# 1AC

### 1ac---Shirley

#### The Advantage is Pharma

#### **In 2013 the Supreme Court erred in *FTC v. Actavis*, allowing 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**

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

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.

#### **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 crush US manufacturing**

Supino 14 (Kate Supino, Associate Director of Finance at National Network for Safe Communities, writer for Global Manufacturing, November 11, 2014. “Can US manufacturers cope with healthcare costs and remain globally competitive?” http://www.manufacturingglobal.com/people-and-skills/can-us-manufacturers-cope-healthcare-costs-and-remain-globally-competitive)

As manufacturers in the U.S. strive to meet the challenge to abide by government regulations for healthcare, two things are clear. First, this challenge presents a clear disadvantage for our manufacturers, compared to overseas manufacturing companies that aren't subject to the U.S.'s employee healthcare mandates. Second, healthcare costs are rising across the board in administrative, direct and indirect ways. Can manufacturers somehow find ways to overcome these challanges? Challenges some manufacturers’ face The employee healthcare mandates pose a specific challenge to manufacturers in the U.S., some of whom employ more than 300,000 employees. Manufacturers like General Electric, Ford and Hewlett-Packard bear the brunt of rising healthcare costs while their counterparts in other countries escape the added strain on operating expenses. If the auto industry and others are to survive, however, rising healthcare costs must be contained. The impact of healthcare expenses There are several ways in which healthcare costs affect manufacturers. One is the added load to administrative employees. Increased oversight and constantly trying to find new ways to keep employees happy with their healthcare benefits have human resource personnel working overtime, sometimes literally. As the following article shows, the more time that is spent on managing increasingly complex healthcare paperwork, and helping employees in [choosing a health insurance plan](http://www.healthplans.com/health-insurance-guides/choosing-a-health-insurance-plan) that functions for their individual needs, the less time can be devoted to improving employee morale and affecting general positive change in the workplace. That's an intangible cost that builds with time. The direct costs associated with ever rising healthcare costs are more immediate and possibly more dangerous. As more procedures and coverage are allowed, insurance companies continue to raise their rates, despite previous government assurances that rates would reduce. When rates rise, manufacturers have no choice but to pay up or risk harsh government penalties. And in a global trade economy that already has the United States manufacturing industry on its knees, healthcare costs have the potential to take some of the frailer manufacturers out of the picture altogether. So how can manufacturing companies compete in the global marketplace with their hands tied by healthcare costs? The solution may be a multi-pronged approach that addresses all the issues facing manufacturers. Standardising healthcare administration One possibility may be a standardisation of healthcare administration. If all manufacturers worked together to develop a comprehensive method of managing healthcare administrative requirements, it would place the bulk of their healthcare admin work on autopilot. Whether manufacturers would be willing to consider such a unified effort, as well as be willing to invest the time and money necessary to grow such a standardized system, is in the cards. One thing is certain. Healthcare costs aren't going to go down. The promises that Americans thought they heard aren't going to happen, so the sooner all manufacturers get on board the global survival train, the better off they'll be. Now isn't the time to be divided or to argue about whether the new system is wrong or right. Now is the time to act.

#### 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.

#### 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.

#### **Bio Innovation solves everything**

NAS 8 – (National Academy of Sciences, “The Role of the Life Sciences in Transforming America's Future Summary of a Workshop,” December 3, 2008, Board on Life Sciences Division on Earth and Life Studies, National Research Council)

A Critical Time for the Life Sciences Speaker after speaker at the Summit agreed: the life sciences are poised to usher in a period of unprecedented health and prosperity. Basic scientific research into how living things function is producing new understanding of how living systems work and new ways of using biological processes to meet human needs. If current opportunities are grasped, the life sciences can help produce enough food for a growing population, cure chronic and acute diseases, meet fImportant segments of the life sciences are merging with the physical sciences and engineering to create “transdisciplinary” scientific endeavors focused on pressing global problems. This blending of d Massachusetts Institute of Technology (MIT) President Susan Hockfield. They improve human health. They foster potential of vaccines and antibiotics, among many other research results, have improved the lives of people everywhere. The progress made in combating heart disease is a prime example of the payoffs from investment in the life sciences, said Hockfield. Over the past 30 years, the National Institutes of new knowledge in medicine. Fostering Industries to Counter Global Problems The life sciences have applications in areas that range far beyond human health. Life-science based approaches could contribute to advances in many industries, from energy production and pollution remediation, to clean manufacturing and the production of new biologically inspired materials. In fact, biological systems could provide the basis for new products, services and industries that we cannot yet imagine. Microbes are already producing biofuels and could, through further research, provide a major component of future energy supplies. Marine and terrestrial organisms extract carbon dioxide from the atmosphere, which suggests that biological systems could be used to help manage climate change. Study of the complex systems encountered in biology is decade, it is really just the beginning.” Advances in the underlying science of plant and animal breeding have been just as dramatic as the advances in genetic can put down a band of fertilizer, come back six months later, and plant seeds exactly on that row, reducing the need for fertilizer, pesticides, and other agricultural inputs. Fraley said that the global agricultural system needs to adopt the goal of doubling the current yield of crops while reducing key inputs like pesticides, fertilizers, and water by one third. “It is more important than putting a man on the moon,” he said. Doubling agricultural yields would “change the world.” Another billion people will join the middle class over the next decade just in India and China as economies continue to grow. And all people need and deserve secure access to food supplies. Continued progress will require both basic and applied research, The evolution of life “put earth under new management,” Collins said. Understanding the future state of the planet will require understanding the biological systems that have shaped the planet. Many of these biological systems are found in the oceans, which cover 70 percent of the earth’s surface and have a crucial impact on weather, climate, and the composition of the atmosphere. In the past decade, new tools have become available to explore the microbial processes that drive the chemistry of the oceans, observed David Kingsbury, Chief Program Officer for Science at the Gordon and Betty Moore Foundation. These technologies have revealed that a large proportion of the planet’s genetic diversity resides in the oceans. In addition, many organisms in the oceans readily exchange genes, creating evolutionary forces that can have global effects. The oceans are currently under great stress, Kingsbury pointed out. Nutrient runoff from agriculture is helping to create huge and expanding “dead zones” where oxygen levels are too low to sustain life. Toxic algal blooms are occurring with higher frequency in areas where they have not been seen in the past. Exploitation of ocean resources is disrupting ecological balances that have formed over many millions of years. Human-induced changes in the chemistry of the atmosphere are changing the chemistry of the oceans, with potentially catastrophic consequences. “If we are not careful, we are not going to have a sustainable planet to live on,” said Kingsbury. Only by understanding the basic biological processes at work in the oceans can humans live sustainably on earth.

#### 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.**

#### 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

#### **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.

#### 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

#### “At least” means we only have to meet the latter half of the resolution

OED 21, Oxford English Dictionary, “east, adj., pron., and n., and adv.”, https://www.oed.com/view/Entry/106755?rskey=4Ogpdk&result=2&isAdvanced=false#eid1257794650

Uses of the noun following prepositions, forming adverbial phrases.

a. at least (also at the least (now less common), † atte leste).

(a) Modifying a designation of quantity or extent, indicating that the amount is the smallest admissible or is otherwise a minimum, e.g. at least two, at least once, at least double.

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We meet – Presumptive Illegality means the plan is a per-se prohibition with a mechanism for exception  
Jason Gordon, 09-21-2021, Associate Professor of Legal Studies & Management at Georgia Gwinnett College, “Antitrust - Rule of Reason and Per Se Illegality” https://thebusinessprofessor.com/en\_US/business-transactions/antitrust-rule-of-reason-and-per-se-illegality

What is Per Se Illegality?

A naked restraint of trade is one that is explicitly anticompetitive, such as an agreement controlling the price of a good or the output from production. A naked restraint with no pro-competitive justification is generally held to be per se illegal. That is, these practices are, by their nature, anticompetitive and thus per se illegal. A court will not evaluate any alleged pro-competitive justifications for such activity.

Example: Agreements setting a minimum or maximum price, output limitations, geographic apportionment of a region, bans on price competition would all qualify as per se illegal. Horizontal agreements among competitors are much more likely to be per se illegal. In vertical agreements between producer, wholesaler, and retailer, it is often difficult to determine if they are anticompetitive . These types of relationship must be examined under the rule of reason. All of these types of restraint are discussed further below.

What is the Rule of Reason?

The rule of reason applies to a restraint that is not deemed a naked restraint. Per Section 1, every contract, combination, or conspiracy is illegal if it constitutes undue or unreasonable restraint of trade. The test for reasonableness concerns whether the challenged contracts or acts unreasonably restrict competitive conditions in the market or industry. Unreasonableness can be based upon the nature or character of the agreement or surrounding circumstances. The rule of reason balances pro-competitive and anti-competitive effects. In determining whether a restraint of trade is reasonable, the court would consider:

facts peculiar to this business,

actual and probable effects of restraint (including the effect on competitors);

history of the restraint;

purpose of restraint;

scope of the restraint;

convenience to suppliers and consumers; and

creation of new products.

In essence, if the activity promotes competition, it may justify the anticompetitive aspects.

What is the Quick-Look (or Truncated) Rule of Reason?

This is a test employed by the court in very limited circumstances. It is feasible that a naked restraint may be legal if there is a pro-competitive justification. Under the quick-look test, a court will allow a defendant to introduce evidence that conduct that would otherwise be per se illegal has a pro-competitive aspect. If a pro-competitive justification is plausible, the court will employ a full rule-of-reason analysis.

#### Prohibit can mean ‘severely hinder’---doesn’t necessitate a ban

Washington Court of Appeals 19 (KORSMO-judge. Opinion in State v. Kimball, No. 35441-5-III (Wash. Ct. App. Apr. 2, 2019). Google scholar caselaw. Date accessed 7/13/21).

His argument runs counter to the meaning of the word "prohibit." It means "1. To forbid by law. 2. To prevent, preclude, or severely hinder." BLACK'S LAW DICTIONARY 1405 (10th ed. 2014). As "severely hinder" suggests, a "prohibition" need not be an all or nothing proposition.

#### And, anticompetitive business practices are those which give companies an unfair advantage in the market

**Encyclopedia.com,** 20**18** [ “Federal Trade Commission,” Federal Trade Commission via Social Sciences and Law, Political Science and Government, and U.S. Government, May 23, 2018; https://www.encyclopedia.com/social-sciences-and-law/political-science-and-government/us-government/federal-trade-commission

Anticompetitive business practices are those in which a company or companies gain an unfair advantage in the market, making it difficult or impossible for other companies to compete with them. As a result, the dominant company may be able to profit without providing the best product or the best prices, because the consumer can no longer choose a better option. Some examples of business practices that can be anticompetitive include: price fixing, in which two or more companies conspire to set prices as they please, so that market forces no longer work; tie-in sales, in which two products are sold in a bundle, so that the consumer cannot buy one without the other; exclusive dealership agreements, in which a retailer or wholesaler is required to buy from a certain supplier or manufacturer; interlocking corporate directorships, in which one individual serves as director of two or more companies that are supposed to compete with each other; and mergers or acquisitions, in which two or more companies join together (or consolidate), becoming substantially more powerful than any of their competitors. When one company gains exclusive control over the market for a particular product or service (meaning that it has eliminated its competitors), it is called a monopoly.

#### And, “at least” means we only have to meet the latter half of the resolution

OED 21, Oxford English Dictionary, “east, adj., pron., and n., and adv.”, https://www.oed.com/view/Entry/106755?rskey=4Ogpdk&result=2&isAdvanced=false#eid1257794650

Uses of the noun following prepositions, forming adverbial phrases.

a. at least (also at the least (now less common), † atte leste).

(a) Modifying a designation of quantity or extent, indicating that the amount is the smallest admissible or is otherwise a minimum, e.g. at least two, at least once, at least double.

#### 2. No brightline between per se and rule of reason – Semantics ensures all plans can equally be twisted to meet or not meet this interp.

Manne ’21 [Geoffrey; 2021; President and Founder of the International Center for Law and Economics and Distinguished Fellow at the Northwestern University Center on Law, Business, and Economics, “The Rule of Reason as a Discovery Procedure: A Response to Ramsi Woodcock's Hidden Rules of a Modest Antitrust,” 105 Minn. L. Rev. Headnotes 422, 448-453]

D. THE OVERSTATED DIFFERENCE BETWEEN RULE OF REASON AND PER SE

It is also inaccurate to frame per se rules as entailing no indeterminacy whatsoever. There will always be procedural, theoretical, and/or evidentiary predicates for legal liability. Per se rules are triggered by factors that can be subject to significant interpretation. And rules of reason may be designed to provide firms with safe harbors. Accordingly, the distinction between these standards is often overblown.

