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#### The Advantage is Pharma

#### **In 2013 the Supreme Court erred in *FTC v. Actavis*, forcing the FTC to pursue antitrust violations against “pay-for-delay” settlements in too narrow circumstances. District courts interpret *Actavis* as excluding next generation biologics, leading to runaway monopolization and skyrocketing healthcare costs**

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It was not until 2013 that the U.S. Supreme Court addressed the legality and antitrust consequences of these agreements in FTC v. Actavis. 13 The Court held that these pay-for-delay agreements could have anticompetitive effects and were not shielded by patent law from antitrust scrutiny or justified by public policy favoring settlements. 14 Furthermore, it held the judicial standard of review for reverse payment agreements under federal antitrust law was the rule of reason. 15 It rejected the Federal Trade Commission's (FTC) argument that these settlements should be presumptively illegal or per se illegal because the Court could not conclude that these agreements would almost always be anticompetitive, noting that some might be justified for procompetitive reasons. 16

Since Actavis, the FTC has found the number of patent settlement agreements that on their face show pay-for-delay is decreasing, i.e., explicit cash settlement payments, but that the number of settlements with restrictions on generic entry that include other alleged forms of compensation have more than doubled from 2015 to 2016.17 Moreover, the FTC reports do not include every type of pharmaceutical agreement, and suggest that the form of pay-for delay has become more opaque and that any celebration of the demise of the pay-for-delay problem is premature. 18 The FTC only recently began requiring biologic companies to report their patent settlement agreements involving biologic drugs, and no FTC reports have yet been issued.1 9

Efforts to curb collusive pay-for-delay agreements are complicated by the different pharmaceutical manufacturing processes that enhance opportunities to game the system and by divergent regulatory and reporting regimes that can create undue confusion when interpreting and applying related case law. In large part, these differences are due to two different forms of pharmaceuticals - small and large molecule drugs - each with their own pathway to regulatory approval.2 0

Small molecule drugs are synthetic and have simpler, well-defined manufacturing processes. 21 Many of the drugs on the market, such as Aspirin, are small molecule drugs. 22 Large molecule drugs, also known as biologics, are generally produced using larger, complex molecules in living cells and are the fastest growing part of the drug market, often launched at eye-popping prices. 23 Not only do biologics offer some revolutionary advances in treating and curing previously incurable diseases, including some cancers, but also the biologics market is expected to increase from $239.2 billion in 2020 to $464.7 billion worldwide by 2023.24

Unlike small molecule drugs that can be replicated with relatively greater ease and confidence, large molecule biologics involve between dozens and hundreds of operating procedure controls to create the specific conditions that ensure an unexpected factor does not alter the resulting product.25 Not only must a manufacturer know what components to use, it must also know the precise sequence to assemble those pieces. 26 This also means that any attempts to make a "copycat" or "generic" version of a biologic drug - i.e., biosimilars - are more expensive. On average, some estimate that the cost of developing a generic is roughly $2 million, while developing a biosimilar may require $200 million or more. 27

Though biosimilars compete with biologics as generics compete with brands, biosimilars are subject to different regulations and state laws governing when and how they can be substituted or interchanged with the branded drug at the doctor and pharmacy level. 28 With small molecule drugs, the FDA determines whether the generic is a reliable copy or substitute for a brand drug (or an AB-rated generic); under many state laws, this FDA determination allows and often mandates a pharmacy to substitute a generic for a prescribed brand drug. 29 As a result, generics have an almost automatic path to competition in many situations.

In contrast, the FDA only recently developed the regulations allowing it to determine that a biosimilar is "interchangeable" with a biologic.30 As of September 2020, the FDA has yet to designate a single biosimilar or biologic drug in the U.S as "interchangeable."3 1 Indeed, the FDA has been relatively slow to even approve biologic and biosimilar drugs for sale in the U.S., making biosimilar introduction relatively slow in the U.S compared to Europe. 32 While there are seventy-one biosimilar drugs approved in Europe as of January 2020, only twenty-six biosimilars had been approved in the U.S. 33

But even when the FDA actually approves a biosimilar as an "interchangeable" drug, most states do not have laws that permit or mandate the substitution of the "interchangeable" drug with the biologic. 34 The pharmaceutical industry successfully lobbied for laws requiring naming conventions for biosimilar drugs that make it difficult for pharmacists to identify similar biologic drugs.35 States, for their part, have generally not updated their laws to provide more substitution of biosimilars or those drugs with interchangeability designations.

However, with the end of the "golden age" for small-molecule brand drugs in sight and $200 billion in brand sales subject to generic competition by 2025, companies increasingly see biologics and biosimilars as the future of the pharmaceutical market.36 As explained infra, biologic drugs' large price tag derives, in part, from a lack of meaningful competition in the U.S. and few pricing constraints. 37 Some $67 billion of the biologic market is vulnerable to biosimilar competition as major patents are set to expire in 2020;38 the use of patents and pay-for-delay agreements by biologics companies remains a potent threat to any real competition.

For instance, Humira has been the top-selling rheumatoid arthritis and immunology drug in the U.S. for more than six years, generating over $20 billion in sales for 2018 alone.39 Popularity and high sales' volume alone do not explain the enormous revenues, which can be primarily attributed to its high price: in 2020, $72,000 per patient annually. 40 Yet, in 2018, AbbVie Humira's manufacturer - cut Humira's price by 80% in Europe once biosimilar versions became available. 41 Meanwhile, Humira has entered a number of settlement agreements with biosimilar competitors, two of whom had already received FDA-approval in 2016 and 2017.42 None of the biosimilar companies will enter the U.S. market until 2023, leaving U.S. consumers to pay up to 500% more than their European counterparts for the same drug. 43 In contrast, the same biosimilar companies received entry dates into European markets more than five years before entry in the U.S.44 In total, eight companies with Humira biosimilars have settled with AbbVie, extending Humira's U.S. monopoly, and its supracompetitive prices in the U.S., seven years past its main ingredient's patent expiry date. 45

A class action, In re Humira (Adalimumab) Antitrust Litigation,46 alleges that AbbVie's multiple agreements are actually market allocating agreements and settlements qualifying as reverse payments. As of this writing, the In re Humira litigation is undergoing appeal after a district court ruled in favor of AbbVie, noting that while the behaviors seem unsavory, they were legal "exploited advantages" derived from the current regulatory system.47 The court went further astray, finding that the agreements were not anticompetitive, and in contradiction with Actavis's rejection of the scope of the patent doctrine, did so by relying upon the alleged strength of AbbVie's Humira patents.48 But neither the parties nor the Court in In re Humira questioned the basic application of Actavis to the agreements in this case. Though the In re Humira district court dismissed the case in favor of defendants,49 this Note argues that the In re Humira district court was correct to engage in an Actavis analysis but did so incorrectly.

A constrictive reading of Actavis to not include biologics, despite similar economic incentives to game the system and collusively divide the markets, would undoubtedly result in the proliferation of collusive biologic settlement agreements that will increase the already staggering biologic prices. There is clear congressional intent that supports treating biologic and small molecule collusive agreements under the same standards.50 Further, using the ongoing In re Humira litigation as a framing device, an opportunity for courts to explicitly determine whether and how to apply the Actavis framework to biologic drug settlements, this Note will demonstrate how the reasoning and analysis of Actavis applies to qualifying settlements in the biologic sphere and is consistent with precedent, congressional intent, and public policy.

While differences between biologics and small molecule pharmaceutical production warrant different FDA manufacturing procedures, 51 recent and ongoing legislative proposals addressing pay-for-delay agreements apply the same legal standards to adjudication of agreements for biologic and small molecule drug manufacturers. 52 Some commentators, however, have advocated a narrow interpretation of Actavis to apply only to small molecule drugs53 because the Court only discusses the relevant regulatory framework for small molecule drugs in that case. 54 They argue that the Actavis result was founded and based on the language and intent of the Hatch-Waxman Act. 55 Just as the courts then spent years litigating whether Actavis only implicated cash-only "payments," 56 savvy pharmaceutical attorneys are likely to argue that Actavis should apply only to drugs covered by the Hatch-Waxman Act.

Part II will first discuss various forms of antitrust abuses that arise in the pharmaceutical space and are often utilized as part of or together with reverse payment agreements. It goes on to explain the legal and regulatory backgrounds of small and large molecule drugs, focusing on how the biologic regulatory regime differs. Part III then discusses the consequences of lax antitrust scrutiny on pharmaceuticals, and finishes with the allegations, arguments, and findings currently on appeal in In re Humira. Lastly, Part IV proposes a two-fold solution to the problems posed by Actavis's lack of legal clarity. First, there must be regulation or precedent that clearly indicates that for antitrust purposes, biologic settlement agreements should be subject to the same antitrust scrutiny as those concerning small molecule drugs. In re Humira provides the perfect opportunity; and as the Part IV analysis will show, applying Actavis to biologics is in the spirit of the law, aligns with public policy, and follows precedent - despite the In re Humira district court ruling in favor of the defendants. Second, this Note suggests a need for a corresponding legislative solution. This Note's purpose is to demonstrate that the way a drug is manufactured, approved, or allowed to compete does not alter the application of antitrust law seeking to rid the market of collusive agreements between rivals.

#### **Even individual pay for delay agreements cause consumers billions** of dollars in losses, only antitrust regulation makes healthcare accessible

Deb, 20

(Chaarushena, Yale Law School, and Gregory Curfman, MD, Deputy Editor, JAMA, “Relentless Prescription Drug Price Increases”, *JAMA 323*(9): 826-828, 03-03-2020, doi:10.1001/jama.2020.0359)\\JM

One in 4 people in the US has difficulty paying the cost of their prescription medications. This stark fact was recently reported in a 2019 Kaiser Family Foundation public opinion poll among a nationally representative random sample of 1205 adults.1 Persons who reported having the greatest difficulty affording their prescription drugs were those who most needed them, including those who took 4 or more prescription drugs, spent $100 or more per month on their drugs, and reported being in fair or poor health. In response to relentless increases in prescription drug prices and the burden they place on consumers, the federal government has begun to take some action. The House of Representatives passed H.R.3, The Elijah E. Cummings Lower Drug Costs Now Act, which would allow Medicare to negotiate the price of 250 drugs per year; cap payments for drugs in the US at 120% of the average prices in 6 other countries; prohibit drug price increases beyond the rate of inflation; allow private insurers to purchase drugs at Medicare’s negotiated price; and cap out-of-pocket drug spending for older adults at $2000 annually. But this comprehensive legislation is very unlikely to pass in the Senate, as Majority Leader Mitch McConnell, referring to drug price negotiation as “socialist price controls,”2 has made it clear that he will not take it up. Meanwhile, Senators Chuck Grassley (R-IA) and Ron Wyden (D-OR) have introduced bipartisan drug pricing legislation that, like the House bill, would place penalties on pharmaceutical companies if they raise prices faster than inflation. However, this provision in the bill, considered crucial by the sponsors, is also its greatest obstacle to passage, as many Republican senators oppose the idea as a form of government price setting. Thus, without substantial compromise, the prospects for passage of this bill in a Republican Senate are not bright. The Trump administration has proffered its own proposal to control the prices of prescription drugs, which is focused primarily on facilitating importation of prescription drugs from Canada. Senator Bernie Sanders (I-VT) has introduced drug importation legislation in the Senate, the Affordable and Safe Prescription Drug Importation Act, which the Congressional Budget Office estimates would save $7 billion over the next decade. However, both Canadian officials and the pharmaceutical industry are strongly opposed to these importation proposals, creating major hurdles for passage. With the fate of federal initiatives to control drug prices uncertain, individual states have begun to focus on this issue. Since 2015, a total of 35 bills have been passed in 22 states that include provisions requiring drug price transparency to aid consumers in purchasing prescription drugs.3 However, these state actions generally do not help patients because they do not require the disclosure of real transaction prices at each stage of the drug distribution process. The Trump administration has also proposed a price transparency rule, whereby pharmaceutical companies would be required to include their wholesale acquisition (list) prices in drug advertisements. This proposal, however, is unlikely to survive a legal challenge by the industry. In another state-level proposal, Governor Gavin Newsom of California recently signed into law a bill, Preserving Access to Affordable Drugs, banning pay-for-delay deals. Such tactics involve payments from brand-name companies to generic companies to keep lower-cost generic drugs off the market, and both brand-name and generic companies profit from these arrangements. These arrangements are commonplace, and with the elimination of market competition, brand-name companies are at liberty to keep their prices high—as high as the market will bear. Although the Supreme Court ruled in Federal Trade Commission v Actavis (2013)4 that such deals may be challenged as anticompetitive, California has been sued on constitutional grounds that the state law banning pay-for-delay interferes with interstate commerce. For now, pending the outcome of the lawsuit, the law remains in effect, but it is uncertain if it will ultimately survive legal challenge. Governor Newsom also recently announced another novel development, in which California will explore manufacturing its own generic drugs as a way of controlling costs to consumers. Exactly how such an ambitious plan would be implemented, however, remains to be determined. In the current presidential election year, the high cost of prescription drugs has emerged as a major campaign issue for all the candidates. In this issue of JAMA, 3 original research articles address different aspects of the prescription drug price quandary. Also relevant to this discussion is a fourth article, published simultaneously in JAMA Internal Medicine, that describes the substantial expenditures by the pharmaceutical industry on political donations and lobbying between 1999 and 2018.5 The pharmaceutical industry often points to the high costs of research and development (R&D) required for the creation of innovative therapies as justification for high pricing, and in the Kaiser Family Foundation opinion poll, 69% of respondents believed that R&D costs were an important contributing factor to high prescription drug costs.1 A previous study of large pharmaceutical companies reported that the estimated R&D cost to bring a new drug to market was $2.87 billion.6 This study came under sharp criticism because the data on which it was based were considered to be “proprietary” and, therefore, were not provided in the published article.7 A new analysis by Wouters and colleagues8 in this issue of JAMA relied only on publicly available data, which were made available primarily by smaller biotechnology companies. Examining 63 of 355 new drugs approved by the US Food and Drug Administration between 2009 and 2018, the authors reported an estimated median R&D cost to bring a new drug to market of $985 million. Although this figure is substantially lower than the previously reported R&D cost for larger companies, it is still a considerable amount for smaller, start-up biotechnology companies to recoup from a new product. In a second article in this issue, Ledley and colleagues9 examined the profitability of 35 large pharmaceutical companies, as compared with 357 nonpharmaceutical companies, listed among Standard & Poor 500 companies between 2000 and 2018. During this period, the median profit margin for large pharmaceutical companies was nearly double that of nonpharmaceutical companies. Specifically, the median net income (earnings) expressed as a fraction of revenue was 13.8% for pharmaceutical companies compared with 7.7% for nonpharmaceutical companies. Although the difference narrowed over the last 5 years, pharmaceutical companies still remained more profitable than nonpharmaceutical companies. The authors also noted that the median annual net income margins of Apple, Alphabet, and Microsoft, technology giants that are increasingly involved in health care, were 19.2%, 21.9%, and 27.6%, respectively, compared with 13.8% for pharmaceutical companies. In the Kaiser Family Foundation opinion poll, 4 of 5 respondents believed that drug company profits are a major factor contributing to the high cost of prescription drugs.1 Thus, most US residents perceive that pharmaceutical companies maintain their high profit margins by keeping prices high. In a third article in this issue, Hernandez and colleagues10 reported on trends in both list prices (defined as the wholesale acquisition price) and net prices (the price after discounts and rebates) for 602 brand-name drugs from 2007 to 2018. Inflation-adjusted list prices increased by 159%, and net prices increased by 60%. Increases in discounts offset 62% of increases in list prices, but there was wide variability among different classes of drugs. Pharmaceutical companies offer discounts to payers to secure a favorable position for their drugs on the payers’ formularies and to stave off competition. Some companies that manufacture brand-name biologic products, for instance, may provide discounts to keep biosimilar products off formularies or to improve the positioning of their other drugs. For example, attempting to establish another robust income stream, biologics manufacturer AbbVie now discounts Humira, which accounts for more than half of its revenue, to secure better formulary positioning of its new biologic for plaque psoriasis, Skyrizi. The financial strategy for some products of some pharmaceutical companies follows this scenario: increase list prices; offer discounts to partially offset the list price increases; restrain competition and enhance market share through optimal formulary placement; and increase volume of sales. It is noteworthy that patients do not receive discounts, and patients who are uninsured, covered by high-deductible plans, or are in the deductible phase of their coverage, must pay list prices. Also, coinsurance payments, which may be required for some more expensive specialty drugs, are determined based on a percentage of the list price. The pharmaceutical industry just announced prescription drug price increases for 2020. According to the health care research firm 3 Axis Advisors, prices were increased for nearly 500 drugs, with an average price increase of 5.17%.11 To mitigate public criticism, most of the price increases were kept below 10%. The list price of the world’s best-selling drug, adalimumab (Humira), was increased by AbbVie by 7.4% for 2020, which adds to a 19.1% increase in list price for years 2018 and 2019. The 2018 price increase alone was estimated to have added $1 billion to US health care costs. In a recent analysis, the Institute for Clinical and Economic Review determined there was insufficient clinical evidence to justify such a large price increase.12 Humira serves as a prime example of the aggressive tactics that may be used by some pharmaceutical companies to maintain high drug prices. In response to these price hikes for Humira, AbbVie has recently been the subject of a series of groundbreaking class-action lawsuits. Insurance payers and workers’ unions allege that AbbVie created a “patent thicket” around the monoclonal antibody therapy, thereby acting in bad faith to quash competition from Humira biosimilars.13 The original Humira patent expired in 2016, but AbbVie has been able to stave off biosimilar market entry by filing more than 100 follow-on patents that extend AbbVie’s monopoly beyond 2030. It is not uncommon for drugs to be protected by multiple patents, but the Humira patent thicket is extreme and allows AbbVie to aggressively extend its high monopoly pricing. A second claim in the lawsuits against AbbVie is that the company allegedly used “pay-for-delay” tactics to negotiate later market entry dates with biosimilar competitors. Pay-for-delay agreements in the pharmaceutical industry have been controversial for years, but the notion of a “patent thicket” greatly exacerbates the issue because the normal route for generics and biosimilars to enter the market is through patent litigation. Typically, a generic or biosimilar drug maker will try to enter the market prior to the patent term expiration date by asserting that the patents they would be infringing are, in fact, invalid. AbbVie contended it would continue to sue biosimilar manufacturers for infringement using its full complement of patents, pushing market entry dates well into the 2030s, leading the biosimilar companies to simply give up and settle the litigation. These settlements will likely allow AbbVie to continue instituting price increases for Humira. The pioneering class-action lawsuits, filed on behalf of the people who actually bear the burden of increasing drug prices, represents a novel way of challenging the drug industry with the aim of increasing access to expensive medicine for all patients. When legislative solutions are unsettled, this innovative lawsuit could establish a new legal pathway for curtailing relentless price increases for expensive prescription drugs. Collectively, the articles in the current issues of JAMA and JAMA Internal Medicine, along with the illustrated cover of JAMA, paint a concerning picture about the relationships among rising drug prices, pharmaceutical industry profits, uncertainty about pharmaceutical R&D costs, and lobbying and political donations to gain influence with legislators. We anticipate that publication of this information will further stimulate the ongoing national debate on prescription drugs and help rein in increasing drug prices while sustaining innovation in drug development, which is so critical to the health of individuals both in the US and around the world.

