### 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

(Sonja, directs RAND Europe’s portfolio of research in the field of healthcare innovation, industry and policy, previously led RAND Europe's institutional partnership with The Healthcare Improvement Studies Institute at Cambridge University, member of the Cambridge Centre for Health Services Research and expert advisor on innovation to the NHS England and NHS Improvement cancer programme, and Carolina Feijao, analyst working in the areas of science and emerging technology at RAND Europe, “Pharmaceutical Innovation for Infectious Disease Management”, Rand Europe, May 2020, https://www.rand.org/content/dam/rand/pubs/perspectives/PEA400/PEA407-1/RAND\_PEA407-1.pdf)\\JM

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

# 2AC

## Pharma ADV

#### 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.

## T

#### “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.

## K

#### Case outweighs—innovation solves extinction via bioterror and disease—default util since it turns all their impact claims, particularly in terms of disease

K. Kirkwood 09. School of Health Studies, Faculty of Health Sciences, University of Western Ontario. 06/01/2009. “In the Name of the Greater Good?” Emerging Health Threats Journal, vol. 2, no. 0. CrossRef, doi:10.3402/ehtj.v2i0.7092.

Public health authorities in many economically advantaged nations are bracing themselves to face future pandemics that will harm large numbers of citizens. Modern medical horrors such as Monkeypox or the much-feared future mutations of Avian Influenza (H5N1) are mentioned in the same breath as virulent strains of influenza, as a danger to our ‘way of living.’ Far beyond sickness and large numbers of death, an outbreak of one of these pandemics poses a real threat to long-term health, as well as to the social and economic well being of significant percentages of our surviving population.1 While confronting issues brought forth by a pandemic, the fundamental nature of ‘public health’ and its focus on the welfare of a population demands special attention to utilitarian considerations of promotion of the greatest good—in this case, health—as well as the limitation of illness and death in the ‘worst-case’ scenarios posed by the most lethal of pandemics. Of particular interest to this paper are questions related to the obligation of health-care workers (HCWs) to report to work in the face of heightened immunological threat and whether those same workers should have greater access to immunizations and treatments than should non-HCWs. Utilitarianism within public health ethics The fundamental feature of the ethical theory of utilitarianism states that moral behavior is that which promotes good and minimizes harm.2 In writings based on public health, utilitarianism is widely recognized as a fragment in the ethical ‘scheme’ of public health,3 but it is not afforded a stronger role for two primary reasons: first, considering its extreme position, utilitarianism is morally problematic,4 as it could literally permit anything in the name of the ‘greatest good to the greatest number,’ and second it is virtually impossible to live a moral life under the most extreme forms of utilitarianism, because the obligations are too difficult to discern (the ‘what’ of promoting the good) and impossible to execute (the ‘how’).5 Utilitarianism, in a moderate form, used in public health ethics, means that our actions and policies should be focused on increasing the total ‘net’ goodness rather than an average ‘net’ good for each person. The institutions of individual rights and the recognition of patient autonomy are not contradictory to this, but are believed to serve the overall good, as individual benefit increases the total good, and serves as a preventative measure of unjustified majoritarian actions against smaller groups. This model of utilitarianism is evident in many aspects of public healthFnot only through health-promotion projects that encourage the otherwise illness-free individuals to take up a more healthful diet and exercise regimen but also through harm-reduction programs, in which people with negative health behaviors such as abuse of drugs or dietary fats are aided to eliminate, or at least minimize the harm they cause to those around them. In everyday practice, the force of this utilitarian aspect has a supportive role along with other ethical elements of public health practice, and presents a balanced moral justification for all actions undertaken in accordance with this practice.6 However, I contend that there must be an ‘escalator clause’ in the utilitarian aspect that suggests that in the event of an extensive threat to the existence of a population, the force of this utilitarian aspect becomes the primary consideration in proportion to the threat. Therefore, the greater the threat, the greater the moral force of utilitarianism in making public health decisions. This also entails that the greater the threat, the greater the moral impetus to minimize the harm to the population. On duty, outbreaks, and distribution of resources Obligations to minimize harm and promote the goods of public health are not particularly controversial in times of relatively stable ‘good-health’ measures among the populace. The more troubling question emerges from the scenario in which promoting health and minimizing illness and death demands more from HCWsFhow can, or should, we compel HCWs to attend to their duties in the event that a highly lethal form of communicable disease should start spreading?7 Although current debates focus on questions of duty, and how much personal risk invalidates that commitment, utilitarian aspects of that obligation are not given enough weight in the debate. In many of the debates, the question of risk is posed in terms of how we do not expect a trained ‘first responder’ to recklessly endanger his or her life to save the life of another. The classic story of the lifeguard is offered as exemplar: a lifeguard is not expected to rescue a drowning swimmer if a shark is clearly present.8 Although this statement seems reasonable, it does not justify itself. By contrast, the consideration of the utilitarian aspect makes the point that in attempting to save a life, two are likely to be lost, thus propagating a greater total harm. The same holds true for the example of firefighters rushing into a house badly damaged by an active fire. Although there may be a life on that second floor to save, we do not expect any number of firefighters to sacrifice their lives for the doomed soul because the loss of many, including the original life in peril, is a maximization of harm, when harm should be minimized. When you control for the risks involved, such as using precautions to assure a level of safety for the rescuers, such as shark nets for the lifeguard, or safety gear for the firefighters, then the obligation to assist comes back into full force, as the potential for greater harm is manageable.9 It is the variable of risk, which creates variable