For example, a great deal of the enforcement activity characterized by Woodcock as movement toward a rule of reason could better be characterized as the creation of bright-line safe harbors for large swaths of conduct. There are--or were--a great number of antitrust safe harbors beginning in the 1980s and coinciding with a number of per se to rule of reason shifts. Copperweld established a safe harbor for within-firm conduct. 75 Brooke Group introduced a safe harbor in predatory pricing cases for above-cost pricing. 76 Trinko created a safe harbor for monopoly pricing (and a presumption of legality for unilateral refusals to deal). 77The Court also adopted safe harbors for [\*449] product innovation by dominant firms. 78There are numerous other examples. 79

Significantly, many of these shifts are described by Woodcock as moves toward the rule of reason from per se illegality--but they needn't be. Where Woodcock describes Jefferson Parish as having the net result that an exemption for "exclusive dealing that forecloses more than 30% of the market is subject to rule of reason treatment on the model of Tampa Electric" 80Edwards and Wright describe it as "a bright line foreclosure safe harbor to analyze the reasonableness of exclusive dealing contracts." 81

Woodcock goes on to interpret the rule set out in Jefferson Parish by noting that:

Justice O'Connor's observation in her celebrated Jefferson Parish concurrence that exclusive dealing contracts "of narrow scope pose no threat of adverse economic consequences" and "may be substantially procompetitive" referred to the character of those contracts that foreclose up to 30% of the market and are effectively per se legal today. Of the ambiguous conduct that forecloses more than that amount, Justice O'Connor expressed no opinion regarding the likelihood of harm. 82

The key language from Justice O'Connor is the following:

Our prior opinions indicate that the purpose of tying law has been to identify and control those tie-ins that have a demonstrable exclusionary impact in the tied-product market or that abet the harmful exercise of market power that the seller possesses in the tying product market. Under the rule of reason tying arrangements should be disapproved only in such instances . . . . In determining whether an exclusive-dealing contract is unreasonable, the proper focus is on the structure of the market for the products or services in question -- the number of sellers and buyers in the market, the volume of their business, and the ease with which buyers and sellers can redirect their purchases or sales to others. Exclusive dealing is an unreasonable restraint on trade only when a significant fraction of buyers or sellers are frozen out of a market by the exclusive deal. 83

The presence of an indeterminate term like "significant fraction" does not render the rule inherently indeterminate (if that word is to have any meaning). And under this enunciated rule, exclusive dealing is unreasonable (illegal) only when it entails "significant" foreclosure. That [\*450] is a bright line, even if "significant" is indeterminate. Conduct that does not foreclose a significant fraction of buyers or sellers is per se legal. In this case, because the conduct in question foreclosed 30% of the market, a figure of 30% to 40% has been interpreted by numerous courts as the boundary of effective per se legality. 84

This may seem like a semantic distinction--but that is somewhat the point. Whether a rule is a bright-line safe harbor embedded in a rule of reason or a rule of per se legality is in the eye of the beholder. Woodcock is aware of this, but unduly dismissive of it. The prior case law did not establish per se rules that were always appreciably distinct from rule of reason analysis; they simply imposed different safe harbors or spheres of per se liability, the boundaries of which inevitably require detailed analysis, at times little different than that entailed by the later rules. 85By the same token, the rule of reason is not monolithic, either, and "[a]pplication of the rule of reason is not a rule of per se legality." 86Indeed, while "[i]n some instances, rule of reason treatment approaches per se legality; in others, the rule amounts to a rule of presumptive condemnation." 87

## 2ac – K

#### Util is good – there’s no ethical alternative to probability times magnitude – AND, being alive is a pre-requisite to the alt.

#### Extinction outweighs – any risk is a reason to err aff.

Seth D. Baum and Anthony M. Barrett 18. Global Catastrophic Risk Institute. 2018. “Global Catastrophes: The Most Extreme Risks.” Risk in Extreme Environments: Preparing, Avoiding, Mitigating, and Managing, edited by Vicki Bier, Routledge, pp. 174–184.

2. What Is GCR And Why Is It Important? Taken literally, a global catastrophe can be any event that is in some way catastrophic across the globe. This suggests a rather low threshold for what counts as a global catastrophe. An event causing just one death on each continent (say, from a jet-setting assassin) could rate as a global catastrophe, because surely these deaths would be catastrophic for the deceased and their loved ones. However, in common usage, a global catastrophe would be catastrophic for a significant portion of the globe. Minimum thresholds have variously been set around ten thousand to ten million deaths or $10 billion to $10 trillion in damages (Bostrom and Ćirković 2008), or death of one quarter of the human population (Atkinson 1999; Hempsell 2004). Others have emphasized catastrophes that cause long-term declines in the trajectory of human civilization (Beckstead 2013), that human civilization does not recover from (Maher and Baum 2013), that drastically reduce humanity’s potential for future achievements (Bostrom 2002, using the term “existential risk”), or that result in human extinction (Matheny 2007; Posner 2004). A common theme across all these treatments of GCR is that some catastrophes are vastly more important than others. Carl Sagan was perhaps the first to recognize this, in his commentary on nuclear winter (Sagan 1983). Without nuclear winter, a global nuclear war might kill several hundred million people. This is obviously a major catastrophe, but humanity would presumably carry on. However, with nuclear winter, per Sagan, humanity could go extinct. The loss would be not just an additional four billion or so deaths, but the loss of all future generations. To paraphrase Sagan, the loss would be billions and billions of lives, or even more. Sagan estimated 500 trillion lives, assuming humanity would continue for ten million more years, which he cited as typical for a successful species. Sagan’s 500 trillion number may even be an underestimate. The analysis here takes an adventurous turn, hinging on the evolution of the human species and the long-term fate of the universe. On these long time scales, the descendants of contemporary humans may no longer be recognizably “human”. The issue then is whether the descendants are still worth caring about, whatever they are. If they are, then it begs the question of how many of them there will be. Barring major global catastrophe, Earth will remain habitable for about one billion more years 2 until the Sun gets too warm and large. The rest of the Solar System, Milky Way galaxy, universe, and (if it exists) the multiverse will remain habitable for a lot longer than that (Adams and Laughlin 1997), should our descendants gain the capacity to migrate there. An open question in astronomy is whether it is possible for the descendants of humanity to continue living for an infinite length of time or instead merely an astronomically large but finite length of time (see e.g. Ćirković 2002; Kaku 2005). Either way, the stakes with global catastrophes could be much larger than the loss of 500 trillion lives. Debates about the infinite vs. the merely astronomical are of theoretical interest (Ng 1991; Bossert et al. 2007), but they have limited practical significance. This can be seen when evaluating GCRs from a standard risk-equals-probability-times-magnitude framework. Using Sagan’s 500 trillion lives estimate, it follows that reducing the probability of global catastrophe by a mere one-in-500-trillion chance is of the same significance as saving one human life. Phrased differently, society should try 500 trillion times harder to prevent a global catastrophe than it should to save a person’s life. Or, preventing one million deaths is equivalent to a one-in500-million reduction in the probability of global catastrophe. This suggests society should make extremely large investment in GCR reduction, at the expense of virtually all other objectives. Judge and legal scholar Richard Posner made a similar point in monetary terms (Posner 2004). Posner used $50,000 as the value of a statistical human life (VSL) and 12 billion humans as the total loss of life (double the 2004 world population); he describes both figures as significant underestimates. Multiplying them gives $600 trillion as an underestimate of the value of preventing global catastrophe. For comparison, the United States government typically uses a VSL of around one to ten million dollars (Robinson 2007). Multiplying a $10 million VSL with 500 trillion lives gives $5x1021 as the value of preventing global catastrophe. But even using “just" $600 trillion, society should be willing to spend at least that much to prevent a global catastrophe, which converts to being willing to spend at least $1 million for a one-in-500-million reduction in the probability of global catastrophe. Thus while reasonable disagreement exists on how large of a VSL to use and how much to count future generations, even low-end positions suggest vast resource allocations should be redirected to reducing GCR. This conclusion is only strengthened when considering the astronomical size of the stakes, but the same point holds either way. The bottom line is that, as long as something along the lines of the standard riskequals-probability-times-magnitude framework is being used, then even tiny GCR reductions merit significant effort. This point holds especially strongly for risks of catastrophes that would cause permanent harm to global human civilization. The discussion thus far has assumed that all human lives are valued equally. This assumption is not universally held. People often value some people more than others, favoring themselves, their family and friends, their compatriots, their generation, or others whom they identify with. Great debates rage on across moral philosophy, economics, and other fields about how much people should value others who are distant in space, time, or social relation, as well as the unborn members of future generations. This debate is crucial for all valuations of risk, including GCR. Indeed, if each of us only cares about our immediate selves, then global catastrophes may not be especially important, and we probably have better things to do with our time than worry about them. While everyone has the right to their own views and feelings, we find that the strongest arguments are for the widely held position that all human lives should be valued equally. This position is succinctly stated in the United States Declaration of Independence, updated in the 1848 Declaration of Sentiments: “We hold these truths to be self-evident: that all men and 3 women are created equal”. Philosophers speak of an agent-neutral, objective “view from nowhere” (Nagel 1986) or a “veil of ignorance” (Rawls 1971) in which each person considers what is best for society irrespective of which member of society they happen to be. Such a perspective suggests valuing everyone equally, regardless of who they are or where or when they live. This in turn suggests a very high value for reducing GCR, or a high degree of priority for GCR reduction efforts.

#### Private investment is crucial to biopharma innovation – alt can’t solve due to lack of incentives, funding, and restrictive regulatory regimes that ensure that new drugs are never produced – researchers spend lifetimes on vaccines that may never work, profit is key

Meigs, 21

(James B., former editor of Popular Mechanics, “Thank God for Big Pharma”, Commentary, June 2021, https://www.commentary.org/articles/james-meigs/big-pharma-covid-vaccines/)\\JM