#### Pay-for-delay raises costs, reduces access, and slows innovation

Shabbir, 21

(Ruqayyah, Ivey Business School at Western University, “The Delay of Competition in the Pharmaceutical Industry: A Closer Look at the Pharmaceutical Giants”, *Western Undergraduate Economics Review,* 20, (2021), https://ojs.lib.uwo.ca/index.php/wuer/article/view/14025)\\JM

Lastly, one of the most controversial and recent acquisitions in the pharmaceutical industry was AbbVie’s purchase of Allergan. In 2019, the American biopharmaceutical company, AbbVie, officially acquired Allergan, an Irish pharmaceutical company. Prior to the official acquisition, there was significant concern regarding how drug prices and future drug innovation would be affected as a result. This concern was substantial enough to bring together 17 consumer advocacy groups. This collective group expressed their worries to the Federal Trade Commission (FTC), based on historical information about AbbVie and the broader pharmaceutical industry. Specifically, the group noted that between 2006 and 2017, AbbVie had tripled its price for Humira (generic name: adalimumab), and “neither inflation, nor higher manufacturing costs could explain these price increases” (Mogin, 2019). Based on these voiced concerns, it would have been important to question what AbbVie would be capable of once it acquired Allergan’s drug portfolio. In addition to expressing concern, the group presented data on recent trends in the pharmaceutical industry. Among data on price increases, there was also concern that AbbVie’s acquisition would hamper innovation, reducing how much firms spend on research and development (R&D). It has been noted that “the share of new drugs coming from the top twenty big pharma firms has dropped every year since 2013, from over 60% to just above 30% in 2018”(Mogin, 2019). Simply stated, large firms are acquiring smaller firms to increase their drug portfolio, rather than working to benefit consumers through increased innovation and R&D. With a focus on mergers and acquisitions (M&A), innovation has become a secondary goal. This directly impacts consumers as it has taken firms longer to introduce new drugs and when these new drugs come to market, they come much later. Firms are simply taking the “easy route” to becoming pharma giants, once again at the detriment of consumers. With discussion concentrated around the time delay in bringing affordable and innovative drugs to market, it is important to introduce the role of pay-for-delay schemes. The previous three case analyses illustrate how certain strategies can still harm consumers through hindered competition, even if there is no overall “lessening of competition” according to the respective country’s competition law. Unlike the tactics used by the firms discussed above, the pay-for-delay tactic is a way for patent-holders (“brands”) to stifle competition in a much more direct way. The pay-for-delay scheme involves brands offering settlements to generics, deterring them from developing and marketing generic versions of their patented drugs once the patent expires. Pay-for-delay deals have “cost consumers and taxpayers $3.5 billion in higher drug costs every year” (Federal Trade Commission, 2019). Recognizing this, the United States’ FTC has made it its priority to prevent these schemes from injuring competition. The controversy surrounding each of the cases discussed above highlights the need for a deeper analysis of competition cases, specifically with respect to how the actions of firms directly and indirectly affect consumers. Although it was found that these firms did not lessen competition, the difficulties they caused other firms and potential entrants resulted in delayed entry of competitors. In the case of Celgene, generics were repeatedly denied access to CRPs, which hindered their ability to validate their drugs and bring them to market. Pfizer engaged in various exclusive dealing arrangements to deter the entry of generics, impeding their ability to sell appropriate quantities once they enter. Finally, AbbVie’s acquisition of Allergan caused great concern among consumers, as past data has shown higher prices, less competition, and slowed innovation as a likely result. With generics entering the industry later than expected and with higher costs due to the strategies pursued by major pharma brands, consumers cannot access cheap drugs in a timely manner. Unfortunately, a population that desperately requires medicine, but can only afford generic versions, will always exist. Therefore, even if competition eventually builds, this does not necessarily mean that consumers will no longer be affected during the period of delay. According to a paper addressed by the NCBI, “1 in 5 Americans do not fill prescription drugs because of prohibitive costs” (Carrier et al., 2016). From a global perspective, this statistic reflects the staggering reality of many other countries. Competition law is often designed in a generalized manner, such that every firm in every industry is subject to the same laws. This helps in promoting fairness and ensuring justice. However, it is important to note that medicine is unlike many other consumer goods. Although the nuanced nature of the medical industry is being increasingly recognized and competition law has recently evolved in the pharmaceutical industry, there must be greater discipline. The three cases discussed in this paper are just a handful of the many cases that do not lessen competition per se, but surely delay competition and the introduction of affordable drugs to consumers in a timely manner.

#### Pharmaceutical innovation is crucial to solving global threats from infectious diseases and bioterror. Alternatives to market-based incentives are guaranteed to fail.

Marjanovic, 20

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We need to ensure scalable and sustainable approaches for pharmaceutical innovation in response to infectious disease threats to public health 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.1 The general threat to public health that is posed by antimicrobial resistance is also well-recognised as an area in need of pharmaceutical innovation. Innovating in response to these challenges does not always align well with pharmaceutical industry commercial models, shareholder expectations and 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. 2 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.3,4 Pharmaceutical companies are collaborating with each other in some of these efforts and participating in global R&D partnerships (such as the Innovative Medicines Initiative effort to 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.3,5,6 The primary purpose of such innovation is to benefit patients and wider population health. Although there are also reputational benefits from involvement that can be realised across the industry, there are likely to be 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.7 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.8,9 Johnson & Johnson has stated that its potential vaccine – which is expected to begin trials – will be available on a not-for-profit basis during the pandemic.10 Pharma is mobilising substantial efforts to rise to the COVID-19 challenge at hand. However, we need to consider how pharmaceutical innovation for responding to emerging infectious diseases can best be enabled beyond the current crisis. Many public health threats (including those associated with other infectious diseases, 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.11 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.12 There are important policy questions as to whether – and how – industry could engage with such public health threats to an even greater extent under improved innovation conditions. The COVID-19 pandemic is a game-changer among global public health threats. The risk to human life (both in terms of morbidity and quality of life), the economic risks, the epidemiology of the disease and speed of escalation have led to a crisis-response by many governments around the world. This has in turn influenced the immediate industry efforts. Many other infectious disease threats may not manifest as crises in the short term and in the same way as COVID-19, but they could nevertheless escalate. They are not considered to be crises from a short term perspective because they are contained to specific regions and affect fewer people at present – or are re-emerging (e.g. Ebola) – or their impacts have not yet materialised at a scale that would qualify as an immediate crisis (e.g. growing risks of antimicrobial resistance to some infectious pathogens). However, such diseases and issues are recognised as global threats that could become crises in the future.13 The emerging threats raise important policy questions about how government and the pharmaceutical industry can work together to ensure that pharmaceutical industry innovation is incentivised sustainably and at scale. This is important to help mitigate against current and emerging threats becoming crises further down the line. At present, there are no clear and specific criteria to determine when a disease can trigger the types of healthcare-innovation-related policy actions that have been deployed in response to the COVID-19 crisis. For example, this applies to criteria for securing financial resources for innovation-related activities, reforming regulation to accelerate trials and regulatory approval processes, and securing reimbursement mechanisms that help enable industry engagement and the search for rapid solutions. The WHO guidance on what constitutes a pandemic phase does provide guidance on national policy response options, but not specifically as they relate to healthcare innovation activity.14 There are also questions as to whether such policy initiatives and incentives should only be applied in crisis situations, or also as part of proactive government and industry efforts to innovate in the areas of public health threats in order to prevent future global calamities. A crisis and ‘emergency mode’ response may be inevitable for some diseases, but more can be done to mitigate against the need for such a response – especially in cases where emerging threats and their consequences can be foreseen and are known to be a risk. We need to anticipate and act now in terms of how we plan and incentivise better for the future, and how we distinguish between different types of infectious disease threats and phases in framing incentives and regulation. Innovative financial instruments must be integral to any sustainable and scalable approach to incentivising pharmaceutical innovation for tackling emerging threats to public health from infectious diseases The pharmaceutical industry has a responsibility to both its shareholders and to society at large. Incentivising the pharmaceutical industry to innovate solely on the grounds of being a socially responsible sector is unlikely to lead to a sustainable and scalable approach for innovating in response to emerging infectious disease threats. There are also potential challenges to the types of innovation (i.e. how radical or incremental) a reliance on incentives rooted solely in a social responsibility argument can lead to. Donating existing compounds for testing is important, but it is different to at-scale, industry-wide intensive investment in R&D geared at developing highly innovative diagnostics, medicines and vaccines. Even in the case of COVID-19, there are significant differences in the scale of innovative activity that focuses on repurposing existing products and technologies – for example, through testing existing antiviral compounds for potential therapeutic value – and more radically innovative R&D efforts aimed at developing something that acts on the COVID-19 virus in fundamentally novel ways.

#### Advancements decrease the barrier to pulling off a successful attack---causes extinction

Farmer 17 (“Bioterrorism could kill more people than nuclear war, Bill Gates to warn world leaders” http://www.telegraph.co.uk/news/2017/02/17/biological-terrorism-could-kill-people-nuclear-attacks-bill/)

Bioterrorists could one day kill hundreds of millions of people in an attack more deadly than nuclear war, [Bill Gates](http://www.telegraph.co.uk/bill-gates/) will warn world leaders. Rapid advances in genetic engineering have opened the door for small terrorism groups to tailor and easily turn biological viruses into weapons. A resulting disease pandemic is currently one of the most deadly threats faced by the world, he believes, yet governments are complacent about the scale of the risk. Speaking ahead of an address to the Munich Security Conference, the [richest man in the world](http://www.telegraph.co.uk/finance/economics/11445375/Bill-Gates-named-worlds-richest-person-for-16th-time.html) said that while governments are concerned with the proliferation of nuclear and chemical weapons, they are overlooking the threat of biological warfare. Mr Gates, whose [charitable foundation](http://www.telegraph.co.uk/technology/bill-gates/9812672/Bill-Gates-interview-I-have-no-use-for-money.-This-is-Gods-work.html)is funding research into quickly spotting outbreaks and speeding up vaccine production, said the defence and security establishment “have not been following biology and I’m here to bring them a little bit of bad news”. Mr Gates will today (Saturday) tell an audience of international leaders and senior officers that the world’s next deadly pandemic “could originate on the computer screen of a terrorist”. He told the Telegraph: “Natural epidemics can be extremely large. Intentionally caused epidemics, bioterrorism, would be the largest of all. “With nuclear weapons, you’d think you would probably stop after killing 100million. Smallpox won’t stop. Because the population is naïve, and there are no real preparations. That, if it got out and spread, would be a larger number.” He said developments in genetic engineering were proceeding at a “mind-blowing rate”. Biological warfare ambitions once limited to a handful of nation states are now open to small groups with limited resources and skills. He said: “They make it much easier for a non-state person. It doesn’t take much biology expertise nowadays to assemble a smallpox virus. Biology is making it way easier to create these things.” The increasingly common use of gene editing technology would make it difficult to spot any potential terrorist conspiracy. Technologies which have made it easy to read DNA sequences and tinker with them to rewrite or tweak genes have many legitimate uses. He said: “It’s not like when someone says, ‘Hey I’d like some Plutonium’ and you start saying ‘Hmmm.. I wonder why he wants Plutonium?’” Mr Gates said the potential death toll from a disease outbreak could be higher than other threats such as [climate change](http://www.telegraph.co.uk/climate-change/) or nuclear war. He said: “This is like earthquakes, you should think in order of magnitudes. If you can kill 10 people that’s a one, 100 people that’s a two... Bioterrorism is the thing that can give you not just sixes, but sevens, eights and nines. “With nuclear war, once you have got a six, or a seven, or eight, you’d think it would probably stop. [With bioterrorism] it’s just unbounded if you are not there to stop the spread of it.” By tailoring the genes of a virus, it would be possible to manipulate its ability to spread and its ability to harm people. Mr Gates said one of the most potentially deadly outbreaks could involve the humble flu virus. It would be relatively easy to engineer a new flu strain combining qualities from varieties that spread like wildfire with varieties that were deadly. The last time that happened naturally was the 1918 Spanish Influenza pandemic, which went on to kill more than 50 million people – or nearly three times the death toll from the First World War. By comparison, the recent Ebola outbreak in West Africa which killed just over 11,000 was “a Richter Scale three, it’s a nothing,” he said. But despite the potential, the founder of Microsoft said that world leaders and their militaries could not see beyond the more recognised risks. He said: “Should the world be serious about this? It is somewhat serious about normal classic warfare and nuclear warfare, but today it is not very serious about bio-defence or natural epidemics.” He went on: “They do tend to say ‘How easy is it to get fissile material and how accurate are the plans out on the internet for dirty bombs, plutonium bombs and hydrogen bombs?’ “They have some people that do that. What I am suggesting is that the number of people that look at bio-defence is worth increasing.” Whether naturally occurring, or deliberately started, it is almost certain that a highly lethal global pandemic will occur within our lifetimes, he believes. But the good news for those contemplating the potential damage is that the same biotechnology can prevent epidemics spreading out of control. Mr Gates will say in his speech that most of the things needed to protect against a naturally occurring pandemic are the same things needed to prepare for an intentional biological attack. Nations must amass an arsenal of new weapons to fight such a disease outbreak, including vaccines, drugs and diagnostic techniques. Being able to develop a vaccine as soon as possible against a new outbreak is particularly important and could save huge numbers of lives, scientists working at his foundation believe.

