requests by the White House economic team, Federal Trade Commission Chair Lina Khan announced Monday that regulators would step up enforcement on oil and gas companies that they say may be colluding to raise fuel costs.

White House National Economic Council Director Brian Deese is leading a review of what might be done to alleviate soaring food prices, working with the Agriculture Department on measures to prevent large agricultural processors and meatpackers from squeezing consumers and farmers.

President Biden has also ordered U.S. transportation agencies to root out anti-competitive behavior in the shipping industry, optimistic that new entrants into the sector will reduce the meteoric delivery costs hurting many small businesses.

The push to use federal competition laws to lower prices reflects not only Biden’s long-standing commitment to antitrust policy, but also the growing political and economic danger the administration sees in sustained high prices. Senior administration officials have been worried about polling showing that voters — including many Democrats — blame Biden’s economic policies for high inflation as the economy bounces back from the coronavirus pandemic.

Publicly and privately, administration officials say they are convinced that inflationary pressures represent a primarily short-term problem that will subside with time. But even if temporary, the current price hikes have no obvious immediate solution — given that supply chain bottlenecks could take years to unwind — and have created consternation among some centrist Democrats about the administration’s multitrillion-dollar spending agenda.

Aggressive antitrust enforcement represents one avenue where the administration can act without congressional approval while demonstrating it is trying to head off the issue.

In a speech earlier this month, Biden cited his push to have the FTC “address any illegal conduct that might be contributing to price increases at the pump.” He added that his executive order from July “opens up competition in the agricultural business, gives more farmers a chance to compete — which will give Americans more food choices at lower cost.” The president has been adamant about antitrust policy since before the presidential campaign, but the issue has taken on new urgency given the price increases.

#### Takes out the DA.

Evan Miller 9/7/21. Senior Associate at Vinson & Elkins “FTC Letter Signals Increased Scrutiny of Oil & Gas M&A Activity.” https://www.jdsupra.com/legalnews/ftc-letter-signals-increased-scrutiny-2957307/

In a recent exchange of letters with the White House, the chair of the Federal Trade Commission (“FTC”) signaled her intent to ramp up antitrust enforcement in the oil and gas industry. The move comes as part of a broader shift in priorities at the FTC in evaluating mergers and is in line with the Biden administration’s recent efforts to increase antitrust enforcement across industries (about which V&E has previously written). While calls for FTC action to combat high gas prices are fairly common from new administrations and Congress, the agency’s recent response includes specific action items that suggest deviations from past policy. These changes could have significant effects on the regulatory environment for energy companies, especially for the retail fuels sector. Indeed, practitioners who regularly represent oil and gas companies before the FTC have noted that they are already receiving inquiries in line with the chair’s letter.

## Politics DA

#### Biomedical innovation does solve---our internal link is bigger.

Michael Chui 20. Partner at the McKinsey Global Institute (MGI), McKinsey's business and economics research arm. James Irvine Foundation and the Asia Society of Northern California, and a member of the Council on Foreign Relations. “The Bio Revolution Innovations transforming economies, societies, and our lives.” <https://www.mckinsey.com/~/media/McKinsey/Industries/Pharmaceuticals%20and%20Medical%20Products/Our%20Insights/The%20Bio%20Revolution%20Innovations%20transforming%20economies%20societies%20and%20our%20lives/MGI-Bio-Revolution-Report-May-2020.ashx>.

Sustainable development, environment. Climate change is one area where biology could play an important role. By 2040 to 2050, the direct applications we sized could reduce annual average man-made GHG emissions by 7 to 9 percent from 2018 levels, or up to eight times the total CO2 emissions from the global airline industry in 2018.161 This would come from a variety of applications such as a shift toward new bioroutes for production and alternative proteins. The knock-on effects include alleviating pressure on cropland and reducing deforestation. Adopting bio innovations, such as using more sustainable inputs rather than plastics, could address other environmental challenges such as waste. At the same time, there is also potential for some of these applications to have unintended consequences on species or ecosystems, given the interconnected nature of biological systems (see chapter 6.5 for other biological applications focused on sustainability).