On March 15, 2020, Joe Biden and Bernie Sanders appeared in a CNN debate. The timing was ominous. COVID-19 had begun its exponential explosion in the United States. New York and other cities were locking down and hospitals were bracing for the inevitable deluge. CNN’s Jake Tapper asked Senator Sanders, “If you were president right now, what would you do to make sure every sick American is able to get treatment?” Sanders quickly zeroed in on what he believed was the core problem. “We have a bunch of crooks who are running the pharmaceutical industry,” he thundered. “Right now, in the midst of this epidemic, you got people…saying, ‘Oh, wow, what an opportunity to make a fortune!’” As president, Sanders vowed, he wouldn’t let that happen. “The drug companies will not rip us off!” His position was hardly out of the mainstream. In a 2019 Gallup poll that measured attitudes toward major industries, the pharmaceutical industry ranked dead last, with 58 percent of respondents holding a negative view. Even Republicans, who usually at least pay lip service to free enterprise, often rail against the industry. Ever alert to populist antipathies, Donald Trump made a habit of slamming Big Pharma in his rallies and on social media. So, as coronavirus fears ramped up in early 2020, it was only natural for both parties to renew their attacks on this most widely loathed branch of the health-care establishment. But while Biden and Sanders debated in Washington, scientists and executives at Moderna, Inc. were preparing as if for war. The 10-year-old biotech firm, located in Cambridge, Massachusetts, was a small but ambitious player in an industry dominated by giants such as Johnson & Johnson, Merck, and Pfizer. In its short life, the company had raised $1.6 billion in venture capital before going public in 2018. Investors believed that Moderna’s core technology—a method of inserting bits of synthetic RNA (DNA’s fragile sister) into human cells—could revolutionize the treatment of cancer and other diseases. But the company had yet to bring a single drug to market—or even to prove that its “messenger RNA,” or mRNA, technique was safe. In January 2020, when news broke that a mysterious coronavirus was circulating in China, Moderna’s scientists quickly realized that a vaccine against the new disease might be a perfect application for their process. On a Saturday—January 11, 2020—a heroic Chinese researcher made the new virus’s genetic sequence public. Moderna’s technicians took that data and then worked through the weekend engineering a vaccine using their mRNA technique. By Monday, they were finished. “This is not a complicated virus,” Moderna’s French-born CEO, Stéphane Bancel, later told the New York Times. Developing a potential vaccine based on genetic data is one thing. Proving that it is effective and safe and then manufacturing and distributing it on a massive scale—those are challenges of different order. Fortunately, the Trump administration’s Operation Warp Speed stepped in to provide the resources Moderna didn’t have: $1 billion to support the production and testing of the vaccine and another $1.5 billion to pay for 100 million doses. Though the Warp Speed program wasn’t officially announced until April, in March—as Sanders was denouncing Big Pharma “crooks” from the CNN podium—Moderna was already ramping up a huge manufacturing operation to produce its exquisitely delicate vaccine. It needed to expand its workforce by 50 percent virtually overnight. Perhaps hardest of all, the company had to conduct the clinical trials that would confirm its vaccine’s safety and efficacy. Normally, these steps take two to five years. Sometimes, researchers work for decades without ever producing a viable vaccine. Moderna would get the job done in 10 months. At the same time, some of the biggest players in the pharmaceutical industry were racing to get their own vaccines into the testing pipeline. Pfizer, working with the German firm BioNTech, also had an mRNA vaccine in development. Johnson & Johnson, AstraZeneca, Novavax, Sanofi, and GlaxoSmithKline were working on different approaches. No one knew which of these vaccines would get to the finish line first. It seemed likely that some—perhaps most—of the candidates wouldn’t survive the testing gauntlet. Such high-visibility failures could cost these companies billions and damage their reputations for years. In general, developing a vaccine for a new disease is a surprisingly risky investment for any drug company. Competitors might beat you to market, making your product an also-ran. Or, as happened in the cases of SARS and Zika, the disease might subside quickly, making it impossible to test the vaccine’s efficacy. Even successful vaccines aren’t usually big moneymakers. Unlike drugs for chronic conditions, most vaccines need to be administered, at most, only a few times in a patient’s life. That doesn’t add up to a lot of billing cycles. Under normal conditions, steely-eyed investors shoulder most of the financial risks of drug development. And companies usually wait until they think a drug or vaccine is likely to get FDA approval before building out the necessary manufacturing facilities. But these weren’t normal conditions. By offering up-front money to the drug makers who needed it and placing advance orders for hundreds of millions of doses, Operation Warp Speed helped share the risks. Drugmakers expanded facilities and started cranking out tens of millions of doses even as their vaccines were still in the testing phase. When Bancel left a much larger firm to become CEO of Moderna in 2011, he had warned his wife that the company’s mRNA technique had only a 5 percent chance of yielding successful products. But if it worked, it would “change the course of medicine.” The company attracted serious investment, but it also faced devastating setbacks. Several promising treatments failed in early phases. In 2016, the journal Science slammed Moderna, comparing it to the scandal-plagued blood-testing start-up Theranos. Bancel knew that failing to deliver a viable COVID-19 vaccine might be a nail in his company’s coffin. Results from the vaccine’s all-important Phase III clinical trial were due in mid-November. As he later recounted to the New York Times, Bancel anxiously retreated to his home office and waited for the results. They were stunning: The vaccine was 94.5 percent effective in preventing infection.1 And the handful of infections that did occur were all mild. The audacious biotech company had not only proved that its technique was workable and safe, it had developed a vaccine with the potential to save millions of lives. Bancel burst out of his office to tell his wife and two teenage children. “The four of us were crying,” he said. Early in the pandemic, the FDA said it would accept a vaccine that was only 50 percent effective. And many experts thought such a vaccine would take a minimum of two years to develop. Instead, the Moderna and Pfizer vaccines both gained approval before the year was out. In other words, the U.S. had vaccines “ready at half the time the most optimistic timeline projected, with twice the efficacy hoped for,” noted Zeynep Tufekci, one of the smartest pandemic-policy analysts. Other companies were close behind with their own vaccines. “This will go down in history as one of science and medical research’s greatest achievements,” the acclaimed medical researcher Eric Topol wrote at the time. “Perhaps the most impressive.” By April 2021, the U.S. was administering more than 3 million shots a day; more than half the country’s adult population had received at least one dose. By May, the biggest hurdle wasn’t the supply of vaccines but the reluctance of some segments of the population to get vaccinated. Nonetheless, deaths and hospitalizations plummeted. People began returning to offices, restaurants, and places of worship. They were taking off their masks and hugging their friends and relatives again (overcautious admonitions from public-health officials notwithstanding). America was coming back to life. Big Pharma had delivered. Would it be asking too much to expect Americans to pause briefly at this moment and say, “Thanks!”? \_\_\_\_\_\_\_\_\_\_\_\_\_ SADLY, YES. Anyone who thinks the public, the media, or our political leaders might show a smidgeon of appreciation for these lifesaving vaccines hasn’t followed the history of the pharmaceutical industry. It seems the more lives the drug companies save, the more people revile them. Yes, yes, I know—the opioid crisis; high drug prices; that slimy “pharma bro” Martin Shkreli—we’ll get to all that. But first, let’s focus on our current situation. The U.S. is emerging from pandemic hell while much of the rest of the world struggles with recurring waves of infection. Shouldn’t we take a minute to study how we achieved this miracle and to think about policies that might help us do even better next time? “This is not the time for profiteering,” Bernie Sanders said at that March 2020 debate. But profiteering—or, to put it more politely, the hope of earning a healthy return on investment—was an indispensable ingredient in the vaccine triumph. It wasn’t the only ingredient. The people who choose to work in pharmaceuticals don’t do it solely with the expectation of getting filthy rich. (Surely, investment banking, a job in the digital economy—or perhaps a career in politics—would be easier paths to that goal.) Most of them genuinely care about alleviating human suffering. Nor was the vaccine breakthrough purely a free-market triumph; the federal government provided both crucial investment and logistical support. Operation Warp Speed was a staggering example of how public-private partnerships can combine the power of government with the resourcefulness of private industry. But none of it would have happened without those greedy investors who, year after year, poured billions into companies like Moderna, risking massive losses in the long-shot hope of spectacular returns. One is tempted to thank God that no one listened to Bernie Sanders. But that would be premature. Although Sanders didn’t win the Democratic nomination, his progressive brand of politics is growing ever more dominant in the Democratic Party. And, despite Biden’s campaign image as a benign centrist, as president he has shown little willingness to restrain the radical flank of his coalition. In fact, many of his administration’s proposals come straight out of the progressive playbook. In early May, the White House announced that it will rescind intellectual-property protections for COVID-19 vaccines. Various progressive groups, along with the Word Trade Organization, had been pushing for such a move for weeks. The activists aren’t just demanding that the pharma companies give up their patents. They also want to force them to perform a “technology transfer,” teaching manufacturers in India and elsewhere their proprietary methods for creating the breakthrough vaccines. The news was a blow to vaccine makers. Obviously such a move would strip these companies of some of the profits they’d counted on in return for developing successful vaccines. Worse, if tech-transfer rules are enforced, it will also undermine their ability to make money on future breakthroughs. For example, Moderna spent a decade developing methods to handle those fragile strands of mRNA. If some of those methods are revealed to competitors around the world, the company will have less market advantage when it comes to developing future products. The message to investors is clear: Don’t invest in companies trying to save lives. If they succeed, the government might throw away their patents. Ironically, the Biden administration’s move probably won’t do much to increase global vaccine supply. The technology involved in producing mRNA vaccines is extremely finicky and complex. It could take many months, possibly years, for overseas producers to get up to speed. And before that process even starts, all negotiations on the issue have to go through the WTO, a notoriously slow-moving organization. Economics writer James Surowiecki suggests a better plan: The U.S. government (and those of other wealthy nations) should simply pay the drugmakers to ramp up production, license their technology where feasible, and send billions of doses wherever they’re needed. “I guarantee they will find a way to do it,” he wrote on Twitter. But paying pharma companies to make more vaccines would offend the sensibilities of Biden’s progressive flank. White House insiders told the New York Times, “It is bad politics for the president to side with pharmaceutical executives.” So Team Biden took the easier path: blowing up the business model for making vaccines and stripping pharma investors of their returns. While it was Sanders who said he’d make sure no drug companies “make a fortune” during the pandemic, it is Biden who is making good on the promise. As so often happens when progressives make policy, their zeal to punish their enemies takes precedence over their desire to achieve actual results. Meanwhile, in Congress, Sanders and his progressive colleagues in the Senate and the House have their own plan to cut Big Pharma down to size. They have introduced three bills intended to force down drug prices and strip drug companies of their patents if they don’t play ball. In the business of saving lives, no good deed goes unpunished. Normally, conservative lawmakers push back when Democrats try to hog-tie an industry with excessive regulations. But Big Pharma can no longer count on support from Republicans. “Pfizer & others should be ashamed that they have raised drug prices for no reason,” Trump tweeted in 2018. It was one of his many swipes at the industry. His administration made several abortive attempts to control drug prices under Medicare Part B. Senate Republicans Josh Hawley and Rick Scott proposed their own price-control plan in 2019, though it never came up for a vote. If congressional Democrats prioritize sweeping pharma regulations under the current administration, will Republicans even push back? Don’t count on it. Without question, there are a number of areas where the U.S. system of developing and regulating drugs does need reform. But some of the things that bother Americans most about Big Pharma—high prices and industry consolidation—are themselves partly the result of layer after layer of health-care regulations. Smart proposals to unwind some of that complexity would be welcome. Not so welcome would be new rules that would squeeze out the profits from new drugs and vaccines, thereby cutting off the pipeline of private investment. “It is true that the American medical system is complex, and pricing is opaque and that can lead to abuses,” George Mason University economist Alex Tabarrok told me in an email. “But Americans are fortunate that it pays to invest in new drug research and development.” For progressives, of course, that is precisely the problem: It pays to invest in new drug research. The idea that someone would make a profit off of curing a disease strikes them as immoral. In the progressive worldview, intentions always matter more than outcomes. If some of the people involved in drug development hope to get rich, it doesn’t matter that their drugs save lives; any product that emerges from that corrupt system must be viewed as the fruit of a poisoned tree. An academic critique of the pharma industry entitled “Thick as Thieves?”—written by a patient advocate and a business-ethics professor—makes this point explicitly. The industry’s “profound focus on self-interest places in question how much of what it does actually benefits society,” they write. Do you see the trap here? It’s not enough to do good; you must be good—you must save lives for entirely selfless reasons. (Former philosophy students may hear an echo of Kant’s unachievable “categorical imperative” here.) This moral framework puts pharmaceutical companies in a bind: The more lives a company’s innovation might save, the more it is criticized for not giving it away for free. The drug company Burroughs Wellcome learned this the hard way over three decades ago. In 1987, just three years after HIV, the virus that causes AIDS, was identified, the company introduced AZT, the first effective treatment for the horrific disease. Fortune called that accomplishment “the pharmaceutical equivalent of an under-two-minute mile.” Like many breakthrough drugs, AZT was extremely expensive to produce, and it was initially approved for just a small number of patients. So Burroughs put what most people saw as an obscenely high price on it. The outrage was instantaneous. Over the next two years, the company was pilloried in the press and its leaders were called to defend themselves on Capitol Hill. AIDS activists slapped “AIDS Profiteer” stickers on other Burroughs products in drugstores and invaded the company’s headquarters with chainsaws. The Burroughs executives might have been pharmacological geniuses, but they were public-relations dunderheads. Ever since, progressives have seized on every example of a Big Pharma “abuse”—whether fairly or not—as arguments to take down the industry as a whole. And too often, Big Pharma makes itself a Big Target. For example, it’s true that some companies, especially Purdue Pharma, were dangerously lax in the ways they promoted and distributed prescription opioids. Criticism is called for. But, as Jacob Sullum has documented in a series of articles at Reason, the popular notion that patients were routinely prescribed opioids for pain and then became hopeless addicts is largely a myth. Study after study has shown that illicit drugs such as heroin and fentanyl—and not prescribed pain meds—cause the vast majority of opioid deaths. That’s why it isn’t surprising that the opioid crisis has continued long after authorities radically curtailed access to prescription painkillers. (Indeed, today, many cancer patients and others have difficulty obtaining adequate pain medication.) When firms dramatically hike prices on drugs that had previously been more affordable, they offer another occasion for outrage. Turing Pharmaceuticals founder Martin Shkreli became a household name by buying up the license to produce the anti-parasitic Daraprim, and then he boosted the price from $13.50 to $750 a dose. Shkreli was condemned by everyone from Sanders to Trump and then compounded the damage with his smirking responses to criticism. As one industry consultant put it to me, “Shkreli essentially wadded himself up into a softball for the press.” In reality, Turing was exploiting FDA rules that make it hard for new companies to win approval for their own generic versions of drugs that are no longer under patent. Since the market for Daraprim is fairly small, Shkreli knew it was unlikely that another drugmaker would want to go through the arduous approval process just to sell a generic version of the medication. Shrkeli milked that near-monopoly power shamelessly, but he didn’t write the rules. It would have been useful for politicians and the press to explore ways to fix those perverse incentives. But they preferred to beat up on Shkreli—and on the pharma business as a whole. Again. “Pharma is the whipping boy for the whole medical establishment,” the industry consultant told me. The reason? “Drugs are the one component of healthcare where the prices are exposed to the consumer.” And, due to higher co-pays, “you have to reach into your own pocket to pay part of it.” Another factor—ironically—is the generally low prices consumers pay for drugs once their period of patent protection ends and they go generic (notwithstanding outliers like Daraprim). Because new drugs typically spend so many years in development, most are on the market for only a decade or so before their patents expire. “Suddenly a drug you’ve been taking for years drops dramatically in price,” he says. “People think,‘Why wasn’t this $8 all along? It must be some sort of scam.’” When introducing a trio of bills aimed at forcing down drug prices in March 2021, Sanders said, “The greed of drug companies is out of control and the cost is human lives.” Now, it’s true that drug prices are confusing, and often alarmingly high, at least on paper. But the fault does not lie primarily with the drug companies. As Scott Gottlieb wrote in a piece published before he became FDA commissioner under Trump, “by the time a drug reaches your medicine cabinet, it passes through a long series of intermediaries who each take a cut of money.” The system, which grew up in response both to the regulatory environment and the needs of insurance companies, is too mind-numbing to describe in full. In a nutshell, it includes wholesalers and “pharmacy-benefit managers” (PBRs) who negotiate with the drug manufacturers on behalf of health plans. Drugmakers pay huge rebates to those PBRs, who pass much of that money on to the health plans, and, indirectly, to consumers. It’s a crazy-quilt system that gives pharma companies incentives to place the highest possible list prices on their drugs. They know that almost no one actually pays those prices. (Though, as always, people without insurance wind up getting the worst possible deal.) And Big Pharma critics get to rail against their cruelty and greed. \_\_\_\_\_\_\_\_\_\_\_\_\_ THE TRUTH IS, in most areas of human health, the pharmaceutical companies are not the problem; they are the solution. Yes, there are legitimate concerns about how Big Pharma sets prices. If companies are colluding to limit competition or prop up prices, for example, those cases should be investigated as antitrust violations. But the majority of complaints about the pharmaceutical business aren’t just exaggerated; they get the issue entirely backwards. Activists who want to rein in the drug companies are attacking the part of our health-care system that works best. “New drugs are one of the best and cheapest ways to increase lifespan and improve life,” Tabarrok told me. The numbers are staggering. Deaths due to heart disease have been cut roughly in half since the 1950s, in large part thanks to cholesterol-lowering and other drugs. A 2019 study in the journal International Health looked at the impact of new drugs in reducing deaths from 66 diseases in 27 countries. The study measured the total number of “life-years” the population gained as a result of these new drug treatments (up to the age of 85). It found that if no new drugs had been introduced between 1981 and 2013, the number of life-years lost to these diseases would have been more than twice as high. It’s true that many new drugs that target specific forms of cancer or rare diseases are fantastically expensive. Critics complain that some of the most expensive drugs extend life for only a few weeks or months. But those weeks and months add up. Look at how cancer survival rates have diverged between the U.K., where the National Health Service more strictly limits access to treatments deemed not cost-effective, and the U.S., where novel treatments are more available. One study found that, two years after diagnosis, 31 percent of U.S. lung-cancer patients were still alive, while only 19 percent of English patients were. (Of course, drug treatment may be only one of several factors contributing to that outcome.) Medications for everyday chronic diseases are especially cost-effective. “It is a mistake to focus on the upfront individual cost of medications while ignoring the huge savings generated by preventing disease complications with early medical interventions,” writes Larry Hausner, former CEO of the American Diabetes Association. Common drugs for hypertension and hyperglycemia can dramatically delay or prevent the onset of diabetes, one of today’s most debilitating and expensive diseases. “Preventing just 30 percent of pre-diabetics from contracting diabetes would save the health-care system $74 billion,” Hausner writes. Critics of Big Pharma tend to look at our current medicine cabinet of treatments and conclude that those drugs could be delivered much more cheaply. They aren’t wrong about this. If we voided existing patents and allowed anyone to manufacture these drugs, they could be produced at a fraction of today’s prices. After all, it is the research, and not the chemicals that go into them, that makes new drugs so expensive. But anti-pharma activists rarely consider how society will then incentivize the next generation of medical innovation. New and better pharmacological tools are still sorely needed. For example, a study by the Alzheimer’s Association estimates that a new drug that delayed the onset of Alzheimer’s by five years would result in steadily growing savings in health-care expenditures. Within 25 years, those would amount to $367 billion a year. Besides the dollars, such a drug’s contribution to human happiness would, of course, be incalculable. Our modern system of drug testing and regulation grew partly in reaction to the thalidomide tragedy of the early 1960s. That case involved a popular sedative developed in Germany, though never approved in the U.S. When doctors began prescribing it to treat morning sickness during pregnancy, a horrifying side effect emerged: a birth defect in which the baby’s limbs failed to develop properly. The case produced global outrage and revealed that many clinical trials meant to test drug safety and efficacy were slipshod. In the U.S., the FDA moved to expand the clinical-trial process and tighten up standards for drug approval. (Germany, Britain, and other developed countries did the same.) All in all, that was a good thing. Over time, however, the approval process has grown into an obstacle course that can last years and cost upwards of $1 billion to navigate—whether or not a drug is successful. Those lengthy trials also spin off detailed reports listing every possible side effect reported by participants. These might be significant, or they might be completely unrelated to the drug being tested. Either way, they serve as road maps for legal firms that want to build class-action suits targeting drug companies. Extended clinical trials and frequent legal challenges create what economists call “barriers to entry” for pharmaceutical entrepreneurs. Small companies find it much harder to navigate this swampy regulatory and legal terrain. Even big pharmaceutical players often seek greater clout and security through mergers and acquisitions. Which is how we wind up with global drug companies with names like GlaxoSmithKline. But big companies also have more to lose. David Taylor, a leading pharmacologist in Britain, writes, “More and more promising drug candidates are terminated early in the process, at the first sign of any potential problem.” Neither aspirin nor penicillin would have made it to the market under today’s industry drug-development regimes, he adds. This high failure rate can be devastating to the morale of pharmaceutical researchers. “It is not unusual for a medicinal chemist,” Taylor writes, “to have spent ~~his/her~~ their whole career in the industry and to have never worked on a successful product.” The inherent conservatism of drug regulators isn’t due to lack of professionalism or insufficient humanitarian concern. (“The people at the FDA really try to be good stewards,” the industry consultant told me.) But, as Milton Friedman pointed out decades ago, “the pressure on the FDA is always to be late in approval.” Here’s why: Imagine the agency is tasked with approving a new drug. It could accidentally certify the drug as safe and effective when it is actually dangerous or ineffective. In statistics, this is known as a Type I error. Or it could refuse to certify a drug that is, in fact, safe and beneficial—a Type II error. In the first case, the backlash tarnishes the FDA and endangers the careers of those who made the decision. But if the agency refuses to authorize a promising drug (or delays it for years), the damage happens off the public’s radar. It’s impossible to prove that particular patients would have survived if they’d gotten the drug in time. “When the FDA fails to approve a good drug,” economist Tabarrok writes, “people die, but the bodies are buried in an invisible graveyard.” This is especially true in the case of very serious diseases. After all, questions of safety and efficacy aren’t always black and white. A drug with potentially deadly side effects would be a wildly inappropriate treatment for, say, teenage acne. But those same risks might be willingly accepted by a patient with Stage 4 cancer. In a fascinating biostatistical analysis, three researchers (two of them associated with MIT and one with Pfizer) confirmed that the FDA’s “current standards of drug approval are weighted more toward avoiding a Type I error than avoiding a Type II error.” In cases of devastating illnesses such as pancreatic cancer, they found, the approval standards were too restrictive by an order of magnitude. Those researchers advocate that the FDA employ more nuanced statistical analyses that would allow it to weigh each drug’s potential benefits more fairly. Big Pharma critics complain that the industry churns out too many “me-too” drugs. Stanford Medicine magazine editor Rosanne Spector writes that drug companies “chemically rejigger an oldie but goodie, craft a new name, mount a massive advertising campaign and sell the retread as the latest innovative breakthrough.” The argument goes that, if fewer such drugs were approved, overall drug prices would be lower. There are cases where a new drug, under a fresh patent, offers few advantages over an older, cheaper generic drug. But that is not an argument against new drugs. It is an argument against today’s byzantine system of drug pricing. Too often, neither doctors nor consumers have clear incentives—or the right information—to choose less expensive alternatives. But limiting new drugs, even ones that are similar to existing drugs, doesn’t solve that dilemma. If you ask physicians, they prefer more options, not fewer. As the late analyst Peter Huber pointed out, “human biological diversity is much broader than regulators and researchers had assumed.” Drugs designed for the average patient might not work for particular patients. In cancer and other fields, doctors have discovered that only rarely does a single drug serve as a silver bullet. But a combination of drugs tailored to the individual patient—a kind of silver shotgun blast—can often be effective. Of course, the FDA approval process isn’t set up to test such combination therapies. Fortunately, the revolution in genetic testing, combined with big-data techniques, means we have entered the era of personalized medicine: treatments micro-tailored to the individual patient. But designing such personalized drug cocktails requires having a vast range of drugs to choose from. As Tabarrok writes, we need to “give physicians a larger armory and let them decide which weapon is best for the task.” \_\_\_\_\_\_\_\_\_\_\_\_\_ HISTORICALLY, our drug-approval process has focused on delivering medicines that benefit the largest group of patients with the fewest possible risks. The progressives who want to overhaul our medical system believe that the range of future drug choices should be restricted even more, with low prices being the main goal. In contrast, a growing movement in health care calls for expanding options, and giving physicians and their patients more freedom to assess risks and benefits for themselves. “For more than 80 years, the FDA has infringed on the right of people to make their own lifesaving decisions,” writes surgeon Jeffrey Singer. I doubt many Americans would want to do away with the FDA’s entire testing regimen. But what if patients had the option of choosing medications that hadn’t yet received the FDA’s blessing but had been approved by similar regulatory agencies in a few other developed countries? That’s the idea behind the Reciprocity Ensures Streamlined Use of Lifesaving Treatments (RESULT) Act, twice proposed by Senators Ted Cruz and Mike Lee. In a world where medicine is more personalized, it makes sense to give doctors and their patients more options—and more control. Such a bill has no chance of moving forward in today’s Congress. But the concept should be championed, even if, for now, it is more thought experiment than policy. Progressives have a bad habit of taking the benefits of free-market economies for granted. Cheap food, smartphones, housing, electric cars—they believe all of these things will remain abundant no matter how much we hobble the market system that produces them. In fact, they believe that if we rid the system of “excessive” profits—and remove those venal profiteers—all those good things will be even more affordable. They’ll be distributed more “equitably.” Nowhere is this wishful thinking more prevalent than on the topic of health care. Big Pharma critics often argue that if the big companies were cut down to size, drug research would sail along much the same at universities and at federally funded research centers. They are partly right: nonprofit and federally funded research contributes a lot to biomedical progress. And the U.S. National Institutes of Health plays a big role in early drug development. (Moderna consulted with NIH when designing its vaccine.) Certainly, there’s room for more private-public partnerships to develop treatments for very rare diseases and to address other challenges that the market overlooks. But for the drugs that are most likely to help most of us, the brutally expensive work of drug testing can happen only with massive private investment. Though progressives might find the idea distasteful, the investors who pour billions into pharmacological research do more to save and improve lives than any top-down government program could. Even our miracle vaccines would not have arrived so quickly had investors not spent years gambling fortunes on longshots like Moderna’s mRNA research. It was those years of tinkering and failing that allowed the company to refine its techniques. And then, when every day counted, Moderna was able to deliver a vaccine faster than any expert could have predicted. Now that it has been validated, the mRNA technique holds out realistic promise to create new treatments for cancer and other diseases. Not to mention faster and more flexible new vaccines for the possible pandemics to come. “If I am stricken with a deadly disease,” Tabarrok told me, “I sure hope that someone will profit from curing my disease!” Any regulatory scheme that sucks the profit out of drug innovation would slow the development of new drugs and vaccines to a trickle. Sure, university and government researchers would still come up with promising candidates for new drugs. But fewer companies would have the resources to turn those leads into products. They would sit on the shelf. Meanwhile victims of diseases such as cancer, diabetes, and Alzheimer’s would never know about the drugs that might have helped their condition, the drugs that never made it through the pipeline. That would be the ultimate Type II error—exactly the kind of error that was avoided in the miraculous innovations of the past year, from Moderna’s leap of faith to Operation Warp Speed to the accelerated vaccine approvals. We need to learn from that example and continue to chip away at the sclerotic ideas and regulatory policies that make drugs too expensive and their development and deployment too slow. Big Pharma has saved us from the pandemic. It could do so much more. But, between Biden in the White House and Bernie in the Senate, Big Pharma will likely be a lot less eager to go all-in next time we face a global health crisis. The precedent set by these threats to strip away hard-earned patents will never go away. Drug companies are now on warning that they’re better off sticking to inventing new meds for hair loss and erectile dysfunction. Trying to save lives only gets them in trouble.