#### **Disease alone causes extinction.**

Ord ‘20 [Toby; reporter for the Guardian; 3-6-2020; "Why we need worst-case thinking to prevent pandemics"; Guardian; https://www.theguardian.com/science/2020/mar/06/worst-case-thinking-prevent-pandemics-coronavirus-existential-risk]

The world is in the early stages of what may be the **most deadly pandemic** of the **past 100 years**. In China, thousands of people have already died; large outbreaks have begun in South Korea, Iran and Italy; and the rest of the world is bracing for impact. We do not yet know whether the final toll will be measured in thousands or hundreds of thousands. For all our advances in medicine, humanity remains much **more vulnerable** to pandemics than we would like to believe. To understand our vulnerability, and to determine what steps must be taken to end it, it is useful to ask about the very worst-case scenarios. Just how bad could a pandemic be? In science fiction, we sometimes encounter the idea of a pandemic so severe that it could cause **the end of civilisation,** or even of **humanity itself.** Such a risk to humanity’s entire future is known as an **existential risk.** We can say with certainty that the novel coronavirus, named Covid-19, does not pose such a risk. **But could the next pandemic?** To find out, and to put the current outbreak into greater context, let us turn to the past. In 1347, death came to Europe. It entered through the Crimean town of Caffa, brought by the besieging Mongol army. Fleeing merchants unwittingly carried it back to Italy. From there, it spread to France, Spain and England. Then up as far as Norway and across the rest of Europe – all the way to Moscow. Within six years, the Black Death had taken the continent. Tens of millions fell gravely ill, their bodies succumbing to the disease in different ways. Some bore swollen buboes on their necks, armpits and thighs; some had their flesh turn black from haemorrhaging beneath the skin; some coughed blood from the necrotic inflammation of their throats and lungs. All forms involved fever, exhaustion and an intolerable stench from the material that exuded from the body. There were so many dead that mass graves needed to be dug and, even then, cemeteries ran out of room for the bodies. The Black Death **devastated Europe.** In those six years, between a **quarter and half of all Europeans were killed**. The Middle East was ravaged, too, with the plague killing about **one in three Egyptians and Syrians**. And it may have also laid waste to parts of central Asia, India and China. Due to the scant records of the 14th century, we will never know the true toll, but our best estimates are that somewhere between **5% and 14% of all the world’s people were killed**, in what may have been the **greatest catastrophe** humanity has seen. The Black Death was not the only biological disaster to scar human history. It was not even the only great bubonic plague. In AD541 the plague of Justinian struck the Byzantine empire. Over three years, it **took the lives** of roughly **3% of the world’s people.** When Europeans reached the Americas in 1492, the two populations exposed each other to completely novel diseases. Over thousands of years, each population had built up resistance to their own set of diseases, but were extremely susceptible to the others. The American peoples got by far the worse end of the exchange, through diseases such as measles, influenza and, especially, smallpox. During the next 100 years, a combination of invasion and disease took an immense toll – one whose scale may never be known, due to great uncertainty about the size of the pre-existing population. We can’t rule out the loss of more than 90% of the population of the Americas during that century, though the number could also be much lower. And it is very difficult to tease out how much of this should be attributed to war and occupation, rather than disease. At a rough estimate, as many as 10% of the world’s people may have been killed. Centuries later, the world had become so interconnected that a truly global pandemic was possible. Towards the end of the first world war, a devastating strain of influenza, known as the 1918 flu or Spanish flu, spread to six continents, and even remote Pacific islands. About a third of the world’s population were infected and between 3% and 6% were killed. This death toll outstripped that of the first world war. Yet even events like these fall short of being a threat to humanity’s long-term potential. In the great bubonic plagues we saw civilisation in the affected areas falter, but recover. The regional 25%-50% death rate was not enough to precipitate a continent-wide collapse. It changed the relative fortunes of empires, and may have substantially altered the course of history, but if anything, it gives us reason to believe that human civilisation is likely to make it through future events with similar death rates, even if they were global in scale. The Spanish flu pandemic was remarkable in having very little apparent effect on the world’s development, despite its global reach. It looks as if it was lost in the wake of the first world war, which, despite a smaller death toll, seems to have had a much larger effect on the course of history. The full history of humanity covers at least 200,000 years. While we have scarce records for most of these 2,000 centuries, there is a key lesson we can draw from the sheer length of our past. The chance of human extinction from natural catastrophes of any kind must have been very low for most of this time – or we would not have made it so far. But could these risks have changed? Might the past provide false comfort? Our population now is a **thousand times greater** than it was for most of human history, so there are vastly **more opportunities** for new **human diseases to originate.** And our farming practices have created **vast numbers of animals** living in **unhealthy conditions** within **close proximity to humans**. This increases the risk, as many major diseases originate in animals before crossing over to humans. Examples include HIV (chimpanzees), Ebola (bats), Sars (probably civets or bats) and influenza (usually pigs or birds). We do not yet know where Covid-19 came from, though it is very similar to coronaviruses found in bats and pangolins. Evidence suggests that diseases are crossing over into human populations from animals at an increasing rate. **Modern civilisation** may also make it much easier for a **pandemic to spread**. The higher density of people living together in cities **increases the number of people** each of us may infect. Rapid **long-distance transport** greatly increases the **distance pathogens can spread**, reducing the **degrees of separation** between any two people. Moreover, we are no longer divided into isolated populations as we were for most of the past 10,000 years. Together these effects suggest that we might expect **more new pandemics**, for them to **spread more quickly**, and to reach a **higher percentage** of the **world’s people**. But we have also changed the world in ways that offer protection. We have a healthier population; improved sanitation and hygiene; preventative and curative medicine; and a scientific understanding of disease. Perhaps most importantly, we have public health bodies to facilitate global communication and coordination in the face of new outbreaks. We have seen the benefits of this protection through the dramatic decline of endemic infectious disease over the past century (though we can’t be sure pandemics will obey the same trend). Finally, we have spread to a range of locations and environments unprecedented for any mammalian species. This offers special protection from extinction events, because it requires the pathogen to be able to flourish in a vast range of environments and to reach exceptionally isolated populations such as uncontacted tribes, Antarctic researchers and nuclear submarine crews. It is hard to know whether these combined effects have increased or decreased the existential risk from pandemics. This uncertainty is ultimately bad news: we were previously sitting on a powerful argument that the **risk was tiny**; now **we are not.** We have seen the indirect ways that our actions aid and abet the origination and spread of pandemics. But what about cases where we have a much more direct hand in the process – where we deliberately use, improve or create the pathogens? Our understanding and control of pathogens is very recent. Just 200 years ago, we didn’t even understand the basic cause of pandemics – a leading theory in the west claimed that disease was produced by a kind of gas. In just two centuries, we discovered it was caused by a diverse variety of microscopic agents and we worked out how to grow them in the lab, to breed them for different traits, to sequence their genomes, to implant new genes and to create entire functional viruses from their written code. This progress is continuing at a rapid pace. The past 10 years have seen major qualitative breakthroughs, such as the use of the gene editing tool Crispr to efficiently insert new genetic sequences into a genome, and the use of gene drives to efficiently replace populations of natural organisms in the wild with genetically modified versions. This progress in biotechnology seems unlikely to fizzle out anytime soon: there are no insurmountable challenges looming; no fundamental laws blocking further developments. But it would be optimistic to assume that this uncharted new terrain holds only familiar dangers. To start with, let’s set aside the risks from malicious intent, and consider only the risks that can arise from well-intentioned research. Most **scientific and medical research** poses a negligible risk of harms at the scale we are considering. But there is a small fraction that uses **live pathogens** of kinds that are known to **threaten global harm**. These include the agents that cause the **Spanish flu, smallpox, Sars and H5N1 or avian flu**. And a small part of this research involves **making strains** of these pathogens that pose **even more danger** than the natural types, increasing their **transmissibility**, lethality or resistance to vaccination or treatment. In 2012, a Dutch virologist, Ron Fouchier, published details of an experiment on the recent H5N1 strain of bird flu. This strain was extremely deadly, killing an estimated **60% of humans it infected** – far beyond even the Spanish flu. Yet its inability to pass from human to human had so far **prevented a pandemic**. Fouchier wanted to find out whether (and how) H5N1 could naturally develop this ability. He passed the disease through a series of 10 ferrets, which are commonly used as a model for how influenza affects humans. By the time it passed to the final ferret, his strain of H5N1 had become directly transmissible between mammals. The work caused fierce controversy. Much of this was focused on the information contained in his work. The US National Science Advisory Board for Biosecurity ruled that his paper had to be stripped of some of its technical details before publication, to limit the ability of bad actors to cause a pandemic. And the Dutch government claimed that the research broke EU law on exporting information useful for bioweapons. But it is not the possibility of misuse that concerns me here. Fouchier’s research provides a clear example of well-intentioned scientists enhancing the destructive capabilities of pathogens known to threaten global catastrophe. Of course, such experiments are done in secure labs, with stringent safety standards. It is highly unlikely that in any particular case the enhanced pathogens would escape into the wild. But just how unlikely? Unfortunately, we don’t have good data, due to a lack of transparency about incident and escape rates. This prevents society from making well-informed decisions balancing the risks and benefits of this research, and it limits the ability of labs to learn from each other’s incidents. Security for highly dangerous pathogens has been **deeply flawed**, and remains insufficient. In 2001, Britain was struck by a devastating outbreak of foot-and-mouth disease in livestock. Six million animals were killed in an attempt to halt its spread, and the economic damages totalled £8bn. Then, in 2007, there was another outbreak, which was traced to a lab working on the disease. Foot-and-mouth was considered a **highest-category pathogen**, and required the highest level of biosecurity. Yet the virus escaped from a **badly maintained pipe**, leaking into the **groundwater at the facility**. After an investigation, the **lab’s licence was renewed** – only for **another leak to occur two weeks later.** In my view, this track record of escapes shows that even the **highest biosafety level** (BSL-4) is **insufficient for working on pathogens** that pose a risk of global pandemics on the scale of the Spanish flu or worse. Thirteen years since the last publicly acknowledged outbreak from a **BSL-4 facility** is not good enough. It doesn’t matter whether this is from insufficient standards, inspections, operations or penalties. What matters is the poor track record in the field, made worse by a lack of transparency and accountability. With current BSL-4 labs, an **escape of a pandemic pathogen** is only a **matter of time.**

#### **Generic competition is the backbone of affordable healthcare, drug monopolization spikes costs while competition flattens them**

Gupta et al. 19 [\*Ravi, MD in Department of Medicine, Johns Hopkins Hospital and Johns Hopkins School of Medicine, Baltimore, Maryland, \*\*Nilay D. Shah, PhD in Division of Health Care Policy and Research and Robert D. and Patricia E. Kern Center for the Science of Health Care Delivery, Mayo Clinic, Rochester, Minnesota, and \*\*\*Joseph S. Ross, MD in Section of General Internal Medicine, Department of Medicine, Yale University School of Medicine; Department of Health Policy and Management, Yale University School of Public Health; and the Center for Outcomes Research and Evaluation, Yale–New Haven Hospital; "Generic Drugs In The United States: Policies To Address Pricing And Competition," Clinical Pharmacology & Therapeutics, February 2019: 105(2): 329-337; <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6355356/>]

The cost of prescription drugs in the U.S. continues to be a source of concern for patients, caregivers, and policymakers. In a recent poll of U.S. adults, 77% of respondents with varying political affiliations said that prescription drug costs were “unreasonable” (1). In 2016, the U.S. spent $450 billion on prescription medicines, accounting for 14% of total health care spending and projected to increase to $610 billion by 2021 (2). Much of this increase in drug spending is due to brand-name drugs that are protected from generic competition by patents and regulatory exclusivity (3). Though they constitute only 10% of prescriptions dispensed in the U.S., brand-name drugs account for 74% of drug spending (4). During the market exclusivity period, the brand-name manufacturer can earn sizable profits, which can help to drive further pharmaceutical innovation and investment in drug development.

In the U.S., drug prices typically decline rapidly once generic drugs receive U.S. Food and Drug Administration (FDA) approval and begin to enter the market. The greater the number of generic manufacturers’ versions in a market, the steeper the price decline, with prices decreasing to less than 20% of the original drug’s price (5, 6). In 2016, generic drugs accounted for only 27% of overall U.S. drug spending yet constituted 89% of drug prescriptions in the U.S. (7), a dramatic increase from just 19% of prescriptions in 1984 (8). Low-cost generic drugs generated $253 billion in savings to the U.S. health care system in 2017 and more than $1 trillion in the past decade (4, 9). Appropriate use of low-cost generic drugs is associated with improved patient medication adherence (10, 11) and health outcomes (12).

In the past decade, however, there has been growing concern about the rapid rise in costs and shortages of generic drugs, despite their substantially lower prices when compared to brand-name drugs. A recent U.S. Government Accountability Office report found that 315 of 1,441 (22%) generic drugs sold in the U.S. experienced price increases of 100% or more from 2010 to 2015, many of which were older, small-market medicines (13). Shortages of generic drugs in the U.S. have also risen, quadrupling between 2005 and 2011, from 61 to 250 drugs (14, 15). Large price increases of generic drugs have been associated with decreases in physician prescribing and drug utilization (16). Despite no longer being protected by patents and regulatory exclusivity, these older drugs experiencing price increases and shortages often lack robust competition.

#### Rising healthcare costs destroy US manufacturing

Meidinger, 20

(Roy, author of *The Truth about the Healthcare Industry*, “Healthcare Costs Are Killing US Manufacturing”, IndustryWeek, 09-22-20, https://www.industryweek.com/the-economy/public-policy/article/21142527/healthcare-costs-are-killing-us-manufacturing)\\JM

U.S. payment of healthcare costs by employers causes the loss of U.S. manufacturing companies and manufacturing jobs. Health care costs, both primary and secondary, are passed during each step to the next contributor in the manufacturing process; think of it as value-added tax, moving the health care benefit costs to the next purchaser of services or goods. But each time the cost is passed on to another manufacturer in the supply chain, there is an additional markup for profit; therefore, manufacturing employers’ portion of the $3.6 trillion spent annually on healthcare in the United States is included in manufacturing costs. No other industry has as many links in the supply chain for cost markups or have international competition. A manufactured good is made through several steps to get to finished product, with each step adding the subsequent employee healthcare benefits cost to the finished product. These costs are referred to as the indirect healthcare costs. For instance, Step One, in the manufacture of a car, the miners of the ore have healthcare costs, which are marked up and passed along in the cost of the ore, Then, Step Two, the ore is purified and shaped in the steel mills, which adds more healthcare costs, that are passed on. Then, Step Three, all the various components are assembled by the auto mobile manufacturers, adding more healthcare costs, then finally, Step Four, the retail auto salesforce sells the cars and adds their healthcare costs. Each individual group must sell its products above its break-even point of costs to stay in business and then add another layer of costs to cover profits and taxes. By eliminating the direct and indirect employer’s healthcare costs, the final finished good’s break-even point is much lower and can be competitively priced. International manufacturing competitors do not have these additional layers of healthcare costs. For the United States to compete we must eliminate employer paid health care insurance.

#### Strong US manufacturing base is crucial to deter nuclear escalation of multiple hotspots

Eaglen et al 12 (Mackenzie, resident fellow in the Marilyn Ware Center for Security Studies at the American Enterprise Institute, Rebecca Grant, IRIS Research Robert P. Haffa, Haffa Defense Consulting Michael O'Hanlon, The Brookings Institution Peter W. Singer, The Brookings Institution Martin Sullivan, Commonwealth Consulting Barry Watts, Center for Strategic and Budgetary Assessments “The Arsenal of Democracy and How to Preserve It: Key Issues in Defense Industrial Policy January 2012,” <https://www.brookings.edu/wp-content/uploads/2016/06/0126_defense_industrial_base_ohanlon.pdf>)

Yet there are severe challenges that could result to the nation’s security interests even with 10 percent cutbacks. Despite the likely potential of lesser resources, the demand side of the equation does not seem likely to grow easier. The international security environment is challenging and complex. China’s economic, political and now military rise continues. Its direction is uncertain, but it has already raised tension, especially in the South China Sea. Iran’s ambitions and machinations remain foreboding, with its nuclear plans entering a new phase of both capability but also crisis. North Korea is all the more uncertain with a leadership transition, but has a history of brinkmanship and indeed even the occasional use of force against the South, not to mention nuclear weapons related activities that raise deep concern. And the hopeful series of revolutions in the broader Arab world in 2011, while inspiring at many levels, also seem likely to raise uncertainty in the broader Middle East. Revolutions are inherently unpredictable and often messy geostrategic events. On top of these remain commitments in Afghanistan and beyond and the frequent U.S. military role in humanitarian disaster relief. Thus, there are broad challenges for American defense planners as they try to address this challenging world with fewer available resources. The current wave of defense cuts is also different than past defense budget reductions in their likely industrial impact, as the U.S. defense industrial base is in a much different place than it was in the past. Defense industrial issues are too often viewed through the lens of jobs and pet projects to protect in congressional districts. But the overall health of the firms that supply the technologies our armed forces utilize does have national security resonance. Qualitative superiority in weaponry and other key military technology has become an essential element of American military power in the modern era—not only for winning wars but for deterring them. That requires world-class scientific and manufacturing capabilities—which in turn can also generate civilian and military export opportunities for the United States in a globalized marketplace.