#### 8 bills thump---antitrust to address drug prices has already been debated.

Diane Bartz 21. Reporter. “U.S. lawmakers introduce eight antitrust bills aimed at drug prices” Reuters. 04-29-21. https://www.reuters.com/world/us/us-lawmakers-introduce-eight-antitrust-bills-aimed-drug-prices-2021-04-29/

ASHINGTON, April 29 (Reuters) - U.S. lawmakers from both parties and both houses of Congress have introduced eight antitrust bills aimed at tackling the problem of high and rising drug prices, including bills to stop brand name drug companies from paying generic firms to stay off the market. In an unusual hearing of the House Judiciary Committee's antitrust panel on Thursday, lawmakers from both parties and from both the Senate and the House said that they had introduced bills aimed at stopping practices that pharmaceutical companies use to fend off generic competition, which studies show tend to push down prices. "Millions of Americans started their day with a dose of prescription medication. Unfortunately, for many patients, those drugs aren't affordable. Prescriptions are left at the pharmacy counter. Doses are skipped or rationed until the next paycheck. That's unacceptable," said Senator Chuck Grassley, a Republican, at the House hearing. Two of the bills, one in the House and another in the Senate, is aimed at stopping product-hopping, or making a minor change to a medication to win a new patent. Others would seek to ban pay-for-delay patent settlements, where brand name drug companies pay generics to delay entering the market. Another enables the Federal Trade Commission to ban sham citizen petitions, where drug companies petition the Food and Drug Administration about a generic company seeking approval for a rival drug with the goal of delaying its approval. And a last pair are aimed at making it easier to bring biosimilars, essentially generic versions of biologic drugs, to market. These medicines are more complicated than chemical medicines because they include living organisms. Each of the bills has a Republican lawmaker and a Democrat as a sponsor of both the House and Senate versions. To become law, bills must pass the House and Senate and be signed by the president.

#### 3. Product hopping legislation passed the Senate Judiciary Committee last session on 22-0 vote.

Michael A. Carrier 21. Distinguished Professor at Rutgers Law School and has testified to Congress on drug-pricing issues. “Helping Consumers Afford Prescription Drugs: An Antitrust Agenda For The New Congress” Health Affairs. 02-01-21. <https://www.healthaffairs.org/do/10.1377/hblog20210126.820337/full/>

As a result of the Georgia Senate elections, Democrats now hold the barest of majorities in Congress. Given the current policy landscape, renewed legislative efforts to rein in prescription drug costs will need to be carefully tailored to attract bipartisan support. Proposals targeting antitrust abuses are a logical first step: they can effectively punish the “bad apples” in the pharmaceutical industry without stifling innovation. Antitrust legislation in the 117th Congress should focus on preventing four types of anticompetitive conduct. Each of these approaches has bipartisan support, and most were included in bills that advanced during the last session. Challenge Pay-For-Delay Settlements For years, brand-name drug companies have paid generic firms to keep their products off the market. The most recent study on the issue found that these agreements cost consumers an estimated $3.5 billion a year. Even though the Supreme Court ruled in Federal Trade Commission v. Actavis that these settlements could violate antitrust law, settling parties have sought to undermine the ruling. Lower courts have frequently succumbed to their arguments, for example, by inadvertently applying the “scope of the patent” framework overruled in Actavis, thereby allowing the settlements to continue. In addition, in recent years, the Federal Trade Commission (FTC) has found pay-for-delay cases increasingly harder to win, as the parties have hidden payments in ever more obscure corners, such as fig-leaf business arrangements with generic companies. Congress can address anticompetitive pay-for-delay settlements by making clear that they are presumptively illegal. The 116th Congress considered several bills addressing these settlements, and the House passed H.R. 1499, the Protecting Consumer Access to Generic Drugs Act of 2019. Congress should pass similar legislation in the 117th Congress. Authorize The FTC To Challenge Product Hopping A second proposal addresses “product hopping,” which occurs when a drug company switches to a slightly different version of a brand-name product just to delay generic competition. Two types of product hopping can harm consumers. In the first, drug companies engage in a “hard switch,” pulling the original from the market while introducing (and heavily marketing) a new version. In the second, a “soft switch,” the companies leave the original on the market. Although courts have understood the coercive effect of introducing a slightly modified version of a drug while taking the original off the market, they have not grasped the harm of soft switches. Courts have held that product hopping in these cases is not harmful to competition on the grounds that two products on the market are better than one. But this argument fails to recognize the unique aspects of prescription drug markets, in which different parties prescribe and pay for drugs. Congress can address the anticompetitive effects of product hopping by giving the FTC power to challenge anticompetitive hard and soft switches as unfair methods of competition under Section 5 of the FTC Act. In the last Congress, the Senate Judiciary Committee, by a 22-0 vote, approved S.1416, which targets product hopping. This legislation should be high on the agenda for the new Congress.