#### Growth’s inevitable---empirics prove it’s human nature

Pethokoukis 21, James---Senior Fellow; Editor, AEIdeas Blog; and DeWitt Wallace Chair (“The 21st-century degrowth movement makes the same mistake about human nature as 20th-century socialists,” AEI, June 28, 2021, accessed Oct 2, 2021, https://www.aei.org/economics/the-21st-century-degrowth-movement-makes-the-same-mistake-about-human-nature-as-20th-century-socialists/)

\*edited for language

After the collapse of the Soviet Empire, Harvard University history professor Richard Pipes wrote in the essay “Human Nature and the Fall of Communism” that “a government that monopolizes a nation’s wealth and prohibits its citizens from accumulating any property beyond mere personal effects ensures its own destruction — if not from social or political explosion, then from chronic apathy, the sociopolitical equivalent of pernicious anemia.”

In other words, the Marxist-Leninist socialist notion that humanity was a blank slate upon which the Communist Party would write and thus create a New Soviet [hu]Man was doomed to failure. It ignored both the reality of human nature and its resilience. Indeed, the result in Soviet Russia was an economy marked by apathy and stagnation, and a society marked by corruption and repression. Again, Pipes:

The Communists wanted their citizens to give up, along with private property, personal ambitions, and to dedicate themselves wholly to the collective good. This aspiration has proven very difficult to realize, even in small utopian communities composed of idealistic volunteers. It was utterly unattainable in a vast empire held together by force. Rather than devote themselves 100 percent to the good of all, the vast majority of Soviet citizens dedicated themselves 100 percent to their private welfare. To members of the elite, the regime was an inexhaustible cornucopia that they skimmed mercilessly. Ordinary citizens interpreted the nationalization of all assets to mean that they had no stake in the country, since it belonged to someone else: since “they” owned it, let “them” take care of it. As a Soviet joke had it, “They pretend to pay us; we pretend to work.” Such attitudes resulted in a progressive alienation of the citizenry from the body politic.

Another anti-capitalist movement also suffers from a misunderstanding of human nature: the degrowthers who decry economic growth as environmentally unsustainable and beneficial only to a sliver of humanity. Of course, this ~~view~~ ignores the billions of still quite impoverished humans who would like to live like those in OECD countries. And then there’s those of us who currently live in rich countries and also would like higher incomes to acquire new goods, services, experiences, and opportunities. But don’t we in rich countries already have enough? Wouldn’t we be fine with stagnation or even a bit less? Certainly anyone having lived through the slow post-financial crisis economy should know better than to even pose such questions. I would also point to this telling example from economist Branko Milanovic’s newsletter:

I think that it could be reasonably argued that no group of people in the history of the world has lived as pleasant lives as today’s Italians. The advantages are well-known: lots of wealth, peace, moderate working hours, strong family and friendship bonds, nice weather, beautiful historical and natural sights, excellent and healthy food. Who then needs to grow? And Italy did not. It has by now stagnated for a generation and while in 1999, its GDP per capita was 3.5 times the world average, it is today 2.5 times. One could say, “it does not matter if people are happy”. But the problem is that, while superficially people may be happy this Summer as they congregate on the beaches and drink aperol, there is a deep malaise induced precisely by the absence of growth. The young are not happy because of lack of opportunities, the middle-aged people are not happy by non-challenging jobs, the old are not happy because their pensions are stagnant. So even if you have achieved a stagnant Arcadia, you cannot be happy and stop running because others are overtaking you and the fundamental features of capitalism, in Italy and elsewhere, are as I have described them above.

#### Decoupling [or dematerialization] makes growth sustainable—empirics, efficiency, substitution, consumption decline, innovation, financial oversight, and new reserves.

McAfee 19—(principal research scientist and codirector of the Initiative on the Digital Economy at MIT, PHD in business administration from Harvard, MS in mechanical engineering from MIT, unrelated to the crazy McAfee). McAfee, Andrew. 2019. More from Less: The Surprising Story of How We Learned to Prosper Using Fewer Resources—and What Happens Next. Scribner.