#### Biologic innovation solves ABR and extends aggregate life expectancy

Ghanemi, 17

(Kadour, Department of Business Management, School of International Pharmaceutical Business, China Pharmaceutical University, and Shuangsheng Yan, Associate Professor, Director, the Philosophy of Teaching and Research Office, Department of Social Science, International Pharmaceutical Business School, China Pharmaceutical University, “Biopharmaceutical Innovation: Benefits and Challenges”, *Open Access Journal of Science, 1(*1), 2017, https://www.researchgate.net/profile/Kadour-Ghanemi/publication/318405175\_Biopharmaceutical\_Innovation\_Benefits\_and\_Challenges/links/5967d0ec0f7e9b8091858df2/Biopharmaceutical-Innovation-Benefits-and-Challenges.pdf)\\JM

The benefits and outcomes of the biopharmaceutical innovation: selected examples One of the most important objectives of the biopharmaceutical innovation is to contribute in the decrease of mortality and premature death averages. Recently the Manhattan institute published a research study about the reasons why the average of lifetime expectancy and longevity varies from a country to another, the effective contribution of new biodrugs proves that the more we use new biodrugs the more we gain longevity and provide welfare to the population [5]. Within this context, an illustrative example could be the use of antimicrobials. Indeed, numerous microbes develop resistance against agents such as antibiotics which require to innovate novel therapeutic agents and vectors to overcome this challenge. In addition, adapting drug formulations to specific patients and cases leads to improved cures and premature mortality reduction, which is a substantial public health goal too. Since the biopharmaceutical field was further revolutionized and initiated-to develop and discover new biodrugs-, we noticed that this contributes to extend the life expectancy average [6] reflecting an important impact. According to a conservative valuation, the biopharmaceutical research and development one-time outlay is around 15 billion US dollars then save approximately 1.6 million life-years per annum, showing that the development of novel biodrugs plays a basic role in prolonging lifetime expectancy and extending healthy productive longevity and lifetime income by around 0.75% to 1.0% per year [7]. Lifetime average expectancy improved from 46.5 years for a person born in 1950-55 to 65.0 years for those born in 1995- 2000 according to the United Nations datum. Such observations support that the new biodrugs have a substantial role in decreasing mortality and premature death average [8]. Moreover, the biopharmaceutical innovation has also numerous economic outcomes and other benefits that cannot be neglected. Indeed, the availability, the abundance and the diverse variety of several new biodrugs in the market result in the prices reduction of some medicines, increase drug accessibility and further develop the drug market [9,10]. Such development in the biodrug innovation makes that the doctors and the healers have a variety of therapeutic options and curative choices to treat their patients. Thus, in case some of the biodrug is not suitable, cannot improve their health or have serious side effects if given to a specific patient, they may prescribe a different biodrug from the same category [11] as an alternative. Laboratories and biopharmaceutical firms ensure and guarantee their funding continuity via, at least partially, the continuous innovation and discoveries. Indeed, it is accepted that the more they invent and innovate the more they get financial incomes. This makes the biopharmaceutical firms relying on diverse sources of income and their financial fund box rich due to the development and innovation which are the future of every company. Such concept pushes to innovate and invest in biodrugs research and development along with the marketing of new medicines [12]. The research and development boost the economy toward an economic growth and prosperity of the firm, and the civil society as a whole, via creating good values to enhance life features [13,14] because there are important interaction and strong relationship between the economic growth and the productivity. When the health outcomes are advanced this will result in a decrease in diseases and disabilities which contributes to a revolution in the development and prosperity of the society [15,16].

#### Aging population prevents international conflict – specifically prevents great power transition

Haas, 20

(Mark L., Raymond J. Kelley Endowed Chair in International Relations and Professor of Political Science at Duquesne University in Pittsburgh. He formerly was a National Security Fellow at the Olin Institute for Strategic Studies and an International Security Fellow at the Belfer Center for Science and International Affairs, both at Harvard University, “War-Weary America's Little-Known Deterrent: Its Aging Population”, National Interest, 04-02-2020, https://nationalinterest.org/feature/war-weary-americas-little-known-deterrent-its-aging-population-140357)\\JM

The United States, like most countries in the world, is aging. According to the United Nations, roughly 15 percent of the U.S. population is older than sixty-five, which is the highest proportion in the country’s history. This percentage is forecasted to continue to grow, reaching nearly 28 percent by the end of the century. By 2050, the United States is expected to have more people over the age of sixty-five than under the age of twenty, which will be a historical first. Although many decry the domestic ramifications created by population aging, this demographic development has a major yet largely unrecognized international benefit: it significantly increases the likelihood of international peace, which is something my colleagues and I have observed. Public opinion and scholarly analyses of aging miss this major positive development. Generational polarization is at an all-time high, as the differences between age groups on numerous issues, including race, climate change, and party preferences, are stark. A 2015 survey funded by the American Association of Retired Persons and other organizations in the field of aging found that the majority of the U.S. public view the elderly as an “other” group that is engaged in a zero-sum competition with the rest of society for resources. Indeed, some studies have found that the very use of generational labels, especially that of “baby boomer,” stimulates negative stereotypes, nicely captured by the dismissive retort popular among members of younger groups: “OK, boomer.” Media and academic analyses of the aging population also appear to be negative, with most analyses concentrating on the population’s likely major domestic costs. Additionally, much attention has been paid to the potential slowing of economic growth and massive new public expenditures for elderly welfare. The international effects created by the shift from a younger to an older world are much more salutary. Countries with large numbers of young people (ages fifteen to twenty-four) as a percentage of the total adult population are more likely to engage in international hostilities than ones with older populations. With a surplus of military-aged citizens, soldiers are cheaper and easier to recruit and replace. Younger populations are also more easily radicalized, especially when the country is poorer with fewer economic opportunities. The reverse dynamics occur in older societies. In fact, aging tends to reduce both states’ capacity and willingness to go to war. As societies age, governments are likely to dedicate an increasing percentage of their budgets to spending on elderly welfare, which is likely to reduce expenditures in all other areas, including the amount of money it spends on the military. Moreover, with fewer military-age citizens, soldiers can demand higher salaries, making them more expensive to recruit and replace. Governments of older societies are therefore less likely to jeopardize their soldiers by engaging in conflict. At the same time, survey data across many generations clearly indicate that the elderly are significantly less supportive of war than are younger individuals. Consequently, as older-age cohorts become a larger percentage of a state’s population, the political pressure against international conflict is likely to increase. It is also important to recognize that while the U.S. population is aging, it is doing so at a slower pace than its main international rivals, China and Russia. For example, while the United States’ working-age population (ages fifteen to sixty-four) is forecasted to increase by 13 percent within the next thirty years, Russia’s is expected to decline by 23 percent and China’s by 18 percent. These very different demographic trajectories give the United States a substantial comparative advantage, both economically and militarily. The effects of aging across the great powers are therefore likely to inhibit the emergence of a dangerous “power transition” (that is when a rising power catches up to the existing leading power) between the United States and its chief international competitors. Studies have shown that the probability of international conflict grows when either the dominant country anticipates a power transition in favor of a rising state or states, or when such a transition actually takes place. By adding substantial support to the continuation of U.S. power superiority, global aging works against either outcome transpiring. It should be noted that immigration accounts for almost all of the United States’ forecasted population growth; if immigration rates are significantly reduced, so will the United States’ major demographic advantages compared to those of other great powers. Demography is not destiny, but it is an extremely powerful force. Because aging states are likely to be significantly less aggressive internationally than younger ones, the future of international relations is likely to be more peaceful than the past—an outcome all can celebrate.

#### Plan: The United States Federal Government should substantially increase prohibitions on anticompetitive business practices by presuming that biosimilar reverse payment settlements are anticompetitive

#### Case by case *Actavis* analysis is woefully inadequate at combatting pay for delay monopolization efforts in the status quo, only broad overhaul solves

Robin Feldman and Evan Frondorf, 2016, Feldman is the Harry and Lillian Hastings Professor of Law and Director of the Institute for Innovation Law, University of California Hastings College of the Law, Frondorf is a Research Fellow at the Institute for Innovation Law, University of California Hastings College of the Law, “Drug Wars: A New Generation of Generic Pharmaceutical Delay”, University of California, Hastings College of the Law UC Hastings Scholarship Repository, https://repository.uchastings.edu/cgi/viewcontent.cgi?article=2527&context=faculty\_scholarship

The strategic behaviors in the Hatch-Waxman arena are troubling from the perspective of the theoretical underpinnings of both patent and antitrust law. The patent concern traces back to the constitutional provision that frames all of patent law. From the activities that should be free to all and reserved to none, the patent system chooses to dedicate to some, for a limited period of time, the exclusive use of an innovation based on the theory that this exclusion will redound to the benefit of society.315 The bargain, however, is not unlimited. When the patent expires, everyone should be free to engage in those activities, returning to a competitive environment. HatchWaxman is intended to ensure the prompt return to a competitive environment at the end of the patent term, as well as to create incentives to weed out weak patent claims that are improperly keeping competitors out of the particular innovative space. Pharmaceutical company behavior that extends the period in which the company can hold off competition runs contrary to the patent bargain.

The behaviors described in this article also raise antitrust concerns, although those concerns are framed at a slightly different angle.316 As a general matter in antitrust doctrine, big is not bad; it is what you do with your size that matters.317 Thus, brand-name companies that have earned a monopoly in the market with their blockbuster drugs are targets of antitrust concern only when they attempt to extend their monopoly improperly by colluding with competitors or inappropriately suppressing competition. As scholarly works by this author and others have noted, agreements not to compete and activities that abuse the regulatory process to block competitors raise antitrust concerns.318 Thus, when pharmaceutical company behavior improperly delays or impedes the entry of generic competition, that behavior runs contrary to the open, competitive market environment for which antitrust law yearns.

The theoretical concerns translate into tangible damage to society as well. With patents, the legal system chooses to tolerate certain societal losses for the innovation effects that may result. When brand-name companies extend their monopoly power beyond the expiration of the patent, however, there are unanticipated deadweight losses to society in the form of higher prices. Whether Congress has chosen the optimal parameters for the patent system is a separate question. Once those parameters are set, behaviors that cause additional deadweight losses for society are contrary to the system’s incentive structure, and the damage to society should not be tolerated. The Hatch-Waxman manipulations also are damaging to society in the form of activities that are wasteful for companies and institutions alike. Hide-and-seek games that the courts, the FDA, the FTC, and the Patent and Trademark Office are forced to play are wasteful to all. The games are particularly burdensome on the court system, with pharmaceutical litigation over generic competition now joining patent troll litigation as a major component of new patent lawsuit filings.319 Sadly, given the amount of money at stake, the behaviors are likely to continue unless the legal system finds a way to change the incentives or to create sufficient disincentives. This is not to suggest that progress has been negligible. The shift from simple pay-fordelay agreements to side deals and then to micro-obstructions reflects the progress that regulatory agencies have begun to achieve in the courts. In addition, although micro-obstructions can create a valuable delay in competition, they are more difficult to achieve and often less lengthy than pay-fordelay.

Nevertheless, although the form of the behavior may have shifted, the behavior remains. And although changes such as the Supreme Court decision in Actavis and various congressional amendments have been important, by the time the changes are implemented, the market has moved beyond. The question is, what should come next.

The following discussion explores new directions for the legal system in its continuing efforts to alleviate the gamesmanship that the Hatch-Waxman system has wrought. The discussion is not intended to provide a blueprint for legislation or a description of specific doctrinal provisions. Rather, it is an attempt to suggest the contours of how new approaches could be structured, and to generate discussion of a shift in approach.

B. Systems, Simplification, Sunshine, and Standards-Based Doctrines

In addition to the approaches that have been undertaken so far, managing the evolution of the Hatch-Waxman games will require a systems approach. One could use an analogy from the medical field itself.320 Under the old approach to cancer treatment, physicians would attack a tumor by trying to reduce its size or deny substances that seemed to be feeding it. Modern medical research has suggested, however, that cancer treatment can be far more effective when using a systems approach. Specifically, tumors seem to operate in a networked or systems fashion. Cutting off one approach may simply lead the tumor to develop work-around approaches, and the new approaches may be even more dangerous and damaging than the original pathway. Thus, attacking the problem by trying to mitigate it when it emerges may be as outdated an approach for the patenting and approval of medicines as it is for treatments in which those medicines will be involved.321

Taking a systems approach may allow us to move away from what one of the authors has called death by tinkering—a problem endemic throughout the patent system.322 In this problematic approach, legal actors address difficult questions by adjusting the doctrines a little here and a little there without developing a comprehensive logic for the full breadth of the legal area. Eventually, the entire doctrinal base threatens to collapse under its own weight.

One can see a classic example of death by tinkering in the Federal Circuit’s failed attempts to create a workable rule for determining what types of inventions should qualify as patentable subject matter. For years, the court clung to its “machine-or-transformation” test, making ever finer distinctions to try to avoid uncomfortable results. In the end, the test required considerable hand waving, and one had to suspend a certain amount of disbelief to overlook the logical discrepancies.323 After a series of three cases gently encouraging the Federal Circuit to develop a workable test, the Supreme Court eventually gave up and supplied its own test.324

A similar phenomenon plagues the various doctrines related to whether the definition of an invention reaches beyond the state of the art at the time of the invention. Doctrines developed for mechanical inventions, in which one generally understands all aspects of the technology, have led to uncomfortable results for biologic inventions, in which many unknown factors may be at play. For example, when an invention is a doorknob, one generally understands the various parts and their operation. There are no unexplained pieces and no hints that the door frame may be integrating with the door in ways no one has dreamed.325 Such is not the case with biotechnology inventions, however, and in that realm, society grants rights in the face of significant unknowns.

Doctrinal rules that fit comfortably with mechanical inventions can lead to uncomfortable results in life science cases. Struggling with the problem, different Federal Circuit panels have created doctrinal rules that contradict each other and point in different theoretical directions.326 The rules reach what seem to be good results in each case, but at the expense of doctrinal coherence and the ability to predict the boundaries of patents going forward. The entire area now threatens to collapse. Doctrines related to defining an invention for purposes of comparing it to later inventions are clashing against doctrines related to defining the invention for purposes of comparing it to earlier inventions. Unless one is happy holding up a piece of fruit and declaring that looking in one direction, it is an apple, and looking in another direction, it is an orange, the doctrines are untenable.327

Therefore, the first step in a systems approach would involve focusing on the extent to which different systems interact in the process. These include not only the patent approval system, but also the patent litigation system,328 FDA approval systems—including the Orange Book, REMS, citizens petitions, and other FDA processes—and antitrust doctrines as they may apply to this arena. Effective progress will require working with all of these systems at the same time, lest adjustments to one area lead to counteraction in another. With thirty years of Hatch-Waxman experience, it is time to consider a comprehensive overhaul of the system for generic approval, one that looks more broadly at the interaction of all of the systems.

The second step is to ruthlessly simplify. For those who value complexity, the Hatch-Waxman system is a garden of delights. Complexity breeds opportunity, however, and, in the case of Hatch-Waxman, the Act’s complexity has spawned opportunities for manipulation. An overhaul of the Hatch-Waxman system that resulted in equivalent or even greater complexity would serve little purpose, other than as a full employment act for lawyers. In contrast, a simplified, slimmed-down system would provide fewer opportunities for clever gamesmanship.