demands on those whose duty it is to care for the population in times of crisis. We consider not only the risk to the obligated but also a question of the scope of risk to the population. In academic and public debates regarding the compulsion to attend to duty in the face of danger, one fallacy has been allowed to stand: the notion that exposure to a pandemic can be avoided if one simply does not come to his or her job as a HCW. Although it is true that working in a hospital during times of influenza outbreak puts one at a greater risk for contracting the illness,10 the more widespread the outbreak, the more people become sick, and the more likely the ‘stayat-home’ HCW will become sick even after having avoided contact in the course of his or her duties. We could reasonably state that, by virtue of staying home during a time of need for his or her service, the HCW improves the odds that he or she will contract this illness outside professional practice as part of the greater number who will be exposed. Another feature of the argument offered to defend dereliction of duty is to suggest that this risk that the HCW takes with his or her own health is a fixed variable, and thus should be considered as an exception to duty. On the contrary, it is a common feature of the infection-control literature that states that doctors and nurses are overwhelmingly neglectful toward their own basic infection-control protocols.11 Therefore, the threat is not a fixed variable, but one that is actually quite within the scope of the control of a HCW. Ethically, one cannot willfully or negligently enhance the exceptions to duty. At the same time, it is an obligation of the management to ensure that diligent HCWs are equipped to do all they can to reduce their risks. During the SARS crisis in Toronto, health-care administrators did not effectively communicate which precautions should be undertaken by HCWs to protect themselves.12 It bears mentioning that once clear direction could be given about the type and execution of masking procedures, the intrahospital transmission of SARS decreased to 0%.13 This fact speaks to the issue of risk, as the non-transmission of SARS correlated with the increased attentions of management and staff to infection-control precautions and the provision and use of proper equipment.14 When we speak in terms of risk and pandemics from the utilitarian perspective discussed herein, we recognize that it is completely nonsensible to sacrifice highly trained HCWs by rushing them ill equipped into dangerous situations. Much as with the example of firefighters and the unsafe burning house, we find it morally unacceptable to treat them as disposable, because of the singularity of their lives and their right to exist as individuals. There is also the detriment we would cause in an event such as a pandemic by losing the people trained to save us to the very threat they were trained to save us from. By that same logic, it could be argued that HCWs should have first access to available and medically accepted vaccinations by virtue of the fact that those HCWs are absolutely essential to our survival. The fear of an Avian Influenza outbreak brought with it much debate about scarce Tamiflu supplies and giving HCWs preferential access.15 However, the added value of a HCW is the fact that he or she will be facing the greater risk by virtue of faithful and responsible execution of his or her duty, and if this is trueFand we have seen from the example of SARS that it is not always the case that HCWs exercise due diligence or face unmanageable risks of infection simply by being ‘on-site’Fthen we should do more to protect them. Nevertheless, if the claim is that they can excuse themselves from duty because of risk, then we excuse ourselves from privileging their protection, through the preferential access to measures such as Tamiflu. The same should be true for access to vaccines or treatments: those who are compelled into service to defend the overall health of a society at tremendous risk should be first in line, as their opportunity for infectionFand to act as a vector for infection both within and outside their health-care facilitiesFmeans that the greater good is served by privileging their access to prophylaxis. A common objection to this comes from the perspective of social justice. The objection would point out that those who are least able to prevent their own infection, such as those from the lower socioeconomic classes, retirees and pensioners, and other vulnerable groups, would be denied access to the protections and treatments that are going to HCWs whoFto varying degreesFenjoy more comfortable socioeconomic positions. Although this question of access is valid in questions of many public health interventions, the preference of HCWs in questions of preferential access to vaccines and treatments is not unjust in these terms. Fundamentally, justice addresses unjustified imbalances in treatment. Aristotle famously mandated that equals should be treated as equals, and unequals as unequals.16 The key point of justice is that there should be a valid justification for differential treatment, and in that light, in this context, we are describing pandemics that pose a unique and credible threat to the public in a manner that could fundamentally undermine our way of life. Preferential treatment of HCWs, in this limited context, is a just and defensible practice. It is this same special status that we afford those who can save us from the most lethal and dangerous illnesses in times of public health emergency that also places greater demands on those same people. The greater the risk to society, the greater the responsibilities on those who can reduce the body count. The relationship between the duty of a HCW and the lethality of a disease is proportional—danger and obligation increase in step with each other, as opposed to other conceptions that suggest a threshold of exception as the risk of illness becomes too great. The fundamental flaw with this suggestion is that a negation of duty in such an outbreak simply allows the outbreak to pose an even greater threat to the populationFincluding that same derelict HCWFrather than confronting the illness in the relatively controlled environment of a hospital. Conclusions Utilitarianism in the form of promoting the good and diminishing the bad is a key moral belief in the realm of public health. It is one view in concert with others, all working to counterbalance each view to achieve a tenable moral equilibrium. In the extreme cases under consideration herein, such equilibrium dictates that the moral force of health promotion and harm minimization increases in relation to the threat posed to the well being of a larger society. In the case of widespread death or disability caused by a pandemic, this paper contended that an increased threat generates a heightened obligation on the part of HCWs, while also creating a reasonable expectation that those same HCWs will have preferential access to vaccines and treatments.