What’s behind the broad and deep dematerialization of the American economy? Why are we now post-peak in our consumption of so many resources? In the next chapters I’ll present my explanation of the causes of dematerialization. First, though, I want to give a short explanation of what the causes are not. In particular, I want to show that the CRIB strategies born around Earth Day and promoted since then for reducing our planetary footprint—consume less, recycle, impose limits, and go back to the land—have not been important contributors to the dematerialization we’ve seen. Since Earth Day, we have demonstrably not consumed much less or gone back to the land in large numbers. We have recycled a lot, but this fact is irrelevant because recycling is a separate phenomenon from dematerialization. Much more relevant than recycling are the limits we’ve imposed in a couple of areas. The history of these limits is instructive because it helps us separate great ideas (limits on pollution and hunting animals) from truly terrible ones (limits on family size). All, Consuming The C part of the CRIB strategy—a plea for us to consume less for the planet’s sake—has largely fallen on deaf ears. To see this, let’s look at change in the real GDP of the United States. It grew by an average of 3.2 percent per year between the end of World War II and Earth Day. From 1971 to 2017, it grew by an annual average of 2.8 percent. Population growth also slowed down after the postwar baby boom, but it remained positive. America’s population increased by an average of 1.5 percent a year from 1946 to 1970, and by 1 percent annually from 1971 to 2016. So while we have slowed down some, we certainly haven’t come close to embracing degrowth in our population or consumption. But the American economy has changed significantly since Earth Day and has become relatively less oriented around making and building things. Services, ranging from haircuts to insurance policies to concerts, now make up a much larger share of the economy than they did in 1970. US personal consumption of services has risen from 30 percent of GDP in 1970 to 47 percent in 2017. So, has the decline in resource use come about because we don’t make or consume as many products as we used to? No. While it’s true that products have been declining in relative terms (in other words, as a percentage of total GDP) compared to services, our total consumption of products has still been increasing in absolute terms. So has our industrial production—the total amount of things made in America. What’s more, the United States has not recently shifted away from “heavy” manufacturing. We still make lots of vehicles, machinery, and other big-ticket items, just as we used to. But we don’t make them the same way we used to. We now make them using fewer resources. To see this, let’s add a line showing US industrial production to our graph from the previous chapter of GDP and total metal consumption. This updated chart makes clear that the country hasn’t stopped producing things. Instead, America’s manufacturers have learned to produce more things from less metal. So to summarize, growth of consumption has in some cases slowed down in recent years. But growth in resource use has done much more than slow down—it has reversed course and is now generally negative. We have not as a society embraced degrowth. Instead, we’ve done something far stranger and more profound: we’ve decoupled growth—in consumption, prosperity, and our economy—from resource use. Early in the Industrial Era, the French diplomat Alexis de Tocqueville published his 1835 book, Democracy in America. One of the first major investigations into the character of the then-young country, it remains one of the best.I De Tocqueville observed almost two centuries ago that the people of the United States liked their things: “In America, the passion for material well-being… is general.… Minds are universally preoccupied with meeting the body’s every need and attending to life’s little comforts.” What’s new is that providing for our needs and comforts now requires fewer materials, not more. Recycling: Big, and Beside the Point Recycling is big business: 47 percent, 33 percent, 68 percent, and 49 percent of all the tonnage of aluminum, copper, lead, and iron and steel (respectively) consumed in the United States in 2015 came from scrap metal rather than ore taken from the earth. Similarly, almost 65 percent of paper products came from recycled newspapers, pizza boxes, and so on rather than from felled trees. Yet recycling is irrelevant for dematerialization. Why? Because recycling is about where resource-producing factories get their inputs, while dematerialization is about what’s happened to total demand for their outputs. Paper mills, for example, get their raw material from two main sources: recycling centers and forests. American consumption of output from all paper mills combined has been declining since 1990, the year of peak paper in the United States. This decline is purely a matter of how much total demand there is for paper; it has no direct relationship to the amount of recycling taking place. But is there any indirect relationship? How much would our total consumption of resources such as paper or steel change without recycling? It’s impossible to answer with certainty, but my intuition is that if recycling didn’t exist, our total consumption of resources such as aluminum, copper, iron, and steel would be declining even more quickly. This seems counterintuitive; the conclusion is supported by a simple chain of reasoning. Recycling metals makes economic sense exactly because it’s cheaper to melt down and reuse scrap than it is to dig out and process ore. Without this scrap, a ton of metal would probably cost more, all other things being equal. And as a general rule, we use less of a thing when it costs more. So it seems most likely to me that we’d use less metal overall in a hypothetical zero-recycling economy than we do in our actual enthusiastic-about-scrap-metal-recycling economy. This does not mean that I think metal recycling is bad. I think it’s great, since it gives us cheaper metal products and reduces total greenhouse gas emissions (since it takes much less energy to obtain metal from scrap than from ore). But recycling, whatever its merits, is not part of the dematerialization story. It’s a different story. Back to the Land Is Bad for the Land The back-to-the-land movement is a fascinating chapter in the history of American environmentalism, but a largely insignificant one. There were simply never enough homesteaders and others who turned away from modern, technologically sophisticated life to make much of a difference. Which is a good thing for the environment. As Jeffrey Jacob documents in his book New Pioneers, the back-to-the-land movement in the United States began in the mid-1960s and continued into the next decade. According to one estimate, as many as 1 million North American back-to-the-landers were living on small farms by the end of the 1970s. This, though, was a weak current against the strong tide of urban growth; the number of American city dwellers increased by more than 17 million between 1970 and 1980. Going back to the land might have been widely discussed, but it was comparatively rarely practiced. We should be thankful for this because homesteading is not great for the environment, for two reasons. First, small-scale farming is less efficient in its use of resources than massive, industrialized, mechanized agriculture. To get the same harvest, homesteaders use more land, water, and fertilizer than do “factory farmers.” Farms of less than one hundred acres, for example, grow 15 percent less corn per acre than farms with more than a thousand acres. And bigger farms get better faster. Between 1982 and 2012 farms under one hundred acres grew their total factor productivity by 15 percent, whereas farms over a thousand acres grew theirs by 51 percent. So more homesteaders would have meant more land under cultivation, more water and fertilizer used, and so on. Second, rural life is less environmentally friendly than urban or suburban dwelling. City folk live in high-density, energy-efficient apartments and condos, travel only short distances for work and errands, and frequently use public transportation. None of these things is true of country living. As economist Edward Glaeser summarizes, “If you want to be good to the environment, stay away from it. Move to high-rise apartments surrounded by plenty of concrete.… Living in the country is not the right way to care for the Earth. The best thing that we can do for the planet is build more skyscrapers.” And if homesteaders decide not only to ignore Glaeser’s advice but also to leave modernity further behind and heat their homes with coal or wood, they do still more environmental harm. Coal home furnaces create lots of atmospheric pollution, much more than comes from other kinds of fuel. Poland, for example, today has 80 percent of all homes in Europe that burn coal, and thirty-three of the Continent’s fifty most polluted cities. And burning wood means chopping down trees. A lot of them. It’s almost certainly the case that the English turned to coal for home heating in the middle of the sixteenth century because they’d cut down such a huge percentage of their trees that the price of wood skyrocketed. So if we care about the environment, we should probably be glad that the back-to-the-land movement stalled out, and that industrial-scale, high-yield agriculture has become the norm. A comprehensive review published in Nature Sustainability in 2018 concluded, “The data… do not suggest that environmental costs are generally larger for [high-yield] farming systems.… If anything, positive associations—in which high-yield, land-efficient systems also have lower costs in other dimensions—appear more common.” Imposing Limits: The Worst Idea, and the Best One Of the four elements of the CRIB strategy, the drive to impose limits has by far the most checkered history. It yielded both the most harmful strategies, and the most helpful ones. The Population Implosion In 1979 the government of the People’s Republic of China announced its new family planning policy, which soon became known as the one-child policy. It was enacted despite the steady decline in the country’s birth rate throughout the 1970s. But after reading Limits to Growth, A Blueprint for Survival, and other books limning the looming dangers of unchecked population expansion, the missile scientist Song Jian came to believe that even faster birth rate reductions were required. He became the architect of the new policy, the main effect of which was to limit ethnic Han Chinese families to a single child. Exceptions to this restriction included giving some couples the right to a second child if their first was a girl, but the one-child policy soon became a central fact of Chinese family life. It is hard to see it in a positive light. After the policy was officially abandoned in late 2015, journalist Barbara Demick wrote its unflattering obituary: “Family planning became a powerful bureaucracy, with officials who terrorized parents. They beat and burned down the houses of people who violated the family-planning limits. They snatched over-quota baby girls from the arms of their mothers and gave them to orphanages, which in turn put them up for adoption, earning a three-thousand-dollar ‘donation’ for each baby.” The Chinese government maintains that approximately 400 million births were prevented by the one-child policy, but this is probably a large overestimate. As the economist Amartya Sen points out, “The additional contribution of coercion to reducing fertility in China is by no means clear, since compulsion was superimposed on a society that was already reducing its birth rate.” In their 2013 essay “How Will History Judge China’s One-Child Policy?” the demographers Wang Feng, Yong Cai, and Baochang Gu compared the policy unfavorably to two of their country’s great twentieth-century convulsions: the Cultural Revolution and the Great Leap Forward. They wrote, “While those grave mistakes both cost tens of millions of lives, the harms done were relatively short-lived and were corrected quickly afterward. The one-child policy, in contrast, will surpass them in impact by its role in creating a society with a seriously undermined family and kin structure, and a whole generation of future elderly and their children whose well-being will be seriously jeopardized.” History, in short, will judge this government-imposed limit on family size harshly.II Rational Restrictions Imposing limits on family size is a terrible idea for reasons both practical and moral. But it’s an excellent idea to impose limits on pollution, and on hunting some animals and selling products that come from their bodies. Such restrictions have yielded the great triumphs of the conservation and environmental movements in America and other countries. In 1970, the same year as the original Earth Day festival, the United States established the federal Environmental Protection Agency and made major amendments to 1963’s Clean Air Act. This was the start of a cascade of laws and regulations aimed at reducing pollution and other environmental harms. These have worked amazingly well. For example, atmospheric levels of sulfur dioxide in the United States have dropped to levels not seen since the first years of the twentieth century, and other kinds of air pollution have also dropped sharply. From 1980 to 2015, total emissions of six principal air pollutants decreased by 65 percent. As lead was banned from paint and gasoline, the concentration of that element in the blood of young children dropped by more than 80 percent between 1976 and 1999. Because lead retards brain development during youth, these declines are tremendously important. According to one study, American children in 1999 had IQs that were on average 2.2 to 4.7 points higher than they would have been had lead concentrations remained at their 1970 levels. More work certainly remains, but thanks to the limits imposed on pollutants, America’s soil, air, and water are all much cleaner than they were on Earth Day. The conservationists who grew concerned in the early years of the twentieth century about what hunting was doing to the populations of many animals were the predecessors of Earth Day’s environmentalists. Conservationists were spurred to action by the shocking extinction of the passenger pigeon. That such an abundant bird could be eradicated stunned many and spurred new laws restricting trade in animal products. The first of these was the Lacey Act, passed by Congress in 1900 and named for John Lacey, a Republican representative from Iowa. As he said during debate on the bill, “The wild pigeon, formerly in flocks of millions, has entirely disappeared from the face of the earth. We have given an awful exhibition of slaughter and destruction, which may serve as a warning to all mankind. Let us now give an example of wise conservation of what remains of the gifts of nature.” The Lacey Act and its successors imposed three kinds of limits on taking and consuming animals. First, hunting of some animals was fully banned. Protected species include the sea otter, which was protected by a 1911 international moratorium; the snowy egret, which was ruthlessly hunted for its gorgeous plumes until passage of the Weeks-McLean Law Act in 1913; and dolphins and manatees, which were sheltered by 1972’s Marine Mammal Protection Act. Second, many limits have been imposed on when and where animals can be hunted. Sport and food hunting are illegal in most national parks, for example, and duck, bear, deer, and many other animals have well-defined hunting seasons. Third, bans have been imposed on the commercial trade in many animal products. The most sweeping of these is probably the nationwide ban on the sale of hunted meat. You may see venison or bison meat at a butcher’s counter or on a menu in America, but it always comes from a ranch, not a hunt. These imposed limits have brought many iconic American animals back from the brink of extinction. North America now has more than half a million bison, for example, and over three thousand sea otters live off the coast of Northern California. Some previously threatened animals have come back so well that they’re now widely considered pests. People in many American neighborhoods today feel that there are too many white-tailed deer, Canada geese, and beaver. The story of dematerialization is not the story of following the CRIB strategies. Except for the excellent idea of imposing limits on polluting and pursuing animals, these strategies were ignored (we didn’t embrace degrowth and stop consuming), abandoned (we stopping going back to the land), irrelevant (dematerialization has nothing to do with recycling), or deeply misguided (China’s attempt to limit family size was a huge mistake). So how did we finally start getting more from less? How did we become post-peak in our use of so many resources? The next three chapters will take up this critical question. CHAPTER 7 What Causes Dematerialization? Markets and Marvels The triumph of the industrial arts will advance the cause of civilization more rapidly than its warmest advocates could have hoped. —Charles Babbage, The Exposition of 1851; or, Views of the Industry, the Science, and the Government of England, 1851 If CRIB strategies aren’t responsible for the large-scale dematerialization of the American economy that has taken place since Earth Day, then what is? How have we got more from less? I believe that four main forces are responsible, and that it’s helpful to think of them as two pairs. In this chapter we’ll look at the first pair, then take up the second in chapter 9. Capitalism and technological progress are the first pair of forces driving dematerialization. This statement will come as a surprise to many, and for good reason. After all, it’s exactly this combination that caused us to massively increase our resource consumption throughout the Industrial Era. As we saw in chapter 3, the ideas of William Jevons and Alfred Marshall point to the distressing conclusion that capitalism and tech progress always lead to more from more: more economic growth, but also more resource consumption. So what changed? How are capitalism and tech progress now getting us more from less? To get answers to these important questions, let’s start by looking at a few recent examples of dematerialization. Fertile Farms America has long been an agricultural juggernaut. In 1982, after more than a decade of steady expansion due in part to rising grain prices, total cropland in the country stood at approximately 380 million acres. Over the next ten years, however, almost all of this increase was reversed. So much acreage was abandoned by farmers and given back to nature that cropland in 1992 was almost back to where it had been almost twenty-five years before. This decline had several causes, including falling grain prices, a severe recession, over-indebted farmers, and increased international competition. A final factor, though, was the ability to get ever-more corn, wheat, soybeans, and other crops from the same acre of land, pound of fertilizer and pesticide, and gallon of water. The material productivity of agriculture in the United States has improved dramatically in recent decades, as we saw in chapter 5. Between 1982 and 2015 over 45 million acres—an amount of cropland equal in size to the state of Washington—was returned to nature. Over the same time potassium, phosphate, and nitrogen (the three main fertilizers) all saw declines in absolute use. Meanwhile, the total tonnage of crops produced in the country increased by more than 35 percent. As impressive as this is, it’s dwarfed by the productivity improvements of American dairy cows. In 1950 we got 117 billion pounds of milk from 22 million cows. In 2015 we got 209 billion pounds from just 9 million animals. The average milk cow’s productivity thus improved by over 330 percent during that time. Thin Cans Tin cans are actually made of steel coated with a thin layer of tin to improve corrosion resistance. They’ve been used since the nineteenth century to store food. Starting in the 1930s, they began also to be used to hold beer and soft drinks.I In 1959 Coors pioneered beer cans made of aluminum, which is much lighter and more corrosion resistant than steel. Royal Crown Cola followed suit for soda five years later. As Vaclav Smil relates, “A decade later steel cans were on the way out, and none of them have been used for beer since 1994 and for soft drinks since 1996.