From this perspective, the 2009 Biologics Price Competition and Innovation Act (“BPCIA,” also commonly known as the “Biologics Act”) is not encouraging. The legislation was intended to provide a pathway for swift approval of biosimilars, or what could be called generic biologic drugs, in the same way that Hatch-Waxman provided a speedier pathway for ordinary generic drugs. Biologics are complex cell-derived drugs that include antibodies that fight autoimmune diseases and proteins that boost white blood cell counts during chemotherapy. The Biologics Act, however, is even more complex and convoluted than Hatch-Waxman and seems designed on entirely the wrong template.329 It took until September 2015—six years after the act’s passage—for the first biosimilar to reach the market.330 Simplification is not the instinct of lawyers in general nor of patent lawyers in particular. Lawyers are trained to see the nuances in any circumstance and may wish to keep options open for whatever their clients need. Moreover, the patent bar has never been accused of an attraction to exorbitant simplicity. Overcoming these instincts, which are deeply imbedded in the habits of patent stakeholders, will be an essential component of designing a more effective system.

The third step is to let the sun shine in. Both markets and regulators work best when information is fully available—information that invites competition where competition is needed and exposes behavior that regulators can challenge. Moreover, in a world of instant communication, information plays a powerful role in disciplining behavior. Information in pharmaceutical deals and pricing is increasingly segmented, however, and hidden from key players in the industry—whether those players are competitors, regulators, or consumers.

In particular, pharmaceutical pricing is not necessarily drug-specific anymore. Rather, pharmaceutical benefit managers, known as “PBMs,” negotiate the prices for the vast majority of commercially insured drug purchases.331 In other words, PBMs are third-party intermediaries that negotiate drug prices between payers and others. This frequently results in bundled drug pricing, tucked into which may be pricing that reaps supracompetitive rewards or blocks generic competition. For example, a drug company could offer attractive discounts on one drug in exchange for pricing or listing practices that block competition where prices are elevated or competition would be a greater threat.

None of this information is available, either to the market or to regulators. The pharmaceutical ecosystem would benefit tremendously from sunshine rules that require disclosure of PBM pricing deals and rebates. This is not to suggest regulation of pricing, but rather to provide the information that markets and regulators need for efficient functioning.

A fourth step would be to move away from the Supreme Court’s rule of reason analysis for pharmaceutical deals that involve generics. Despite the opening that the Supreme Court created in Actavis, the lower courts largely have been unable or unwilling to walk through it. The burden remains too great for anyone to bear. Rather, with deals involving generic entry, Congress should place the burden on those making the deals to show that they are proper.332 The taint of anticompetitive behavior is too strong throughout these arrangements, and the extent to which these deals undermine HatchWaxman’s intent to introduce generics early and often is too great. One who creates complexity, and the resultant capacity to hide behind that complexity, should have the burden to demonstrate that the effects are justifiable. The most important step, however, is to make more liberal use of standards-based legal doctrines. The Hatch-Waxman system and its various amendments have tended to focus on precise and particularized legal rules. Brand-name drug companies are forbidden from receiving more than one thirty-month stay; the FDA must take final action on a citizen petition in 150 days.

Some fixes have leaned toward the standards approach. For example, the FDA’s ability to deny a citizen petition at any time if it believes a petition was “submitted with the primary purpose of delaying the approval of an application” is an excellent standards-based approach. The amendment granting that power, however, goes on to require that the “petition does not on its face raise valid scientific or regulatory issues,”333 a provision that moves back toward the realm of rule-based approaches. A classic standards-based approach can be found in the tax code’s step transaction doctrine. The doctrine allows tax authorities to collapse all the steps of a transaction together if the authority deems that they are part of an overall plan by the taxpayer.334 The doctrine is aimed at ensuring that taxpayers may not avoid legal restrictions by taking individual steps or a circuitous route.335 A more liberal use of this type of standards-based approach could give courts and regulators the latitude to shut down strategic behavior, as opposed to playing cat and mouse across the regulatory provisions.

#### Only federal action solves, state and local solutions are preempted on pro-competition grounds

Samp 14, Richard A. Samp, Chief Counsel of the Washington Legal Foundation, The Role of State Antitrust Law in the Aftermath of Actavis, 15 MINN. J.L. SCI. & TECH. 149 (2014).

Those holdings suggest some limits on the extent to which states should be permitted to impose antitrust liability on companies that enter into reverse payment drug patent settlements. In particular, any state-law liability is preempted to the extent that it would upset the balance between federal antitrust law and patent law established by Actavis because such liability would “stand[ ] as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.”73

V. ACTAVIS’S PREEMPTIVE EFFECT

Application of state antitrust law to reverse payment settlements is not merely a hypothetical possibility. There are a fair number of pending lawsuits that challenge reverse payment settlements on state-law grounds. The California Supreme Court has agreed to review one such suit.74 In seeking affirmance of the appeals court’s dismissal of the suit, the defendants argue inter alia that the suit is preempted by federal law.75

As noted above, there is precedent for a finding that state antitrust law is preempted to the extent that it conflicts with the policy underlying a federal statute.76 Moreover, in the context of patent law, federal courts have not hesitated to preempt state laws that the courts deem to stand as an obstacle to accomplishing Congress’s objectives (i.e., encouraging efforts to develop new and useful products).77 To the extent that any portions of Actavis’s holding can be deemed to reflect the Court’s perception of Congress’s new-product development objectives, a state law is preempted if it is inconsistent with that holding and seeks to impose a greater degree of antitrust liability on the parties to a reverse payment settlement.

Actavis’s treatment of settlements involving a compromise entry date appears to meet that description. Actavis held that federal antitrust liability could not arise from a settlement in which the generic manufacturer agrees not compete for a number of years and in return is rewarded with an exclusive license to market its product several years in advance of the patent’s expiration date.78 Accordingly, states are not permitted to impose antitrust liability under similar circumstances because doing so would upset the balance that, according to Actavis, Congress sought to achieve between antitrust and patent law.

Other issues left open by Actavis are likely to be answered in the years ahead. For example, the Supreme Court did not specify whether noncash benefits received by a generic manufacturer in connection with a patent settlement can ever serve as the basis for federal antitrust liability. If the Supreme Court eventually answers that question by stating: “No, federal antitrust law will not examine settlement benefits other than cash that flow to the infringing party,” then it is likely that state antitrust law would be required to conform to that rule. The potential grounds for such a ruling (a desire both to promote settlement of patent disputes and to uphold reliance interests in existing patents) are based largely on values embedded in federal patent law.

There is little reason to believe, however, that the Court would prevent application of state antitrust law to patent settlement agreements where state law is fully consistent with federal antitrust law. Even in areas subject to extensive federal regulation, the Supreme Court has upheld the authority of states to engage in parallel regulation that is not inconsistent with the federal regulation.79 Unless the Court were to determine, as in Connell,80 that states could not be trusted to properly accommodate the objectives of the federal statute at issue (here, federal patent law), there is no reason to conclude that Congress would not have wanted states to be permitted to police the same sorts of anticompetitive conduct that is policed by federal antitrust law. Moreover, states are likely free to impose greater penalties on the proscribed conduct than is available under federal law. As the Court explained in California v. ARC America Corp., state antitrust law is not required to adhere to the same set of sanctions imposed by federal antitrust law.81

It seems reasonably clear, however, that Actavis prohibits states from adopting the procedural devices rejected by the U.S. Supreme Court—either a per se condemnation of reverse payment settlements or a presumption of illegality accompanied by “quick look” review. The Supreme Court rejected those approaches because it determined that in many cases there might well be pro-competitive economic justifications for reverse payment settlements and that presuming their illegality could result in the suppression of economically useful conduct.82 State antitrust laws that adopted the FTC’s proposed presumption of illegality would be subject to similar criticism, and thus would likely be impliedly preempted as inconsistent with the careful balance between antitrust and patent law established by Actavis

# 2AC

## Case

## 2AC – T Private Sector

#### Counter-Interp:

#### The private sector is an industry

The Law Dictionary, No Date [The Law Dictionary: Featuring Black's Law Dictionary Free Online Legal Dictionary 2nd Ed. “Private Sector” , <https://thelawdictionary.org/private-sector/>; date accessed 11/11/21]

What is PRIVATE SECTOR?

An industry that is composed of private companies. The corporate sector and the personal sector are encompassed in the private sector and they are responsible for the allocation of the majority of resources within the economy.

#### The private sector includes subsets

Waler and Hofstetter 16 [Katharina, Advisor for vocational skills development and Helvetas’ youth focal person and Sonja, joined Swiss contact in Cambodia in July 2016. She is the Quality Assurance Manager and Deputy Team Leader of the Skills Development Programme; “ Study on Agricultural Technical and Vocational Education and Training (ATVET) in Developing Countries” January, 25, 2016, Federal Department of Foreign Affairs FDFA, Swiss Agency for Development and Cooperation SDC, Global Programme Food Security; <https://www.shareweb.ch/site/Agriculture-and-Food-Security/focusareas/Documents/ras_capex_ATVET_Study_2016.pdf> , date accessed 11/11/21]

In many developing countries, the private sector1 [[BEGIN FOOTNOTE 1]] 1 The private sector is not perceived as a homogenous mass even though the terminology might suggest this to be the case. In this study, the term “private sector” is used to circumscribe the various actors such as small and medium sized companies, large companies, sectorial associations, business associations, chambers of commerce, etc.[[END FOOTNOTE 1]] faces challenges in finding adequately skilled employees. This also holds true for sectors linked to agriculture, e.g. processing, distribution, marketing, etc. The development of ATVET from a purely productivity-oriented approach to provide broader and more specialised skills sets along agricultural value chains is likely to raise the interest of private sector actors. This incentive can result in a stronger and more sustainable financial and conceptual engagement of employers in ATVET.

## 2AC – Guidance CP

#### 6. Guidance fails:

#### a. Delay and struck down by Courts

Baer 20 [Bill Baer Visiting Fellow The Brookings Institution, JD from Stanford Law School, served as Assistant Attorney General in charge of the Antitrust Division of the US Department of Justice from 2013 to 2016, and as Director of the Bureau of Competition at the Federal Trade Commission from 1995 to 1999, 10-1-2020 https://docs.house.gov/meetings/JU/JU05/20201001/111072/HHRG-116-JU05-Wstate-BaerW-20201001.pdf]

So where do we go from here? One strategy has the antitrust enforcers developing new policy guidance in areas such as vertical mergers, standard essential patents, and high tech platforms to nudge the courts towards a less skeptical view of the need for assertive enforcement. The joint DOJ/FTC Horizontal Merger Guidelines have, as I noted earlier, over time increasingly been relied on by the courts as providing a framework for determining whether the combination of two rivals risks harm to consumers and to competition.

There are at least two reasons to doubt whether reliance on that strategy will be sufficient. First, it took years for the courts to embrace the soundness of the merger guidelines—indeed more than a decade. Can we afford to wait that long? Second, there is no guarantee that the courts will embrace that new guidance. The mindset that antitrust enforcers are more likely to be wrong than right, and that as a result, we should at all costs avoid the risk of over-enforcement, is pretty well-entrenched in antitrust jurisprudence. Absent some further direction from Congress, those biases are unlikely to change.

#### b. Judicial interpretations worse

Baer 20 [Bill Baer former visiting fellow in governance studies at The Brookings Institution and assistant attorney general of the Antitrust Division and as the acting associate attorney general of the U.S. Department of Justice, 11-19-2020 https://equitablegrowth.org/research-paper/restoring-competition-in-the-united-states/?longform=true]

The meaning of the antitrust laws rests first with Congress, as does their importance, which is reflected in yearly appropriations. Judicial interpretations have eviscerated competition enforcement. Courts have failed to appreciate the benefits of competition and have underestimated the harm of anticompetitive conduct. They have overestimated the ability of markets to correct themselves without proper antitrust enforcement. And they have even praised the benefits of monopoly.5 Too often, the resulting legal standards allow anticompetitive conduct to escape condemnation. At the same time that the courts have made it harder for antitrust enforcers to win meritorious antitrust cases, Congress has provided the enforcers fewer resources to do their jobs.

## 2AC – States CP

#### Counterplan gets struck down---*Actavis* established per se bans and presumptively illegality were protected by congress’ pro-competition legislation --- that’s SAMP

#### **CP gets struck down by BPCIA field preemption, it’s *distinct* from generic patent law claims**

Vaseliou 19, Thomas Vaseliou is the Articles Editor of the University of Pennsylvania La Review, and has JD from the University of Pennsylvania Law School, “Trolls & The Preemption Dilemma”, University of Pennsylvania Law Review, Volume 167, 2019

For the first time in late 2017, the Federal Circuit used field preemption to invalidate a state unfair-competition law. In Amgen Inc. v. Sandoz Inc., the Federal Circuit held that the Biologics Price Competition and Innovation Act (BPCIA) preempted the state-law claims because the BPCIA was a “comprehensive, carefully calibrated scheme” that “left no room for the States to supplement it.”190 The field-preemption-causing conflict, the Court argued, was the different “available remedies between federal and state law.”191 The field wasn’t patent law generally but specifically biosimilar patent litigation.192 Alternatively, the court concluded that there was also conflict preemption.193

#### **California’s AB 824 struck a balance between pharma and consumers with presumptive illegality of pay for delay agreements BUT will be struck down on preemption grounds now. Only the aff federalizes that process in antitrust litigation.**

Marmaro 21, Morgan Marmaro is the Editor in Chief of Columbia Journal of Law and Social Problems and has a JD from Columbia Law School, "Molecule Size Doesn't Matter: The Case for Harmonizing Antitrust Treatment of Pay-for-Delay Agreements," Columbia Journal of Law and Social Problems 54, no. 2 (Winter 2021): 169-218

While the generic industry has challenged AB 824 on the basis of federal preemption, due process, and dormant commerce clause concerns, 245 the challenges have not been successful and would be further blunted were a federal version of the law created. The new California law provides clarity for lower courts and requires drug companies to produce evidence often concealed under claims of privilege. By providing clear guidelines and preventing judicial "shortcuts" that presume untested patents to be valid and infringed, courts will be less likely to prolong judicial proceedings and dismiss meritorious challenges to anticompetitive agreements. It also reduces the waste of judicial resources analyzing irrelevant factors - such as whether a drug falls under the Hatch-Waxman Act or the BPCIA.

AB 824 achieves this goal in three main ways. First, AB 824 clarifies that for antitrust regulatory purposes, biologic drugs should be treated the same as small molecule drugs. 246 Second, to protect against over-regulation, it provides robust exceptions so that permissible settlement agreements, including those with significant payments that are shown to be procompetitive, will not be subject to expensive litigation. 247 Third, it adjusts burdens of proof in accordance with the directions of the California Supreme Court in In re Cipro Cases I & II to reduce gamesmanship that unduly defeats meaningful enforcement actions. By focusing on payment as "anything of value," AB 824 "allows courts to avoid the 'turducken' 249 approach of 'deciding a patent case within an antitrust case about the settlement of the patent case."' 250 More importantly, it permits government enforcers to bring suits based on the existence of some consideration, without first having to show that the payments are "large" and "unjustified" to survive a motion to dismiss. Instead, AB 824 relies on defendants to justify the size and amount of the consideration provided in exchange for its rival's agreement to delay competition. 251 This aligns the proof with the parties possessing the evidence, thereby reducing the incentives of companies to these agreements to withhold evidence and defeat enforcement actions. AB 824 also incentivizes companies to maintain proper records for settlement purposes.

Lastly, by creating a burden shifting scheme, the law allows all parties to faithfully investigate any suspicious settlement arrangements, while still giving plenty of space for companies to settle disputes legally with reasonable or no payments. However, it does create a rebuttable presumption where payments are present, and also provides a presumption that the relevant product markets are the relevant branded drug and any biosimilar or generic versions to prevent dilatory and wasteful litigation on what is usually a foregone conclusion. 252 While some drug companies have argued that the presumptions will prevent them from settling patent litigation, 253 the law clearly allows them to settle without making excessive payments, and also to settle in any way in which they can demonstrate is procompetitive. 254

As U.S. drug prices continue to soar, even for drugs that have been patented for almost a century and whose original patents have long since expired, it is clear that the system needs updating. The In re Humira litigation, which examines reverse payments that artificially extend a biologic brand drug exclusivity period and that divide markets between biosimilar competitors on a continental basis, is a prime opportunity to strengthen and clarify U.S. jurisprudence on reverse payments and market allocations. Not only can biologic drug regulation be brought into line with small molecule drugs, but the case provides a critical opening to resolve the conflicting legal treatment of reverse payments and what constitutes a payment or a transfer of value. It demonstrates that the regulatory pathway to approval does not diminish the opportunities for anticompetitive abuse, nor is it dispositive in determining levels of antitrust scrutiny. At its core, reverse payment case law is about improperly inducing rivals not to compete - manufacturing method be damned. By clarifying the law through legislation in this complicated area, the risks of decisions that fail to apply existing law such as in In re Humira might be avoided as well.

## 2AC – PTX

#### 1. Won’t Pass – Manchin Hasn’t Agreed to Anything, Progressives will fight revisions, Time is running out, and Nominations and Shutdown Thump

LEBER 1/21 (Rebecca; Vox, “Democrats may have to sacrifice something big for the climate,” <https://www.vox.com/2022/1/21/22892382/joe-manchin-climate-change-biden-negotiations-bbb>, //pa-ww)

Historic climate legislation may still have a chance. Success now hinges on Democrats, once and for all, figuring out exactly what it is Sen. Joe Manchin (D-WV) wants to bring him back to the negotiating table to pass a version of the Build Back Better Act. The party is running out of time to deliver on climate change, but first they need to find a break in the frozen talks. When Democrats took control of the Senate a year ago, they had a mandate to ensure the United States would accelerate a transition away from fossil fuels and to avoid the worst effects of climate change. Without legislation, they underdeliver to a political base worried about the climate, a constituency they are counting on turning out in the midterms. Though the original Build Back Better Act is now dead, Congress still may have a shot at passing a bill to fund $550 billion for implementing clean energy incentives, funding electric vehicles and charging stations, instituting a fee on methane pollution, and helping the most vulnerable communities facing climate disasters. On the eve of his one-year anniversary as president, Biden laid out one last path forward to breaking the Senate stalemate on the original bill. “It’s clear to me ... that we’re going to have to probably break it up,” Biden told reporters at a press conference Wednesday. “I’ve been talking to a number of my colleagues on the Hill — I think it’s clear that we would be able to get support for the $500-plus billion for energy and the environmental issues that are there.” There’s still more wrangling ahead to get Manchin’s support, but the Senate is up against a clock that’s ticking down until the midterms. The Senate doesn’t have forever to figure this out or start from scratch, because it also has to confirm nominees to the administration and avert a government shutdown in February. His vote, along with that of every other Democratic senator, is required to pass it using the reconciliation process, which lets Democrats bypass the Republican filibuster. Manchin has said much work still lies ahead. On Thursday, he told CNN congressional correspondent Manu Raju, “We will just be starting from scratch. The main thing we need to do is take care of the inflation. Get your financial house in order. Get a tax code that works and take care of the pharmaceuticals that are [gouging] the people with high prices. We can fix that. We can do a lot of good things.” Biden suggested Democrats could reach a deal with Manchin and the other holdout, Sen. Kyrsten Sinema (D-AZ), with a slimmed-down version of Build Back Better, possibly by cutting back on the child tax credit and free community college. Importantly, Biden said that even with concessions to Manchin, they could preserve the climate provisions. Then Democrats might take another shot at passing these other priorities later this year. For once, there’s surprising agreement from Democratic leaders that the climate priorities won’t be what are sacrificed in any dealmaking ahead. Biden has been firm on that, and Manchin himself said a few weeks ago, “The climate thing is one that we probably can come to an agreement much easier than anything else. There’s a lot of good things in there.” Other senators have rallied around the imperative that the US not spend another decade delaying billions in clean energy funds and climate adaptation. “I just came off the worst year ever on my farm,” Sen. Jon Tester (D-MT) said. “We need to do something on climate change. I think we spent $144 billion this year on disasters, and I don’t think that included crop insurance. So we need to do something on climate, too.” There is no deal yet on what this slimmed-down BBB would look like, nor has Manchin suggested what he could agree to. And some pieces on climate change could still be cut: Manchin has criticized some provisions of the House bill, like a methane fee on gas producers responsible for excess pollution and tax credits that favor union-made electric vehicles. But much of the work of negotiating a climate agreement has already been done. “There’s already been tough choices and compromise to get to to a place where 50 US senators and the president support the climate provisions,” said Jamal Raad, executive director of Evergreen, a climate group that has been advising Democrats on the legislation. The biggest compromise was cutting out the single most impactful climate policy in the House bill, a clean electricity standard that required utilities to meet benchmarks for wind and solar adoption. The remaining climate policies include $320 billion to finance clean energy adoption nationwide. These tax credits are already priced out for the decade, meeting one of Manchin’s demands to account for the 10-year cost of proposals in the package. Biden and congressional Democrats have hard decisions ahead. If Manchin is still negotiating in good faith, proposals will be on the chopping block. The tall order is getting every Democratic senator to come around to the idea that something will have to give to break through this logjam. “We’re just too close to striking a deal on this transformative climate investment,” Raad said. “We need to find the biggest, most aggressive Build Back Better bill that we can pass, taking the climate provisions with whatever we can agree to on the health care side, and we need to get this done.” More Senate Democrats have said this week they are open to giving Manchin what he wants to see this done. “We need to move to pass a package now that has 50 votes,” Sen. Edward Markey (D-MA) told Axios. “The climate, justice and clean-energy provisions in Build Back Better have been largely worked through and financed, so let’s start there and add any of the other important provisions to support working families that can meet the 50-vote threshold.” For progressive Democrats, following Biden’s suggestion to break down the bill is a hard pill to swallow. That requires choosing among proposals that would all help different American communities. As the Atlantic’s Rob Meyer explained last week: “The greatest risk of all is that Democrats continue to procrastinate. It’s easier, after all, to wheedle Manchin than it is to pick a favorite among favorite proposals.” There’s also the chance that Manchin is not negotiating in good faith, and really does want to poison the bill by starting from scratch and tackling the national debt first. In that scenario, the decisions would be even harder. With the legislative path closed for climate action, activists would want to see Biden gamble on aggressive executive actions to address rising oil production and push clean energy, risking court interference. Democrats can’t count on Republican votes for climate action, but the agency budgetmaking process can still be an opportunity to advance climate policies (this still requires bipartisan support). So it isn’t just Biden and Democratic lawmakers who have hard choices ahead. Climate activists have also grown tired of seeing their demands shrink to a place where Manchin could support them. “We should pass climate legislation immediately, but we need to do so much more than that if we want young people across our country to have any faith in Democrats or our government going forward,” said Varshini Prakash, Sunrise Movement’s executive director.

#### 2. Manchin will water down the climate provisions

FRAZIN 1/23 (Rachel; The Hill, “Biden comments add momentum to spending bill's climate measures,” <https://thehill.com/policy/healthcare/590871-biden-comments-add-momentum-to-spending-bills-climate-measures>, //pa-ww)

Manchin earlier this month said that climate is an area “we probably can come to an agreement much easier than anything else” and specifically touted clean energy tax credits. Not all of the climate change provisions are settled, though. Manchin actively opposes a tax credit for union-built electric vehicles and negotiations are continuing over a program aimed at cutting releases of a powerful planet-warming gas called methane from the oil and gas industry. Senate Environment and Public Works Committee Chairman Tom Carper (D-Del.) told reporters that he would fight to get the methane proposal done. “We're going to get a methane emissions reduction program going. We're going to get it done,” he said. “We worked very hard with Sen. Manchin and his team and others — other stakeholders — to come up with a good plan ... and by golly, we're going to get it done. Sooner rather than later.” A lobbyist following the negotiations who requested anonymity to speak freely said they believe that Biden’s comments put extra attention on areas that aren’t totally resolved, including the methane program. “It does put a higher scrutiny on anything ... where the ink isn't dry,” the person said.

#### 3. Breyer Thumps

DATOC 1/27 (Christian; Washington Examiner, “Breyer retirement could be another Build Back Better roadblock,” <https://www.washingtonexaminer.com/news/white-house/breyer-retirement-could-be-another-build-back-better-roadblock>, //pa-ww)

Supreme Court Justice Stephen Breyer's pending retirement presents President Joe Biden a chance to salvage his public approval, but it also complicates chances of passing a scaled-down version of his Build Back Better spending bill before the midterm elections. Breyer's retirement, which could be formally announced as early as Thursday, allows Biden to make good on a major campaign promise: nominating the first black woman to serve on the nation's highest court. White House press secretary Jen Psaki declined to offer any additional details on possible nominees or a timeline for putting names forward, but she affirmed at Wednesday's press briefing that Biden would stand by his pledge. "The president has stated and reiterated his commitment to nominating a black woman to the Supreme Court and certainly stands by that," she told reporters. "For today, again, I'm just not going to be able to say anything about any specifics until, of course, Justice Breyer makes any announcement, should he decide to make an announcement." Black Americans' perceptions of the president fell more than 20 points during his first year in office, with the latest poll from Quinnipiac finding just 57% approved of his job performance in mid-January. That could largely be attributed to Biden's repeated failures to usher two voting bills, the Freedom to Vote Act and John Lewis Voting Rights Act, through the Senate. Additionally, a new poll from the Republican State Leadership Committee and Cygnal found generic, down-ballot Republicans currently leading Democrats by 6 points among the electorate as a whole ahead of the midterm elections. Breyer is expected to stay on through the end of the current Supreme Court term this summer. The White House is likely to nominate a replacement shortly after that, but the confirmation process will eat up much of 2022's legislative calendar as Democrats prioritize Biden's nominee while they still hold a slim majority in the Senate. The White House and Senate Majority Leader Chuck Schumer will need to work overtime to ensure centrist Democratic Sens. Joe Manchin of West Virginia and Kyrsten Sinema of Arizona, the two obstacles to Biden's social spending legislation, filibuster reform, and voting rights legislation stick with the party. However, unlike legislation, judicial nominees only require simple majority votes to be confirmed. Still, senior Democratic officials told the Washington Examiner that even before the Breyer news, it would have taken weeks for the White House to relaunch a serious third round of Build Back Better negotiations with lawmakers. Furthermore, the opportunity to work with Republicans on passing some Build Back Better provisions, such as extending the expanded child tax credit, as stand-alone bills could die if Biden eventually nominates someone Republicans deem "too liberal" to the court, one senior GOP aide said. Missouri Republican Sen. Josh Hawley, one of the few GOP lawmakers who voiced some approval for a few of Biden's family-centered spending proposals in 2021, drew a clear line in his first reaction to Breyer's retirement. "Moment of truth for Joe Biden. Will this deeply unpopular & divisive president finally reject the radical elements of his party and nominate someone who loves America and believes in the Constitution? Or will he continue to tear apart this country w/ a woke activist?" he wrote. "If he chooses to nominate a left wing activist who will bless his campaign against parents, his abuse of the FBI, his refusal to enforce our immigration laws, and his lawless vaccine mandates, expect a major battle in the Senate." Senate Minority Leader Mitch McConnell declined to offer an initial comment. "We don’t even know who the nominee is yet, so that’s something the president has an opportunity to make, and Justice Breyer will determine when and if there’s a vacancy," he told reporters in Bowling Green on Wednesday. Republican senators will also likely seek to turn the confirmation hearings for whoever Biden nominates into a public spectacle. One senior GOP aide pointed to the confirmation hearings for Supreme Court Justices Amy Coney Barrett and Brett Kavanaugh as examples of what type of questions to expect from Republicans. Another GOP aide cited the confirmation for Justice Clarence Thomas, which Biden, then-chairman of the Senate Judiciary Committee, presided over himself in 1991. During those nearly 24 hours of questioning, Biden zeroed in on Thomas's views on "natural law" and sexual harassment allegations raised by lawyer Anita Hill.

#### 4. Climate Bill inevitable – GOP will get on board post-Midterms

TEIRSTEIN 1/21 (Zoya; Staff Writer – Grist, “f Build Back Better fails, federal climate policy may depend on Republican cooperation,” <https://grist.org/politics/if-build-back-better-fails-federal-climate-policy-may-depend-on-republican-cooperation/>, //pa-ww)

Democrats are blowing the best shot they’ve had to pass a climate bill in a decade. That opportunity lies in the Build Back Better Act, or BBB, a sweeping “soft infrastructure” bill that contains about half a trillion dollars in climate funding. Democrats hoped they could pass the bill via the budget reconciliation process — a Senate procedure that allows the majority party to circumvent minority party opposition and pass legislation that pertains to the budget with 50 votes instead of 60 votes. The bill hit a wall when Democratic Senator Joe Manchin announced that he opposes it. With even one member of their caucus opposed, Senate Democrats can’t move forward with Build Back Better or any other major agenda item on President Joe Biden’s long list of presidential priorities. But Manchin isn’t against all of BBB, only certain parts of it. He hasn’t taken issue with the climate parts of the bill, which Democrats already watered down to appeal to his fossil fuel–friendly tastes. This week, Democratic leadership started thinking seriously about moving forward with BBB by breaking it up into pieces. “I’ve been talking to a number of my colleagues on the Hill,” Biden said at a press conference on Wednesday. “I think it’s clear that we would be able to get support for the $500 billion plus for energy and the environment.” A funny thing happens when you separate out the $500 billion climate portion of the Build Back Better Act from the rest of the package: It starts to look a lot like the kind of climate plan Republicans say they support. Even a few years ago, it would have been hard to imagine Republicans supporting a federal climate plan. The Republican party has eschewed climate action since the 1980s, when oil companies started lobbying Republican lawmakers to vote against climate legislation and making hefty financial contributions to the campaigns of politicians who ran on anti-environmental regulation platforms. But recently, some Republican politicians have realized that their hard line on climate change is alienating portions of their voter base, especially younger Republicans who are beginning to sound a lot like Democrats when it comes to this issue specifically. The physical impacts of climate change have become harder to ignore, and Republicans fear being left behind. “We should be a little nervous,” House Minority Leader Kevin McCarthy said at a political conference in 2019. Progressive Democrats in Congress whipped up a media and activist frenzy when they started touting the benefits of an economy-wide climate and justice plan called the Green New Deal earlier that year. What did Republicans have to tout? Nothing — lawmakers from their party were busy holding press conferences about why the existence of photosynthesis discredits climate change. So some Republicans have been trying to show voters that they’ve turned a new leaf on climate change. They’ve stopped denying the reality of the issue and started to drum up conservative solutions to it instead, ones that they say focus exclusively on emissions — not the “laundry list” of progressive objectives Democrats want to accomplish. Republican Senator Mike Braun of Indiana serves as the co-chair of the Senate Conservative Climate Caucus, which was formed in 2019, and championed a green agriculture bill that passed the Senate last year. Senator Lisa Murkowski of Alaska introduced climate legislation focused on sequestering carbon dioxide in oceans and has been reaching across the aisle to fund clean energy research and development. A cadre of House Republicans unveiled a swath of climate-related bills in 2020. There is clearly an appetite for modest climate action on the right that didn’t exist just a few years ago. What’s more, there’s actually quite a bit of overlap between Democrats’ climate plan in the BBB and Republicans’ preferred ways of fighting climate change. Democrats have been finessing the contours of their climate agenda for months, converting a transformative plan to decarbonize the nation’s power sector into a middle-of-the-road, don’t-rock-the-boat suite of incremental actions that jibe with Manchin’s centrist sensibilities. The bill contains $300 billion in clean energy tax credits, but those credits are technology neutral, so they can be applied toward nuclear energy, hydropower, and geothermal energy, all of which Republicans like because they say they’re more established than solar and wind power and have a proven track record of reliability. The bill also contains funding for capping abandoned oil wells, a method of cutting down on methane emissions that has been embraced in several Republican-led states, and money for advanced battery technology that looks similar to bills House Republicans recently introduced. “Certainly on the policy, there’s nothing in the bill that is inherently partisan, and Republicans have supported some similar things at the state level,” said Matt Grossmann, professor of political science and public policy at Michigan State University, referring to the climate portion of the Build Back Better act. Quillan Robinson, a conservative and director of government affairs at the free-market environmental group the American Conservation Coalition, agreed that there are areas of overlap. “Republicans have pushed very hard against Build Back Better,” he said. “But in terms of some of the specific things in there, there are things Republicans and Democrats can agree on, absolutely,” Robinson added. “There’s probably a whole host of things from potentially clean energy tax credits to investment in things like geothermal that Republicans have and probably will continue to support.” But even though Republicans might theoretically get behind the contents of the climate portion of the Build Back Better Act, that doesn’t mean they’ll be voting for a new version of the package anytime soon. Indeed, this week the New York Times asked all 50 Republican members of the Senate if they would support just the climate portions of the bill, and none of them said yes. That’s in part because the Build Back Better Act was never meant to be a bipartisan piece of legislation — Democrats aimed to pass it without Republicans via the budget reconciliation process. So Republicans, who were locked out of negotiations on this bill, aren’t going to be particularly keen to jump on board now and salvage what’s left of it. Bob Inglis, a former Republican representative from South Carolina who lost his seat after he came out in support of a tax on carbon emissions, said some Republicans might be able to support “a free-standing bill that expands tax credits for wind, solar, batteries, geothermal and electric cars, that aids nuclear power plants at risk of premature closure and that incentivizes carbon capture and storage.” If Republicans and Democrats are able to come together on climate change, it will be for a separate, fully rebranded bill that includes Republicans from the beginning. “It would need to be billed as a new effort to do something rather than ‘we’re trying to do the climate parts of Build Back Better,” Grossmann said. A spokesperson for Representative John Curtis, Republican from Utah, emphasized the nonviability of any legislation that resembles the Build Back Better Act in a comment to Grist. “We have had no input in BBB,” the spokesperson said, “but Congressman Curtis is working with his colleagues on bipartisan climate legislation.” If Republicans do come to the table on climate change, it likely won’t be this Congress, because there’s little political incentive for the party to work with Democrats now. The 2022 midterm elections are rapidly approaching, and Republicans are favored to take back the House and possibly the Senate, too. “If you’re the party that stands the chance of gaining the majority, it doesn’t make sense to help the majority party do something when you can do it next Congress your way,” Grossmann said. In other words: Republicans’ hostility to the Democratic agenda is clearly stronger than their desire to take action to slow down climate change. But Grossmann thinks it’s possible that some Republicans could be willing to work with Democrats in the next Congress. It’s happened before — Republicans and Democrats worked together in a divided Congress to pass the American Energy Innovation Act in 2020, a comprehensive energy bill. And 19 Republicans voted with Democrats to pass Biden’s $1.2 trillion infrastructure bill last fall. “It’s not like it’s some yesteryear period in which we’ve had bipartisan legislation; we had it quite recently,” Grossmann said. “Next year at this time, it could be the case that a gang of senators could move forward with a set of bipartisan energy proposals that would look not that much different from the ones in Build Back Better.” In the interim, Grossmann hasn’t given up on the possibility of a smaller, Manchin-approved climate bill hitting the Senate floor. Such a bill would still bypass Republicans and get passed via a simple Democratic majority. “There’s a lot of agreement on the table and it would be sort of crazy for that agreement to not result in something,” he said. “Usually, when there’s enough agreement to pass something that’s better than the status quo, eventually you get to that agreement.” Whether Democrats are able to create and pass such a bill before the 2022 midterms remains to be seen. If they can’t, the success of a federal climate policy may depend on Republican lawmakers putting their votes where their mouths are.