… At 85 g the first aluminum cans were surprisingly heavy; by 1972 the weight of a two-piece can dropped to just below 21 g, by 1988 it was less than 16 g, a decade later it averaged 13.6 g, and by 2011 it was reduced to 12.75 g.” Manufacturers accomplished these reductions by making aluminum cans’ walls thinner, and by making the sides and bottom from a single sheet of metal so that only one comparatively heavy seam was needed (to join the top to the rest of the can). Smil points out that if all beverage cans used in 2010 weighed what they did in 1980, they would have required an extra 580,000 tons of aluminum. And aluminum cans kept getting lighter. In 2012 Ball packaging introduced into the European market a 330 ml can that held 7.5 percent less than the US standard, yet at 9.5 g weighed 25 percent less. Gone Gizmos In 2014 Steve Cichon, a “writer, historian, and retired radio newsman in Buffalo, NY,” paid $3 for a large stack of front sections of the Buffalo News newspaper from the early months of 1991. On the back page of the Saturday, February 16, issue was an ad from the electronics retailer Radio Shack. Cichon noticed something striking about the ad: “There are 15 electronic gimzo type items on this page.… 13 of the 15 you now always have in your pocket.” The “gizmo type items” that had vanished into the iPhone Cichon kept in his pocket included a calculator, camcorder, clock radio, mobile telephone, and tape recorder. While the ad didn’t include a compass, camera, barometer, altimeter, accelerometer, or GPS device, these, too, have vanished into the iPhone and other smartphones, as have countless atlases and compact discs. The success of the iPhone was almost totally unanticipated. A November 2007 cover story in Forbes magazine touted that the Finnish mobile phone maker Nokia had over a billion customers around the world and asked, “Can anyone catch the cell phone king?” Yes. Apple sold more than a billion iPhones within a decade of its June 2007 launch and became the most valuable publicly traded company in history. Nokia, meanwhile, sold its mobile phone business to Microsoft in 2013 for $7.2 billion to get “more combined muscle to truly break through with consumers,” as the Finnish company’s CEO Stephen Elop said at the time of the deal. It didn’t work. Microsoft sold what remained of Nokia’s mobile phone business and brand to a subsidiary of the Taiwanese electronics manufacturer Foxconn for $350 million in May of 2016. Radio Shack filed for bankruptcy in 2015, and again in 2017. From Peak Oil to… Peak Oil In 2007 US coal consumption reached a new high of 1,128 million short tons, over 90 percent of which was burned to generate electricity. Total coal use had increased by more than 35 percent since 1990, and the US Energy Information Administration (the official energy statisticians of the US government) forecast further growth of up to 65 percent by 2030. Also in 2007 the US Government Accountability Office (GAO), a federal agency known as “the congressional watchdog,” published a report with an admirably explanatory title: “Crude Oil: Uncertainty about Future Oil Supply Makes It Important to Develop a Strategy for Addressing a Peak and Decline in Oil Production.” It took seriously the idea of “peak oil,” a phrase coined in 1956 by M. King Hubbert, a geologist working for Shell Oil. As originally conceived, peak oil referred to the maximum amount of oil that we could annually produce for all of humanity’s needs. The first oil wells pumped out the crude oil that was closest to the earth’s surface or otherwise easiest to access. As those wells dried up, we had to drill deeper ones, both on land and at sea. As the world’s economies kept growing, so did total demand for oil, which kept getting harder and harder to obtain. Peak oil captured the idea that despite our best efforts and ample incentive, we would come to a time after which we would only be able to extract less and less oil year after year from the earth. Most of the estimates summarized in the GAO report found that peak oil would occur no later than 2040. The report did not mention fracking, which in retrospect looks like a serious omission. Fracking is short for “hydraulic fracturing” and is a means of obtaining oil and natural gas from rock formations lying deep underground. It uses a high-pressure fluid to cause fractures in the rock, through which oil and gas can flow and be extracted. The United States and other countries have long been known to have huge reserves of hydrocarbons in deep rock formations, which are often called shales. Companies had been experimenting with fracking to get at them since the middle of the twentieth century, but had made little progress. In 2000 fracking accounted for just 2 percent of US oil production. That figure began to increase quickly right around the time of the GAO report. Not because of any single breakthrough, but instead because the suite of tools and techniques needed for profitable fracking had all improved enough. A gusher of shale oil and gas ensued. Thanks to fracking, US crude oil production almost doubled between 2007 and 2017, when it approached the benchmark of 10 million barrels per day. By September of 2018 America had surpassed Saudi Arabia to become the world’s largest producer of oil. American natural gas production, which had been essentially flat since the mid-1970s, jumped by nearly 43 percent between 2007 and 2017. As a result of the fracking boom the United States has experienced peak coal rather than peak oil. And the peak in coal is not in total annual supply, but instead in demand. Fracking made natural gas cheap enough that it became preferred over coal for much electricity generation. By 2017 total US coal consumption was down 36 percent from its 2007 high point. The phrase peak oil is still around, but, as is the case with coal, it usually no longer refers to supply. As a 2017 Bloomberg headline put it, “Remember Peak Oil? Demand May Top Out Before Supply Does.” Even though the extra supply from fracking has helped push down oil and gas prices, many observers now believe that energy from other sources—the sun, wind, and the nuclei of uranium atoms—is getting cheaper faster and becoming much more widely available. So much so that, as a 2018 article in Fortune about the future of oil hypothesized, “This wouldn’t be just another oil-price cycle, a familiar roller coaster in which every down is followed by an up. It would be the start of a decades-long decline of the Oil Age itself—an uncharted world in which… oil prices might be ‘lower forever.’ ” Analysts at Shell, the company from which the phrase peak oil originated, now estimate that global peak oil demand might come as soon as 2028. Taking Stock of Rolling Stock My friend Bo Cutter started his career in 1968 working for Northwest Industries, a conglomerate that owned the Chicago and North Western Railway. One of his first assignments was to help a team tasked with solving a problem that sounds odd to modern ears: figuring out where CNW’s railcars were. These cars are massive metal assemblies, each weighing thirty tons or more. In the late 1960s CNW owned thousands of them, representing a huge commitment of both material and money. Across the railroad industry, the rule of thumb then was that about 5 percent of a company’s railcars moved on any given day. This was not because the other 95 percent needed to rest. It was because their owners didn’t know where they were. CNW owned thousands of miles of track in places as far from Chicago as North Dakota and Wyoming. Its rolling stock (as locomotives and railcars are called) could also travel outside the company’s network on tracks owned by other railroads. So these assets could be almost anywhere in the country. When the railcars weren’t moving, they sat in freight yards. At the time Cutter started his job, freight yards didn’t keep up-to-date records of the idle rolling stock they contained because, in the days before widespread digital computers, sensors, and networks, there was no way to cost-effectively know or communicate the location of each car. So it was impossible for CNW or any other railroad to systematically track its most important inventory, even though doing so would be hugely beneficial to the company’s bottom line. For example, Cutter’s team knew that if they could increase the percentage of cars moving each day from 5 percent to 10 percent, they would need only half as many of them. Even a single percentage point increase in freight-car use would yield major financial benefits. When Cutter started his assignment, CNW and all other railroads employed spotters, who visited yards and watched trains pass, then telegraphed their findings to the head office. Other railroads passed on similar information to collect the demurrage charges they were owed for each CNW car on their tracks and in their yards. Cutter’s team improved on these methods by making them more systematic and efficient. They put in place a better baseline audit of where railcars were, employed more spotters, painted CNW cars differently so they were easier to see, and explored how to make more use of a new tool for businesses: the digital computer. That tool and its kin are now pervasive in the railroad industry. In the early 1990s, for example, companies started putting radio-frequency identification tags on each piece of rolling stock. These tags would be read by trackside sensors, thus automating the work of spotting. At present over 5 million messages about railcar status and location are generated and sent throughout the American railway system every day, and the country’s more than 450 railroads have nearly real-time visibility over all their rolling stock. The Rare Earth Scare In September of 2010 the Japanese government took into custody the captain of a Chinese fishing boat that had collided with Japanese patrol vessels near a group of uninhabited islands in the East China Sea claimed by both countries. China responded by imposing an embargo on shipments of rare earth elements (REE) to the Land of the Rising Sun. Even though Japan relented almost immediately and released the captain, a global panic began. This is because rare earths are “vitamins of chemistry,” as USGS scientist Daniel Cordier puts it. “They help everything perform better, and they have their own unique characteristics, particularly in terms of magnetism, temperature resistance, and resistance to corrosion.” By 2010 China produced well over 90 percent of the world’s REE. Its actions in the wake of the maritime incident convinced many that it could and would take unilateral action to control the flow of these important materials, and panicked buying soon followed (along with its close cousin rampant speculation). A bundle of REE that would have sold for less than $10,000 in early 2010 soared to more than $42,000 by April of 2011. In September of that year the US House of Representatives held a hearing called “China’s Monopoly on Rare Earths: Implications for US Foreign and Security Policy.” China didn’t attain its near monopoly because it possessed anything close to 90 percent of global reserves of REE. In fact, rare earths aren’t rare at all (one, cerium, is about as common in the earth’s crust as copper). However, they’re difficult to extract from ore. Obtaining them requires a great deal of acid and generates tons of salt and crushed rock as by-products. Most other countries didn’t want to bear the environmental burden of this heavy processing and so left the market to China. In the wake of the embargo, this seemed like a bad idea. As Representative Brad Sherman put it during the congressional hearing, “Chinese control over rare earth elements gives them one more argument as to why we should kowtow to China.” But there was never much kowtowing. By the time of the hearing, prices for REE were already in free fall. Why? What happened to the apparently tight Chinese stranglehold over REE? Several factors caused it to ease, including the availability of other supply sources and incomplete maintenance of the embargo. But as public affairs professor Eugene Gholz noted in a 2014 report on the “crisis,” many users of REE simply innovated their way out of the problem. “Companies such as Hitachi Metals [and its subsidiary in North Carolina] that make rare earth magnets found ways to make equivalent magnets using smaller amounts of rare earths in the alloys.… Meanwhile, some users remembered that they did not need the high performance of specialized rare earth magnets; they were merely using them because, at least until the 2010 episode, they were relatively inexpensive and convenient.” Overall, the companies using REE found many inexpensive and convenient alternatives. By the end of 2017 the same bundle of rare earths that had been trading above $42,000 in 2011 was available for about $1,000.What’s Going On? There is no shortage of examples of dematerialization. I chose the ones in this chapter because they illustrate a set of fundamental principles at the intersection of business, economics, innovation, and our impact on our planet. They are: We do want more all the time, but not more resources. Alfred Marshall was right, but William Jevons was wrong. Our wants and desires keep growing, evidently without end, and therefore so do our economies. But our use of the earth’s resources does not. We do want more beverage options, but we don’t want to keep using more aluminum in drink cans. We want to communicate and compute and listen to music, but we don’t want an arsenal of gadgets; we’re happy with a single smartphone. As our population increases, we want more food, but we don’t have any desire to consume more fertilizer or use more land for crops. Jevons was correct at the time he wrote that total British demand for coal was increasing even though steam engines were becoming much more efficient. He was right, in other words, that the price elasticity of demand for coal-supplied power was greater than one in the 1860s. But he was wrong to conclude that this would be permanent. Elasticities of demand can change over time for several reasons, the most fundamental of which is technological change. Coal provides a clear example of this. When fracking made natural gas much cheaper, total demand for coal in the United States went down even though its price decreased. With the help of innovation and new technologies, economic growth in America and other rich countries—growth in all of the wants and needs that we spend money on—has become decoupled from resource consumption. This is a recent development and a profound one. Materials cost money that companies locked in competition would rather not spend. The root of Jevons’s mistake is simple and boring: resources cost money. He realized this, of course. What he didn’t sufficiently realize was how strong the incentive is for a company in a contested market to reduce its spending on resources (or anything else) and so eke out a bit more profit. After all, a penny saved is a penny earned. Monopolists can just pass costs on to their customers, but companies with a lot of competitors can’t. So American farmers who battle with each other (and increasingly with tough rivals in other countries) are eager to cut their spending on land, water, and fertilizer. Beer and soda companies want to minimize their aluminum purchases. Producers of magnets and high-tech gear run away from REE as soon as prices start to spike. In the United States, the 1980 Staggers Act removed government subsidies for freight-hauling railroads, forcing them into competition and cost cutting and making them all the more eager to not have expensive railcars sit idle. Again and again, we see that competition spurs dematerialization. There are multiple paths to dematerialization. As profit-hungry companies seek to use fewer resources, they can go down four main paths. First, they can simply find ways to use less of a given material. This is what happened as beverage companies and the companies that supply them with cans teamed up to use less aluminum. It’s also the story with American farmers, who keep getting bigger harvests while using less land, water, and fertilizer. Magnet makers found ways to use fewer rare earth metals when it looked as if China might cut off their supply. Second, it often becomes possible to substitute one resource for another. Total US coal consumption started to decrease after 2007 because fracking made natural gas more attractive to electricity generators. If nuclear power becomes more popular in the United States (a topic we’ll take up in chapter 15), we could use both less coal and less gas and generate our electricity from a small amount of material indeed. A kilogram of uranium-235 fuel contains approximately 2–3 million times as much energy as the same mass of coal or oil. According to one estimate, the total amount of energy that humans consume each year could be supplied by just seven thousand tons of uranium fuel. Third, companies can use fewer molecules overall by making better use of the materials they already own. Improving CNW’s railcar utilization from 5 percent to 10 percent would mean that the company could cut its stock of these thirty-ton behemoths in half. Companies that own expensive physical assets tend to be fanatics about getting as much use as possible out of them, for clear and compelling financial reasons. For example, the world’s commercial airlines have improved their load factors—essentially the percentage of seats occupied on flights—from 56 percent in 1971 to more than 81 percent in 2018. Finally, some materials get replaced by nothing at all. When a telephone, camcorder, and tape recorder are separate devices, three total microphones are needed. When they all collapse into a smartphone, only one microphone is necessary. That smartphone also uses no audiotapes, videotapes, compact discs, or camera film. The iPhone and its descendants are among the world champions of dematerialization. They use vastly less metal, plastic, glass, and silicon than did the devices they have replaced and don’t need media such as paper, discs, tape, or film. If we use more renewable energy, we’ll be replacing coal, gas, oil, and uranium with photons from the sun (solar power) and the movement of air (wind power) and water (hydroelectric power) on the earth. All three of these types of power are also among dematerialization’s champions, since they use up essentially no resources once they’re up and running. I call these four paths to dematerialization slim, swap, optimize, and evaporate. They’re not mutually exclusive. Companies can and do pursue all four at the same time, and all four are going on all the time in ways both obvious and subtle. Innovation is hard to foresee. Neither the fracking revolution nor the world-changing impact of the iPhone’s introduction were well understood in advance. Both continued to be underestimated even after they occurred. The iPhone was introduced in June of 2007, with no shortage of fanfare from Apple and Steve Jobs. Yet several months later the cover of Forbes was still asking if anyone could catch Nokia. Innovation is not steady and predictable like the orbit of the Moon or the accumulation of interest on a certificate of deposit. It’s instead inherently jumpy, uneven, and random. It’s also combinatorial, as Erik Brynjolfsson and I discussed in our book The Second Machine Age. Most new technologies and other innovations, we argued, are combinations or recombinations of preexisting elements. The iPhone was “just” a cellular telephone plus a bunch of sensors plus a touch screen plus an operating system and population of programs, or apps. All these elements had been around for a while before 2007. It took the vision of Steve Jobs to see what they could become when combined. Fracking was the combination of multiple abilities: to “see” where hydrocarbons were to be found in rock formations deep underground; to pump down pressurized liquid to fracture the rock; to pump up the oil and gas once they were released by the fracturing; and so on. Again, none of these was new. Their effective combination was what changed the world’s energy situation. Erik and I described the set of innovations and technologies available at any time as building blocks that ingenious people could combine and recombine into useful new configurations. These new configurations then serve as more blocks that later innovators can use. Combinatorial innovation is exciting because it’s unpredictable. It’s not easy to foresee when or where powerful new combinations are going to appear, or who’s going to come up with them. But as the number of both building blocks and innovators increases, we should have confidence that more breakthroughs such as fracking and smartphones are ahead. Innovation is highly decentralized and largely uncoordinated, occurring as the result of interactions among complex and interlocking social, technological, and economic systems. So it’s going to keep surprising us. As the Second Machine Age progresses, dematerialization accelerates. Erik and I coined the phrase Second Machine Age to draw a contrast with the Industrial Era, which as we’ve seen transformed the planet by allowing us to overcome the limitations of muscle power. Our current time of great progress with all things related to computing is allowing us to overcome the limitations of our mental power and is transformative in a different way: it’s allowing us to reverse the Industrial Era’s bad habit of taking more and more from the earth every year. Computer-aided design tools help engineers at packaging companies design generations of aluminum cans that keep getting lighter. Fracking took off in part because oil and gas exploration companies learned how to build accurate computer models of the rock formations that lay deep underground—models that predicted where hydrocarbons were to be found. Smartphones took the place of many separate pieces of gear. Because they serve as GPS devices, they’ve also led us to print out many fewer maps and so contributed to our current trend of using less paper. It’s easy to look at generations of computer paper, from 1960s punch cards to the eleven-by-seventeen-inch fanfold paper of the 1980s, and conclude that the Second Machine Age has caused us to chop down ever more trees. The year of peak paper consumption in the United States, however, was 1990. As our devices have become more capable and interconnected, always on and always with us, we’ve sharply turned away from paper. Humanity as a whole probably hit peak paper in 2013. As these examples indicate, computers and their kin help us with all four paths to dematerialization. Hardware, software, and networks let us slim, swap, optimize, and evaporate. I contend that they’re the best tools we’ve ever invented for letting us tread more lightly on our planet. All of these principles are about the combination of technological progress and capitalism, which are the first of the two pairs of forces causing dematerialization. Technology: The Human Interface with the Material World One of my favorite definitions of technology comes from the philosopher Emmanuel Mesthene, who called it “the organization of knowledge for the achievement of practical purposes.” Sometimes that knowledge is crystallized into products such as hammers and iPhones, and sometimes it exists as techniques such as those for fracking or precision agriculture. Like knowledge itself, technologies accumulate. We haven’t forgotten about the lever, the plow, or the steam engine in the Second Machine Age, and we haven’t had to give them up to use cloud computing or drones. Like innovation itself, technologies are combinatorial; most of them are combinations or recombinations of existing things. This implies that the number of potentially powerful new technologies increases over time because the number of available building blocks does. These facts help me understand why we didn’t start to dematerialize sooner. It could simply be that we didn’t have the right technologies, or enough building blocks, to allow large-scale dematerialization. We had technologies that made it feasible and profitable for us to grow by taking more and more from the earth—more and more metals, fuels, water, fertilizers, and so on—but not ones that made it possible to profitably grow while taking less and less. In the Second Machine Age, that has changed. My other preferred definition of technology comes from the great science fiction author Ursula K. Le Guin, who wrote, “Technology is the active human interface with the material world. Its technology is how a society copes with physical reality: how people get and keep and cook food, how they clothe themselves, what their power sources are (animal? human? water? wind? electricity? other?), what they build with and what they build, their medicine—and so on and on. Perhaps very ethereal people aren’t interested in these mundane, bodily matters, but I’m fascinated by them.” So am I, because these “mundane matters” have twice reshaped the world—first during the Industrial Era, when technological progress allowed us to prosper by taking more from the planet, and now in the Second Machine Age, when we’ve finally figured out how to prosper while taking less. Capitalism: Means of Production Capitalism and religion are the two subjects that leave the fewest people on the sidelines. People have very firmly held opinions on both topics, and few change their minds no matter what evidence and arguments are presented to them. Yet despite this clear history of intransigence, many thinkers and writers have tried to bring others around to their point of view on both topics. Most have failed. I’m going to join this long sad parade by arguing in favor of capitalism. Before I do that, though, I want to define what I’m talking about. Even more than is the case with technology, clear definitions are important with capitalism because it’s such a triggering word. As the psychologist Jonathan Haidt has pointed out, some hear it as a synonym for liberation, others for exploitation. But let me put the dictionary before the thesaurus and offer a definition of what capitalism is before suggesting what it’s like. For our purposes, capitalism is a way to come up with goods and services and get them to people. Every society that doesn’t want its people to starve or die of exposure has to accomplish this task; capitalism is simply one approach to doing it. The important features of this approach are: Profit-seeking companies. Under capitalism, most goods and services are produced by for-profit companies rather than nonprofits, the government, or individuals. Companies can be owned by only a few people (such as the partners in a law firm) or a great many (publicly traded companies have shareholders all over the world) and are assumed to last over time; they don’t have a predefined end date. Free market entry and competition. Companies can go after one another’s markets and customers; there are few if any protected monopolies. It might not be legal to completely copy a rival’s patented product, but it’s perfectly legal to try to come up with something better. In economist-speak, markets are contested. Similarly, people can take their skills from one market to another; they’re not tied to a single geography or job. Strong property rights and contract enforcement. Patents are a form of intellectual property. They can be bought and sold just as other kinds of property—from land to houses to cars—can. Laws and courts ensure that none of these kinds of property can be stolen or destroyed, even by large, powerful entities such as billionaires, giant corporations, or the government. Similarly, if a small company and a big one sign a contract to work together, neither party gets to unilaterally walk away from the agreement without fear of getting sued. Absence of central planning, control, and price setting. The government does not decide what goods and services are needed by people, or which companies should be allowed to produce them. No central body decides if there is “enough” volume and variety in smartphones, caffeinated beverages, steel girders, and so on. The prices of these and most other goods and services are allowed to vary based on the balance of supply and demand, rather than being set in advance or adjusted by any central authority. Private ownership of most things. Smartphones, cups of coffee, steel girders, and most other products are owned by the people or companies that bought them. The companies that produced these things are also owned by people. Many shares of Apple, Starbucks, US Steel, and other public companies are held by mutual funds, pension funds, and hedge funds, but all these funds are themselves ultimately owned by people. Most houses, cars, land, gold, Bitcoin, and other assets are also owned by people rather than the government. Voluntary exchange. The phrase most closely associated with capitalism is voluntary exchange. People can’t be forced to buy specific products, take a certain job, or move across the country. Companies don’t have to sell themselves if they don’t want to. They also don’t have to make some products and not others, or stay within specific markets. The Waffle House chain doesn’t have any of its breakfast restaurants in my state of Massachusetts, but that’s not because lawmakers there are keeping it out. The legislature in Boston doesn’t have that power. I want to highlight a couple of things about this definition. First, capitalism is not without oversight. The government has clear roles to play in establishing laws and settling disputes (to say nothing of setting tax rates, controlling the money supply, and doing other things of critical economic importance). As we’ll see in the next two chapters, every sane advocate of capitalism also recognizes that while voluntary exchange and free market entry are great, they don’t create utopia. Some important “market failures” need to be corrected by government action. The second thing I want to point out is that all of today’s rich countries are capitalist, by this definition. This is not to say that all capitalist countries are alike. Denmark, South Korea, and the United States are very different places. They have dissimilar trade policies, tax systems, social safety nets, industrial structures, and so on. But they all have all of the things listed above; they are all inherently capitalist. Denmark’s economy is not planned and controlled out of Copenhagen, people in Korea own their own houses and furniture,III and contracts in America are generally respected and enforced. Today’s poorer countries, in sharp contrast, reliably do not have all of the things listed above. Their governments tend to run such things as airlines and telephone networks that are run by private companies in rich countries. It’s generally much harder to start a company in less affluent countries, so free market entry and competition are constrained. According to the World Bank, in 2017 it took less than six days to start a business in America, Denmark, Singapore, Australia, and Canada, and seventy days or more in Somalia, Brazil, and Cambodia. The world champion of entrepreneurial sclerosis was Venezuela (a country we’ll talk more about in the next chapter), at two hundred and thirty days. In poorer countries, it’s also often not clear who owns what. Things that are taken for granted in the rich world, such as unambiguous land registries and clear title to houses and other property, are problematic in many developing countries. The biggest difference between rich and poor countries might be whether laws are clearly and consistently enforced. Poorer countries don’t lack laws; they often have extensive legal codes. What’s in short supply is justice for all. Officials are corrupt; the elite get special treatment and rarely lose in court; police, regulators, and inspectors can expect bribes; and contested markets, property rights, and voluntary exchange suffer in countless other ways. It’s not that these abuses don’t occur in rich countries, but they occur much, much less often. I’ll make some more points about capitalism in the next chapter. To wrap up this one, I want to emphasize how well technological progress and capitalism work together. Overcoming the Limits A great way to see what happens when capitalism and tech progress combine is to look back at 1972’s The Limits to Growth, which we first came across in chapter 4. It’s a fascinating document for two reasons. First, it’s one of the most Malthusian books written since Malthus. It’s far gloomier than anything Jevons came up with. The team behind The Limits to Growth tried to model the future of the exponentially growing world economy and concluded, “We can thus say with some confidence that, under the assumption of no major change in the present system, population and industrial growth will certainly stop within the [twenty-first] century, at the latest. The system… collapses because of a resource crisis.” Second, The Limits to Growth provided an invaluable service by recording what the known global reserves of important resources were in 1972. “Known global reserves” are the deposits of a resource that can be profitably extracted given the prevailing knowledge and state of technology. The authors of The Limits to Growth included the known reserves of many resources to show how inadequate they were in the face of exponential growth of both output and resource consumption. The authors had little reason to suppose in the early 1970s that either kind of growth would stop on its own. As we saw in chapter 4, resource consumption went up in lockstep with overall economic output all throughout the twentieth century up to Earth Day. Few people expected that to change. The team behind The Limits to Growth certainly didn’t. The most generous estimate of future resource availability included in The Limits to Growth assumed that exponential consumption would continue, and that proven reserves were actually five times greater than commonly assumed. Under these conditions, the team’s computer models showed that the planet would run out of gold within twenty-nine years of 1972; silver within forty-two years; copper and petroleum within fifty; and aluminum within fifty-five. These weren’t accurate predictions. We still have gold and silver, and we still have large reserves of them. In fact, the reserves of both are actually much bigger than in 1972, despite almost half a century of additional consumption. Known global reserves of gold are almost 400 percent larger today than in 1972, and silver reserves are more than 200 percent larger. And it’s probably not too early to say that we’re not going to run out of copper, aluminum, and petroleum as quickly as estimated in The Limits to Growth. Known reserves of all are much larger than they were when the book was published. Known aluminum reserves are almost twenty-five times what they were in the early 1970s. How could these predictions about resource availability, which were taken seriously when they were released, have been so wrong? Because the Limits to Growth team pretty clearly underestimated both dematerialization and the endless search for new reserves. Capitalism and tech progress combine to drive both of these trends—the use of fewer resources and the hunt for more of them—and neither of these two drivers is about to become less powerful. So we’ll continue to innovate our way to greater dematerialization while we keep finding more reserves. The counterintuitive conclusion from this line of reasoning is that resource scarcity isn’t something we need to worry about. The earth is finite, so the total quantity of resources such as gold and petroleum is limited. But the earth is also very, very big—big enough to contain all we need of these and other resources, for as long as we’ll need them. The image of a thinly supplied Spaceship Earth hurtling through the cosmos with us aboard is compelling, but deeply misleading. Our planet has amply supplied us for our journey. Especially since we’re quickly slimming, swapping, optimizing, and evaporating our way to dematerialization. The Second Enlightenment Abraham Lincoln, the only US president to hold a patent,IV had a deep insight about capitalism. He wrote that the patent system “added the fuel of interest to the fire of genius in the discovery and production of new and useful things.” “The fire of genius” is a wonderful label for technological progress. “The fuel of interest” is equally good as a summary of capitalism. They interact in a self-reinforcing and ever-expanding cycle, and they’re now creating a dematerializing world. Innovators come up with new and useful technologies. They then partner with entrepreneurs or become entrepreneurs themselves as James Watt did. A new company is the result. Investors such as steam-engine backer Matthew Boulton often join in to provide the capital needed for growth in its early days. The start-up enters a market and takes on incumbents like the Newcomen steam engine. Customers like the new technology better and are free to choose it. Rivals can’t just copy the new technology because it’s protected by patents. So they either have to license it or come up with innovations themselves. The start-up grows and prospers and eventually becomes the new incumbent. Its success inspires the next round of innovators, entrepreneurs, and investors, who once again take aim at the incumbent by offering something better to their customers. Because of free market entry, the next innovators and start-ups can come from anywhere. And because innovation is such a distributed, dynamic, and unpredictable activity, it often comes from an unexpected place. It’s not necessary to plan this process. In fact, it’s a terrible idea to try to do so. Any central planner will miss many of the actual innovators or actively try to squelch them to protect the status quo of which the planners themselves are a part. This cycle of capitalist, technology-rich “creative destruction” was beautifully described in the middle of the twentieth century by the Austrian economist Joseph Schumpeter. But since the late nineteenth century and the work of Alfred Marshall and William Jevons, we’ve believed that this cycle would cause us to use up more and more of our planet’s resources. This was true throughout the Industrial Era, and especially in the years around Earth Day and the birth of the modern environmental movement. Environmentalists’ urgent cautions about resource use and planetary depletion were born out of an awareness of how powerfully technological progress and capitalism interacted. But then, for the reasons described in this chapter, that interaction changed. Tech progress and capitalism continued to reinforce each other, and to cause economies to get bigger and people to become more prosperous. But instead of also causing greater use of natural resources, they instead sparked dematerialization, something truly new under the sun. The fuel of interest in eliminating costs was added to the fire of the computer revolution, and the world began to dematerialize. The economic historian Joel Mokyr argues that the Industrial Era was made possible by the values of the Enlightenment. This intellectual movement began in the second half of the eighteenth century with many societies in the West embracing what Steven Pinker characterizes as four values: reason, science, humanism, and progress. According to Mokyr, the Enlightenment created a “culture of growth” that let both capitalism and technological progress flourish. I see an interesting inversion taking place now. If the Enlightenment led to the Industrial Era, then the Second Machine Age has led to a Second Enlightenment—a more literal one. We are now lightening our total consumption and treading more lightly on our planet. In America, the United Kingdom, and other rich countries, we are past “peak stuff” and are now using fewer total resources year after year. We’re accomplishing this because of the combination of technological progress and capitalism, which now let us get more from less.