#### 5. XOs Solve

COLE 1/26 (Brendan; Newsweek, “Pramila Jayapal Urges Executive Action To Get Build Back Better Over the Line,” <https://www.newsweek.com/pramila-jayapal-urges-biden-executive-action-build-back-better-bill-update-1673131>, //pa-ww)

Pramila Jayapal has said some goals of the Build Back Better bill, such as drug pricing and climate change, could be achieved through executive action. The Representative for Washington, the leader of the House Progressive Caucus, rejected calls to immediately splinter off climate change elements of the much-delayed $1.75 trillion BBB package in an effort to get it passed. Jayapal also told Newsweek that the landmark spending bill was the focus for the Democratic Party for the next few weeks, now that voting rights legislation had stalled. She said the goal "for the next four weeks" was to get as many of BBB's goals "as we can into a bill that passes the Senate. We only get one shot because it's reconciliation that is required." Reconciliation allows legislation to be passed with a straight majority, in this case requiring all 50 senators who caucus with Democrats in the 50:50-split upper chamber. "It's not like you can break up the bill and have multiple bills on reconciliation. There's only one bill that's why it's all put together," she said in a phone interview this week. A key part of Build Back Better is a $555 billion spending plan to combat climate change, as the Biden administration looks to transition the U.S. away from fossil fuels. But centrist Democrat Joe Manchin wants to cut some—but not all—climate change proposals. The Senator for West Virginia has suggested he backs those on innovation, technology and tax credits for clean technologies. Urgency in the climate crisis has focused some minds on parceling off parts of BBB. Senator Edward Markey, Democrat for Massachusetts, has warned, "we are running out of time," while President Joe Biden said of BBB last week, "we're going to have to probably break it up." But Jayapal pushed back on breaking up the bill at this stage. "Let's try to get as much done as we can in the next month," she said, "and then anything we don't get done, we'll have to look at other options." That includes, she said, a list of "executive actions ... that mirror some of what is in the legislation." "I don't want to imply that we can get the same thing done through executive action because it's just not true," she said, "but we can make some progress on some of the pieces, whether it's around pharmaceutical drug pricing or climate change." Climate change is a focus for lawmakers frustrated at the hold up to Build Back Better, especially in light of recent disasters such as wildfires in Colorado and tornadoes in Kentucky. On Tuesday, Jayapal introduced a new bill which aims to create millions of jobs for those at the frontline who rebuild homes and infrastructure destroyed by climate change-linked disasters. The Climate Resilience Workforce Act would attach labor standards and provide training, investment and citizenship opportunities for resilience workers, many of whom are undocumented immigrants and former prisoners. Jayapal said there will be crossover between her bill and the climate provisions of Build Back Better, such as a Civilian Climate Corps and Justice 40 in which 40 percent of federal investment is committed into disadvantaged communities. "There is no real planning of the federal government around climate resilience and climate disasters," she said. "One of the things that we would do in the bill is we would create climate resilience groups within the government." Meanwhile, Jayapal said "the attention is going to turn back to Build Back Better for the next month" after a move to proceed voting rights legislation to prevent ballot box repression was scuppered last week. "However, I don't want to in any way suggest that we're done with voting rights," she said.

#### 6. Courts Circumvent

LEDERMAN 12/19 (Josh; NBC News, “What the collapse of Build Back Better would mean for climate change,” <https://www.nbcnews.com/politics/congress/what-collapse-build-back-better-would-mean-climate-change-n1286288>, //pa-ww)

The likely demise of President Joe Biden’s Build Back Better legislation would have devastating consequences for U.S. efforts to combat climate change, making it nearly impossible for the U.S. to meet its emissions-cutting pledges under the Paris Agreement. An overwhelming majority of Biden’s proposed climate change investments were in the $1.75 trillion bill; a smaller amount was included in the bipartisan infrastructure law that he signed last month. If the opposition to the bill by Sen. Joe Manchin, D-W.Va., which he announced Sunday in a television interview, holds firm, the Biden administration would be hard-pressed to find other funding streams and executive actions to make up the yawning gap. The sweeping spending bill, which passed the House last month, had included $555 billion in climate-related programs, by far the largest investment in tackling global warming in U.S. history. In April, Biden committed the U.S. to reducing greenhouse gas emissions by 50 percent to 52 percent from 2005 levels by 2030, an ambitious goal that would require drastically cutting pollution from electricity, transportation and manufacturing. Achieving the goal would help put the U.S. on track to zero out its emissions throughout the economy by 2050, in line with what scientists say is needed globally to limit climate change to 1.5 degrees Celsius and avert the most catastrophic effects of global warming. The biggest step Biden proposed was called the Clean Energy Performance Program, or CEPP, in which the government would have paid utility companies that switch quickly from fossil fuels to clean energy and fined those that do not. Electricity accounts for one-quarter of U.S. greenhouse gas emissions, according to the Environmental Protection Agency. Manchin's opposition In October forced Democrats to drop the CEPP from the Build Back Better package. Manchin, whose state relies heavily on coal and whose family is personally invested in the coal industry, argued that the power industry is already shifting to clean energy sources and that paying utility companies to make the switch was unnecessary. In the wake of the setback, the White House argued that it could still meet the administration’s 2030 target even without the CEPP. White House officials repeatedly cited an analysis by the research firm Rhodium Group, which found that achieving the 50 percent reduction without the electricity program was still technically possible. However, the analysis assumed that other tax incentives and energy provisions in the Build Back Better Act would survive, particularly generous tax credits for buying electric vehicles and for renewable energy projects like wind and solar. Senate Finance Committee Chairman Ron Wyden, D-Ore., latched on to the analysis to say the tax provisions alone would be responsible for a cut in electricity emissions of up to 73 percent within a decade. Manchin had opposed many of those tax provisions, too, including a fee on methane emissions in some versions of the bill that he felt were redundant given upcoming EPA regulations on methane. He also objected to limiting tax credits for electric cars and trucks to those made with union labor, describing the requirement as anti-capitalist. Sen. Ed Markey, D-Mass., a member of the Environment and Public Works Committee, said Sunday that major climate and clean energy components of the bill had already been negotiated and that the financing had been worked out. “Let’s pass these provisions now,” Markey said. “We cannot let this moment pass.” If the entire bill is scrapped, there is no clear pathway for the U.S. to meet its goals. That was made clear last month at the U.N. global climate summit in Scotland, where some foreign diplomats questioned U.S. resolve on climate given Democrats’ failure to pass significant legislation before the conference. Manchin said in a statement Sunday outlining his opposition to the bill that the “energy transition my colleagues seek is already well underway” and predicted that the U.S. would continue to lead the world in greenhouse gas emissions reductions. “But to do so at a rate that is faster than technology or the markets allow will have catastrophic consequences for the American people like we have seen in both Texas and California in the last two years,” Manchin wrote. He appeared to be alluding to the Texas power crisis in February, after which critics of renewable energy made widely debunked claims that reliance on wind and solar was responsible for massive power outages. In California, about one-third of electricity comes from renewable sources like wind and solar, with rolling blackouts in recent summers blamed on extreme heat and on wildfire risks. “Sen. Manchin’s statement about the climate provisions in Build Back Better are wrong,” White House press secretary Jen Psaki said in a statement Sunday. “Build Back Better will produce a job-creating clean energy future for this country — including West Virginia.” The Rhodium analysis that found that the U.S. could meet its goals without the electricity program also assumed that stringent new regulations from the EPA and other federal entities would significantly curtail pollution. The regulations, which are being developed now by the Biden administration, are almost certain to be challenged in court, as was former President Barack Obama’s Clean Power Plan, which never took effect because of legal challenges. Blocking Biden’s regulations in court would push the U.S. even further away from meeting its greenhouse gas-cutting goals. Within hours of Manchin’s announcement, environmental and climate advocacy groups responded with panic and frustration while vowing that the fight was not over. The Natural Resources Defense Council warned that “failure is not an option,” while the League of Conservation Voters declared that “this is not the end of the road.” “We are more determined than ever, and we will keep fighting like hell to ensure the Build Back Better Act becomes law,” said the league's senior vice president, Tiernan Sittenfeld.

#### 7. No climate wars OR extinction

Michael Shellenberger 20, Founder and President of Environmental Progress and Co-Founder of the Breakthrough Institute, “Why I Believe Climate Change Is Not the End of the World”, Quillette, 7/8/2020, https://quillette.com/2020/07/08/why-i-believe-climate-change-is-not-the-end-of-the-world/

What the IPCC had actually written in its 2018 report and press release was that in order to have a good chance of limiting warming to 1.5 degrees Celsius from preindustrial times, carbon emissions needed to decline 45 percent by 2030. The IPCC did not say the world would end, nor that civilization would collapse, if temperatures rose above 1.5 degrees Celsius.

Scientists had a similarly negative reaction to the extreme claims made by Extinction Rebellion. Stanford University atmospheric scientist Ken Caldeira, one of the first scientists to raise the alarm about ocean acidification, stressed that “while many species are threatened with extinction, climate change does not threaten human extinction.” MIT climate scientist Kerry Emanuel told me, “I don’t have much patience for the apocalypse criers. I don’t think it’s helpful to describe it as an apocalypse.”

An AOC spokesperson told Axios, “We can quibble about the phraseology, whether it’s existential or cataclysmic.” But, he added, “We’re seeing lots of [climate change–related] problems that are already impacting lives.”

But if that’s the case, the impact is dwarfed by the 92 percent decline in the decadal death toll from natural disasters since its peak in the 1920s. In that decade, 5.4 million people died from natural disasters. In the 2010s, just 0.4 million did. Moreover, that decline occurred during a period when the global population nearly quadrupled.

In fact, both rich and poor societies have become far less vulnerable to extreme weather events in recent decades. In 2019, the journal Global En­vironmental Change published a major study that found death rates and economic damage dropped by 80 to 90 percent during the last four decades, from the 1980s to the present.

While global sea levels rose 7.5 inches (0.19 meters) between 1901 and 2010, the IPCC estimates sea levels will rise as much as 2.2 feet (0.66 meters) by 2100 in its medium scenario, and by 2.7 feet (0.83 meters) in its high-end scenario. Even if these predictions prove to be significant underestimates, the slow pace of sea level rise will likely allow societies ample time for adaptation.

We have good examples of successful adaptation to sea level rise. The Netherlands, for instance, became a wealthy nation despite having one-third of its landmass below sea level, including areas a full seven meters below sea level, as a result of the gradual sinking of its landscapes.

And today, our capability for modifying environments is far greater than ever before. Dutch experts today are already working with the government of Bangladesh to prepare for rising sea levels.

What about fires? Dr. Jon Keeley, a US Geological Survey scientist in California who has researched the topic for 40 years, told me, “We’ve looked at the history of climate and fire throughout the whole state, and through much of the state, particularly the western half of the state, we don’t see any relationship between past climates and the amount of area burned in any given year.”

In 2017, Keeley and a team of scientists modeled 37 different regions across the United States and found that “humans may not only influence fire regimes but their presence can actually override, or swamp out, the effects of climate.” Keeley’s team found that the only statistically significant factors for the frequency and severity of fires on an annual basis were population and proximity to development.

As for the Amazon, the New York Times reported, correctly, that “[the 2019] fires were not caused by climate change.”

In early 2020, scientists challenged the notion that rising carbon dioxide levels in the ocean were making coral reef fish species oblivious to predators. The seven scientists who published their study in the journal Nature had, three years earlier, raised questions about the marine biologist who had made such claims in the journal Science in 2016. After an investigation, James Cook University in Australia concluded that the biologist had fabricated her data.

When it comes to food production, the Food and Agriculture Organization of the United Nations (FAO) concludes that crop yields will increase significantly, under a wide range of climate change scenarios. Humans today produce enough food for ten billion people, a 25 percent surplus, and experts believe we will produce even more despite climate change.

Food production, the FAO finds, will depend more on access to tractors, irrigation, and fertilizer than on climate change, just as it did in the last century. The FAO projects that even farmers in the poorest regions today, like sub-Saharan Africa, may see 40 percent crop yield increases from technological improvements alone.

In its fourth assessment report, the IPCC projected that by 2100, the global economy would be three to six times larger than it is today, and that the costs of adapting to a high (4 degrees Celsius) temperature rise would reduce gross domestic product (GDP) just 4.5 percent.

Does any of that really sound like the end of the world?

The apocalypse now

Anyone interested in seeing the end of the world up close and in person could do little worse than to visit the Democratic Republic of the Congo in central Africa. The Congo has a way of putting first-world prophecies of climate apocalypse into perspective. I traveled there in December 2014 to study the impact of widespread wood fuel use on people and wildlife, particularly on the fabled mountain gorillas.

Within minutes of crossing from the neighboring country of Rwanda into the Congolese city of Goma, I was taken aback by the extreme poverty and chaos: children as young as two years old perched on the handlebars of motorcycles flying past us on roads pockmarked with giant potholes; tin-roofed shanties as homes; people crammed like prisoners into tiny buses with bars over the windows; trash everywhere; giant mounds of cooled lava on the sides of the road, reminders of the volcanic anger just beneath the Earth’s surface.

In the 1990s and again in the early 2000s, Congo was the epicenter of the Great African War, the deadliest conflict since World War II, which involved nine African countries and resulted in the deaths of three to five million people, mostly because of disease and starvation. Another two million people were displaced from their homes or sought asylum in neighboring countries. Hundreds of thousands of people, women, and men, adults, and children, were raped, sometimes more than once, by different armed groups.

During our time in the Congo, armed militias roaming the countryside had been killing villagers, including children, with machetes. Some blamed Al-Shabaab terrorists coming in from Uganda, but nobody took credit for the attacks. The violence appeared unconnected to any military or strategic objective. The national military, police, and United Nations Peacekeeping Forces, about 6,000 soldiers, were either unable or unwilling to do anything about the terrorist attacks.

“Do not travel,” the United States Department of State said, bluntly, of the Congo on its website. “Violent crime, such as armed robbery, armed home invasion, and assault, while rare compared to petty crime, is not uncommon, and local police lack the resources to respond effectively to serious crime. Assailants may pose as police or security agents.”

One reason I felt safe traveling to the eastern Congo and bringing my wife, Helen, was that the actor Ben Affleck had visited several times and even started a charity there to support economic development. If the eastern Congo was safe enough for a Hollywood celebrity, I reasoned, it would be safe enough for Helen and me.

To make sure, I hired Affleck’s guide, translator, and “fixer,” Caleb Kabanda, a Congolese man with a reputation for keeping his clients safe. We spoke on the telephone before I arrived. I told Caleb I wanted to study the relationship between energy scarcity and conservation. Referring to the North Kivu province capital of Goma, the sixth most populated city in the Congo, Caleb asked, “Can you imagine a city of nearly two million people relying on wood for energy? It’s crazy!”

Ninety-eight percent of people in eastern Congo rely on wood and charcoal as their primary energy for cooking. In the Congo as a whole, nine out of 10 of its nearly 92 million people do, while just one out of five has any access to electricity. The entire country relies on just 1,500 megawatts of electricity, which is about as much as a city of one million requires in developed nations.

The main road Caleb and I used to travel from Goma to the communities around Virunga Park had recently been paved, but there was little else in the way of infrastructure. Most roads were dirt roads. When it rained, both the paved and unpaved roads and the surrounding homes were flooded because there was no flood control system. I was reminded of how much we take for granted in developed nations. We practically forget that the gutters, canals, and culverts, which capture and divert water away from our homes, even exist.

Is climate change playing a role in Congo’s ongoing instability? If it is, it’s outweighed by other factors. Climate change, noted a large team of researchers in 2019, “has affected organized armed conflict within countries. However, other drivers, such as low socioeconomic development and low capabilities of the state, are judged to be substantially more influential.”

There is only a barely functioning government in the Congo. When it comes to security and development, people are mostly on their own. Depending on the season, farmers suffer too much rain or not enough. Recently, there has been flooding once every two or three years. Floods regularly destroy homes and farms.

Researchers with the Peace Research Institute Oslo note, “Demographic and environmental variables have a very moderate effect on the risk of civil conflict.” The IPCC agrees. “There is robust evidence of disasters displacing people worldwide, but limited evidence that climate change or sea-level rise is the direct cause.”

Lack of infrastructure plus scarcity of clean water brings disease. As a result, Congo suffers some of the highest rates of cholera, malaria, yellow fever, and other preventable diseases in the world.

“Lower levels of GDP are the most important predictor of armed conflict,” write the Oslo researchers, who add, “Our results show that resource scarcity affects the risk of conflict less in low-income states than in wealthier states.”

If resources determined a nation’s fate, then resource-scarce Japan would be poor and at war while the Congo would be rich and at peace. Congo is astonishingly rich when it comes to its lands, minerals, forests, oil, and gas.

There are many reasons why the Congo is so dysfunctional. It is massive—it is the second largest African nation in area, behind only Algeria—and difficult to govern as a single country. It was colonized by the Belgians, who fled the country in the early 1960s without establishing strong government institutions, like an independent judiciary and a military.

Is it overpopulated? The population of Eastern Congo has doubled since the 1950s and 1960s. But the main factor is technological: the same area could produce much more food and support many more people if there were roads, fertilizers, and tractors.

The Congo is a victim of geography, colonialism, and terrible post-colonial governments. Its economy grew from $7.4 billion in 2001 to $38 billion in 2017, but the annual per capita income of $561 is one of the lowest in the world, leading many to conclude that much of the money that should flow to the people is being stolen.

For the last 20 years, the Rwandan government has been taking minerals from its neighbor and exporting them as its own. To protect and obscure its activities, Rwanda has financed and overseen the low-intensity conflict in Eastern Congo, according to experts.

There were free elections in 2006 and optimism around the new president, Joseph Kabila, but he proved as corrupt as past leaders. After being re-elected in 2011, he stayed in power until 2018, when he installed a candidate who won just 19 percent of the vote as compared to the opposition candidate, who won 59 percent. As such, Kabila and his allies in the legislature appear to be governing behind the scenes.

Low levels of GDP, not climate change, are correlated with armed conflict, such as in the Congo

Billions won’t die

## 2AC – Private DA

#### 3. Non-unique—their ev is about private litigation in the squo—those are advancing because the FTC just dropped the CWS as its gold standard—if it’s a perception link, then that definitely links to the squo since companies are already bringing suits now

Roach 21, Lee Roach, “The FTC Expands Section 5 Enforcement Efforts With Potentially Broad Implications”, <https://www.faegredrinker.com/en/insights/publications/2021/7/the-ftc-expands-section-5-enforcement-efforts-with-potentially-broad-implications>

The Federal Trade Commission (FTC) recently updated its interpretation of its authority to challenge “unfair methods of competition” under Section 5 of the FTC Act. It will no longer limit enforcement actions under Section 5 to conduct that violates the consumer welfare standard. This may significantly expand the sorts of business activities the FTC investigates and challenges.

Although this adjustment, in conjunction with other recent developments at the FTC, is widely interpreted to signal increased scrutiny of Big Tech companies, the FTC’s pivot on its Section 5 authority may have broader implications. Companies should monitor the FTC’s next steps closely for further insights on conduct it may challenge in the future.

On July 1, the FTC voted to expand its enforcement efforts under Section 5 of the FTC Act. Section 5 authorizes the FTC to investigate and challenge “unfair methods of competition in or affecting commerce” (15 U.S.C. § 45(a)(1)) — language that is seemingly open-ended. Courts have not precisely defined the outer-bounds of the FTC’s Section 5 authority.

Previously, according to a 2015 policy statement, the FTC was “guided by” the consumer welfare standard when using its Section 5 authority, and focused on whether the conduct in question artificially raised prices. This hewed closely to how courts have interpreted the other main federal antitrust statutes, the Sherman Act and the Clayton Act. In fact, in that same 2015 policy statement the FTC clarified that it would be “less likely to challenge an act or practice as an unfair method of competition on a standalone basis if enforcement of the Sherman Act or Clayton Act is sufficient to address the competitive harm arising from the act or practice.” And even where the Sherman Act or Clayton Act may not have prohibited certain conduct, the FTC’s record of enforcement has tended to focus on “incipient” conduct that could in the future lead to clear violations of those statutes, such as invitations to collude or exchanges of competitively sensitive information.

The FTC’s move on July 1 constitutes a meaningful departure from its prior interpretation of Section 5, and signals that the FTC may now interpret “unfair methods of competition” more expansively than in the past. Indeed, in a statement released in conjunction with the move, new FTC Chair Lina Khan stated that the 2015 policy statement “contravene[d] the text, structure, and history of Section 5 and largely wr[ote] the FTC’s standalone authority out of existence.” The move also harkens to previous advocacy by Chair Khan that the consumer welfare standard is an inadequate tool for challenging Big Tech companies.

Importantly, however, nothing limits the FTC’s newly expansive understanding of its Section 5 authority only to Big Tech companies. In fact, prior statements by those commissioners who voted with Chair Khan to expand the FTC’s authority under Section 5 seem to indicate just the opposite. To take but one example, two years ago FTC Commissioner Rohit Chopra released a statement, joined by fellow Commissioner Rebecca Kelly Slaughter, criticizing an FTC settlement with online cosmetics company Sunday Riley Modern Skincare LLC. The company had posted false reviews of its products online in order to drive traffic. Commissioner Chopra argued this “false advertising [was] an unfair method of competition,” and thereby criticized the FTC’s action for failing to address the conduct as an antitrust violation and not simply a consumer protection violation.

#### 4. No economic competitiveness impact

Walt, 20

(Stephen, Robert and Renée Belfer professor of international relations at Harvard University, "Will a Global Depression Trigger Another World War?", Foreign Policy, 5/13/2020, <https://foreignpolicy.com/2020/05/13/coronavirus-pandemic-depression-economy-world-war/> JHW)

If one takes a longer-term perspective, however, a sustained economic depression could make war more likely by strengthening fascist or xenophobic political movements, fueling protectionism and hypernationalism, and making it more difficult for countries to reach mutually acceptable bargains with each other. The history of the 1930s shows where such trends can lead, although the economic effects of the Depression are hardly the only reason world politics took such a deadly turn in the 1930s. Nationalism, xenophobia, and authoritarian rule were making a comeback well before COVID-19 struck, but the economic misery now occurring in every corner of the world could intensify these trends and leave us in a more war-prone condition when fear of the virus has diminished. On balance, however, I do not think that even the extraordinary economic conditions we are witnessing today are going to have much impact on the likelihood of war. Why? First of all, if depressions were a powerful cause of war, there would be a lot more of the latter. To take one example, the United States has suffered 40 or more recessions since the country was founded, yet it has fought perhaps 20 interstate wars, most of them unrelated to the state of the economy. To paraphrase the economist Paul Samuelson’s famous quip about the stock market, if recessions were a powerful cause of war, they would have predicted “nine out of the last five (or fewer).” Second, states do not start wars unless they believe they will win a quick and relatively cheap victory. As John Mearsheimer showed in his classic book Conventional Deterrence, national leaders avoid war when they are convinced it will be long, bloody, costly, and uncertain. To choose war, political leaders have to convince themselves they can either win a quick, cheap, and decisive victory or achieve some limited objective at low cost. Europe went to war in 1914 with each side believing it would win a rapid and easy victory, and Nazi Germany developed the strategy of blitzkrieg in order to subdue its foes as quickly and cheaply as possible. Iraq attacked Iran in 1980 because Saddam believed the Islamic Republic was in disarray and would be easy to defeat, and George W. Bush invaded Iraq in 2003 convinced the war would be short, successful, and pay for itself. The fact that each of these leaders miscalculated badly does not alter the main point: No matter what a country’s economic condition might be, its leaders will not go to war unless they think they can do so quickly, cheaply, and with a reasonable probability of success. Third, and most important, the primary motivation for most wars is the desire for security, not economic gain. For this reason, the odds of war increase when states believe the long-term balance of power may be shifting against them, when they are convinced that adversaries are unalterably hostile and cannot be accommodated, and when they are confident they can reverse the unfavorable trends and establish a secure position if they act now. The historian A.J.P. Taylor once observed that “every war between Great Powers [between 1848 and 1918] … started as a preventive war, not as a war of conquest,” and that remains true of most wars fought since then. The bottom line: Economic conditions (i.e., a depression) may affect the broader political environment in which decisions for war or peace are made, but they are only one factor among many and rarely the most significant. Even if the COVID-19 pandemic has large, lasting, and negative effects on the world economy—as seems quite likely—it is not likely to affect the probability of war very much, especially in the short term.

## 1AR

### Private DA

#### Their card talks about net prices and a difference between list (gross) prices and admits that the squo is still bad prices that is still bad

**Drug prices are decreasing now:**

Adam J. **Fein, 1/5**/20**21** (Dr. Fein is CEO of Drug Channels Institute, a subsidiary of Pembroke Consulting, Inc, “Surprise! Brand-Name Drug Prices Fell (Again) in 2020,” <https://www.drugchannels.net/2021/01/surprise-brand-name-drug-prices-fell.html>, Retrieved 9/8/2021)

It was another year of unexpected drug price developments. In 2020, brand-name drug net prices dropped for the third consecutive year. Meanwhile, brand-name drug list prices grew at their slowest rate in at least 20 years. See our updated analysis below. I also review the factors behind declining brand-name drug prices. These factors are firmly in place for 2021. . Our new Congress may try tackle drug prices in the new year. Let’s hope that their policy perceptions catch up to today’s realities. DATA DISAMBIGUATION To examine drug pricing, we rely on data from SSR Health, an independent organization that collects and reports data on pharmaceutical prices. SSR Health is widely regarded as the leading provider of these data. In a testament to SSR Health’s influence, the Institute for Clinical and Economic Review (ICER) relies on these net price data in its cost-effectiveness evaluations. Read more about SSR Health on its US Brand Rx Net Pricing Tool webpage. SSR Health’s list and estimated net pricing figures are based on approximately 1,000 brand-name drugs with disclosed U.S. product-level sales from approximately 100 currently or previously publicly traded firms. The products and companies in the SSR Health numbers account for more than 90% of U.S. branded prescription net sales. SSR Health updates these figures quarterly, and its historical figures date from the first quarter of 2007. Here’s our quick refresher on drug pricing terminology: The manufacturer of a drug establishes the drug’s list (gross) price, called the Wholesale Acquisition Cost (WAC). A manufacturer’s gross revenues equal its revenues from sales at a drug’s WAC list price. A drug’s net price equals the actual revenues that a manufacturer earns from a drug after rebates, discounts, and other reductions. A drug’s net revenues equal its revenues from sales at the drug’s net price. The major components of gross-to-net price differences for brand-name drugs include: Rebates to commercial payers, Medicare Part D plans, the Medicaid program, and other payers Discounts to healthcare providers under the 340B Drug Pricing Program Manufacturers’ payments to drug channel participants (admin fees to PBMs; fees and discounts to drug channel participants; and fees and discounts to pharmacies) Patient assistance and copayment support funds Negotiated and statutory rebates to third-party payers are the largest and most significant components of gross-to-net differences. DRUG PRICING FACTS The chart below summarizes the list and net price changes for a broad set of brand-name drugs over the past seven years: [Click to Enlarge] Consistent with our previous analyses, these data show significant gaps between list and net price changes: List-price growth has dropped significantly. From 2010 to 2015, growth in list prices was increasing by 10% to 15%. Growth has slowed sharply over the past five years, from 13.5% in 2014 to 4.2% through the first three quarters of 2020. Net prices for brand-name drug prices are dropping. For 2020, list prices grew by 4.2%, but net prices declined by -2.2%. The gross-to-net gap in prices was -6.4%. These industry data are consistent with the manufacturer-specific disclosures about changes in list and net drug prices that I discuss in Five Top Drugmakers Reveal List vs. Net Price Gaps (Plus: The Trouble With Insulin Prices). The gross-to-net bubble keeps inflating. Drug Channels Institute coined the term gross-to-net bubble to describe the speed and size of growth in the total dollar value of manufacturers’ gross-to-net reductions. This terminology has been embraced by industry participants, the government, and others who cover the industry. As list prices rise, the dollar value of the manufacturer’s rebates and discounts grows. The manufacturer provides larger rebates to offset the increase in list prices. Hence, the total value of the gross-to-net bubble expanded to an astounding $175 billion for 2019, despite the slowing growth in list prices and the negative growth rates for net prices. However, the total value of rebates and discounts grew at the slowest rate in recent years. See The Gross-to-Net Bubble Hit $175 Billion in 2019: Why Patients Need Rebate Reform. GETTING READY FOR 2021 This week, the media fixated on manufacturers’ list price increases for 2021. But the factors that are widening gross-to-net differences will continue in 2021. These include (but are not limited to): Growing concentration within the PBM industry Increasingly crowded, highly competitive therapeutic categories Higher risks of formulary exclusion Deeper mandatory rebates and discounts to government payers Explosive growth in 340B Drug Pricing Program discounts Consequently, higher utilization—not net drug costs—will remain the biggest factor driving overall drug spending growth. Utilization is a positive trend, because it means that more people have access to—and are remaining adherent to—the drug therapy their physician has prescribed. **No other part of the healthcare system** has seen its average prices drop year after year. In his excellent book The Great American Drug Deal, Peter Kolchinsky made an astute observation: “Doctors and hospitals do not go generic. Surgery will only climb in price. For all the outrage over companies raising the prices of their branded drugs year after year, this is the norm for land values, housing costs, and the prices of many other products.” The latest data show that the situation is even worse than Peter described. **Brand-name drug prices continue to decline** while the prices of other healthcare products and services continue to rise. Politicians, journalists, and academics who focus on list prices distort the truth about drug prices. As I noted in my final post of 2020: When Americans complain about “drug prices,” most are actually complaining about the share of costs they pay—and how those costs are computed. The gross-to-net gaps shown above have significant negative consequences for many patients. See Drug Pricing Policy in 2021: Four Crucial Consequences of Pharmacy Benefits Today. As we enter the new year, I’ll do my best to keep Drug Channels focused on honest, fact-based discussions of today’s realities and what they mean. In the meantime, I hope the pharma industry’s critics reflect on these actual data. As my friend Mike Marks once told me: A learning experience is what you get when you expected something else.