## 2ac – DA

### at: Business Confidence---2ac

#### Biz Con low and so many thumpers---Supply Chain overwhelms

Mourgelas, 11/8

(Isabella, “CEO Optimism At Lowest Level Since Fall Of 2019”, Chief Executive, 11-08-2021, https://chiefexecutive.net/ceo-optimism-at-lowest-level-since-fall-of-2019/)\\JM

CEO optimism in the business environment 12 months from now continued to decline for the third consecutive month in November. At 6.4, the leading indicator is at multi-year lows, fueled by obscurity surrounding supply chains, inflation, increased taxes and government spending, which, CEOs predict, will cause consumer demand to tamper out. Their outlook for business by November 2022 is now 5 percent dimmer than what it is today. Those are the key findings from Chief Executive’s latest poll of 169 U.S. CEOs, fielded November 2-4, which asks America’s business chiefs to rate the environment today and 12 months out based on their assessment of business conditions—and forecast the impact on their company’s growth. This month, CEOs’ rating of current business conditions remained unchanged since October, at 6.7 out of 10, according to the 10-point scale. Strong consumer demand, as well as the easing of government mandates both in the U.S. and abroad are encouraging business growth in the present, CEOs say. Their rating for business conditions 12 months out, however, continued to fall for a third consecutive month, down to 6.4, nearly 4 percent lower than it was just one month prior, in October, and the lowest rating since October 2019—when CEOs said disputes and hostility in Washington were ruining an otherwise positive climate for business. Two years later, there is similar sentiment surrounding the impact of politics and government on business, and this month’s rating is below every reading in 2020, when Covid-19 caused severe crises worldwide. And although most businesses have regained their footing, polled CEOs say they’re uncertain that things will improve further from here. CEOs’ list of concerns has hardly changed in months: Supply chain disruptions, labor constraints and inflation pressures, coupled with expected tax increases, increased government spending and renewed mandates have convinced many CEOs that the 2022 landscape isn’t likely to be business friendly.

#### Circuit splits on *how* Actavis is applied now, but the aff makes antitrust predictable

Kevin Noonan, June 12, 2017, Kevin E. Noonan is a partner with McDonnell Boehnen Hulbert & Berghoff LLP and serves as Chair of the firm’s Biotechnology & Pharmaceuticals Practice Group. An experienced biotechnology patent lawyer, Dr. Noonan brings more than 20 years of extensive work as a molecular biologist studying high-technology problem “The Effects of the Actavis Decision on Reverse Payment Settlement Agreements in ANDA cases -- Four Years After”, JDSUPRA, https://www.jdsupra.com/legalnews/the-effects-of-the-actavis-decision-on-70263/

However, these instructions left much of the work of deciding the quantum of evidence and scope of proof necessary for a court to make an antitrust determination to the lower courts. The value and extent of the majority's teachings on this question drew the Chief Justice's disdain in dissent, wherein he wrote "[g]ood luck to the district courts that must, when faced with a patent settlement, weigh the 'likely anticompetitive effects, redeeming virtues, market power, and potentially offsetting legal considerations present in the circumstances.'"

With this as background, it is instructive to review how the district courts and some appellate courts have grappled with the task given them (over the Chief Justice's misgivings) by the Actavis majority. Generally (and in anticipation of the Supreme Court's decision), settlements were crafted to avoid bald reverse payments in favor of non-monetary considerations. These include terms of such agreements where the branded company agreed not to produce an "authorized generic" version of a branded drug, or entering into supply agreements with the generic drug maker for active pharmaceutical ingredient (API) manufacturing, or licensing other, unrelated patents. These gambits yielded variable results for various challenges, either by the FTC or by consumer complaints (often brought by wholesale or resale pharmacies or other drug suppliers, or unions or other benefits providers.

The FTC has provided consolidated evidence and reports on these results; overall the number of ANDA settlements containing reverse payment terms has decreased by about 50% since the Actavis decision, with the trend being more prevalent for first ANDA filers. There has also been a reduction in the number of settlements involving first filers containing agreements by the branded drug maker not to market an "authorized generic" in competition with the generic entrant. The FTC Report reveals that 81-87% of ANDA litigation settlement agreements filed in FY 2014 did not contain any compensation from the branded to the generic company and/or restrictions on generic market entry.

In the courts, there is general recognition that both "extreme" positions were rejected by the Supreme Court; the patent grant does not give blanket immunity to antitrust liability, but the existence of the agreement does not presume liability either. In applying the "rule of reason," courts have come to different conclusions and used different standards (resulting in the unpredictability the Chief Justice foresaw). One of the first questions addressed has been whether the Court's decision limits antitrust scrutiny to those agreements containing payments of money. One case that addressed this question was In re Lipitor Antitrust Litigation (D. N.J. Sept. 12, 2014), where the District Court ruled that the Actavis standard is not limited to money settlements. A "payment," according to the Court, could be anything having value, but even though settlement agreements not having monetary terms (classic "reverse payments") can satisfy the Actavis standard, plaintiffs must plead sufficient facts to establish the economic value of what a generic drug maker receives:

[W]here Plaintiffs rely on a non-monetary reverse payment of an inchoate claim, they must plead plausible facts including an estimate the monetary value of same so the Actavis rationale can be applied. . . . To meet this standard, Plaintiffs must stand in the shoes of the underlying parties at the time of the settlement, and determine an estimate of the monetary value of the settlement at that time.

In the Lipitor case the District Court dismissed on the pleadings; the mere existence of a settlement is not enough, according to the opinion, a plaintiff must plead sufficient facts to establish the economic value of what the generic drug maker received, so that benefit could be used according to the Supreme Court's Actavis scheme for applying the rule of reason to the parties' activities. In this regard, the developing consensus for bringing an antitrust case puts on the plaintiff the burden of showing an agreement falls within the scope of Supreme Court's factors that indicate a court should perform a "rule of reason" antitrust assessment, which then shifts the burden to the defendant (or, more typically, defendants) to show the pro-competitive features of the agreement. The ultimate burden of establishing an antitrust violation always remains on the plaintiff.

For its part, the FTC has continued to mount antitrust challenges to settlement agreements in ANDA litigation, with varying results. When successful, however, the penalties can be chilling: for example, in two recent cases (In re: Opana ER Antitrust Litigation (MDL) (N.D. Ill. 2017); In re: Lidoderm Antitrust Litigation (N.D. Cal. 2017)) the Commission required antitrust defendants to abstain from settlements containing no-authorized generic and other terms for 10 years. In another recent case, Teva was forced to disgorge $1.2 billion received as the result of settlement (Federal Trade Commission v. Cephalon Inc. (E.D. Pa 2016)).

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#### ---regulatory uncertainty---dries up investment in medical innovation **Erixon 16** (Fredrik Erixon, Director for the European Centre for International Political Economy, a global economy think tank, he graduated from University of Oxford, London School of Economics, and Bjorn Weigel, on the board for the ECIPE,  “Risk, Regulation, and the Innovation Slowdown” <https://www.cato.org/policy-report/septemberoctober-2016/risk-regulation-innovation-slowdown>)

Economic regulation reduces the scope for innovators and entrepreneurs to experiment and contest markets. Yet perhaps even more detrimental to innovation has been the rise of social regulations (e.g. environment, consumer, and health protection) and how they increasingly interfere with potential innovation. Product regulations in areas like medicine and medical devices have not just raised the cost of innovation, but created uncertainty about the chances of new innovations to be approved by authorities. Such uncertainty is toxic for company managers — and especially managers with owners who demand a high degree of predictability. Consider the use of the “precautionary principle” in European legislation. It is used for many different purposes, but no one knows what it really entails for regulation. A classic example is how it has destroyed the ambitions of biotechnological firms to innovate in the field of genetically modified organisms: both approvals and rejections of a genetically modified crop cite the precautionary principle. Another example is how chemical firms have reduced their innovation investments because they have spent a decade conforming to a 2006 regulation — based on the precautionary principle — on the evaluation and authorization of chemicals that have been on (and approved for) the market for decades. Western regulations are getting ever more complex — and with the accumulation of regulations, the regulatory landscape facing innovators is ever more opaque. Such regulations hurt innovators and entrepreneurs that aspire to contest markets. Start-ups find it ever more challenging to manage political risks and investors shy away from new innovations that face an unclear legal territory. Take drones as an example. The technological challenges facing drone manufacturers and users are less daunting to many investors than unclear legal circumstances. Large firms have problems too, but their understanding of regulation — and their capacity to use it for competitive purposes — has become a new incumbency advantage, protecting firms against competition.

#### 3---Government innovation fails---they have an incentive to slash R&D

McArdle 9 (Megan, columnist at Bloomberg View and a former senior editor at The Atlantic “Why I Oppose National Health Care” https://www.theatlantic.com/business/archive/2009/07/why-i-oppose-national-health-care/22300/)

Basically, for me, it all boils down to public choice theory. Once we've got a comprehensive national health care plan, what are the government's incentives? I think they're bad, for the same reason the TSA is bad. I'm afraid that instead of Security Theater, we'll get Health Care Theater, where the government goes to elaborate lengths to convince us that we're getting the best possible health care, without actually providing it. That's not just verbal theatrics. Agencies like Britain's NICE are a case in point. As long as people don't know that there are cancer treatments they're not getting, they're happy. Once they find out, satisfaction plunges. But the reason that people in Britain know about things like herceptin for early stage breast cancer is a robust private market in the US that experiments with this sort of thing. So in the absence of a robust private US market, my assumption is that the government will focus on the apparent at the expense of the hard-to-measure. Innovation benefits future constituents who aren't voting now. Producing it is very expensive. On the other hand, cutting costs pleases voters this instant. This is, fundamentally, what cries to "use the government's negotiating power" with drug companies is about. Advocates of such a policy spend a lot of time arguing about whether pharmaceutical companies do, or do not, spend too much on marketing. This is besides the point. The government is not going to price to some unknowable socially optimal amount of pharma market power. It is going to price to what the voters want, which is to spend as little as possible right now. It's not that I think that private companies wouldn't like to cut innovation. But in the presence of even rudimentary competition, they can't. Monopolies are not innovative, whether they are public or private.