#### Crisis representations are good even though there’s no ideal relationship to the suffering of others --- encourages an awareness that our relative position in the world is a matter of luck, and any alternative means we can’t talk about, plan for, or anticipate catastrophes

**Recuber 13** [Timothy, sociologist who teaches in the Writing Program at Princeton University, he studies the representation of death and disaster in mass media and consumer culture, “Disaster Porn!,” *Contexts,* Vol 12, Issue 2, May 1, 2013]

The Ethics of Watching

As early as 1993, in his book Distant Suffering, sociologist Luc Boltanski argued that an emerging, Western “crisis of pity” signaled not only a loss of confidence in the veracity of reportage on global humanitarian issues, but “also relieve[d] the anxiety, loss of self-esteem and sense of indignity which is often said to be provoked by seeing wounded, imprisoned, tortured, starving or even dead people, without being able to do anything.”

Prevailing notions of disaster porn today, in which any and every form of disaster-related media is potentially pornographic, exacerbate this tendency. If documentaries, news reports, filmed dramatizations of real events, and completely fictional Hollywood blockbusters can all be written off as disaster porn, we run the risk of ignoring the suffering of others and relieving our own anxieties about viewing their misfortunes. Those who decry disaster porn no doubt do so to preserve “the grieving of their privacy and the dead of their dignity,” as Susan Llewelyn Leach wrote in 2005. But the ideal of truly ethical or authentic spectatorship of disaster may be impossible, given the inherent inequity of watching the misery of others from a position of relative comfort.

The dangers of disaster porn—namely, the lack of compassion it is said to engender—have also been overstated. After all, alongside the increasing visibility of both disaster media and its critics, Americans appear to have donated more money to victims of disasters than ever before. According to the website Charity Navigator, Americans gave $1.6 billion to relief efforts for the 2004 South Asian tsunami, contributed $3.3 billion to Hurricane Katrina relief in 2005, and then in 2010, in the midst of a significant recession, gave $1.4 billion to victims of the Haiti earthquake. If donations to the Red Cross are a good metric, then Americans gave much more money for disaster relief in South Asia and Haiti than they had for any previous foreign disasters, especially those—like the 1984-85 Ethiopian famine and the 1985 Mexico City earthquake—that pre-date the term disaster porn itself. Whatever its deleterious effects, the supposed proliferation of disaster pornography over the last decade does not seem to have decreased Americans’ sympathy for disaster victims, at least as measured by their charitable donations.

If mass media is to be a force for good, then journalists, cultural critics, and especially social scientists should avoid broad-stroke condemnations of the disaster porn genre. Such condemnations encourage audiences to remain in the relative safety of ironic detachment—comfortably critical of media processes and effects, rather than struggling with the nature of their own discomfort over injustice and its potential claims on our emotions.

The Uses of Exposure

To cast something off as disaster porn is, borrowing the language of sociologist C. Wright Mills, to reframe a “public issue” as merely a “private trouble.” It substitutes aesthetic questions about one’s personal viewing preferences for ethical considerations about one’s actual ability to help. In the current media landscape, saturated with so-called disaster porn, this has not yet become the norm—as evidenced by high levels of charitable giving for even very distant disasters. But if graphic scenes of others’ suffering become subject to a widely held taboo, then viewers may feel absolved of the obligation to think and act on such suffering—or even to pay attention in the first place.

The desire to turn away from death and disaster is understandable in a media-saturated world where there is an endless surfeit of tragedies to display. But as sociologist Iain Wilkinson has recently argued, such moral engagement with the suffering of others, “in all its real-life perplexities, compromises, and difficulties is…an indispensable component of the quest for social understanding.”

Disaster porn, then, in all its iterations and for all its flaws, is a vital political terrain in which publics are at least implicitly asked to struggle with the social significance of the suffering of others. It connects public issues like war, famine, earthquakes, and terrorist attacks to the private lives of those they affect, and shows us how disruptions of social structure become disruptions in individual biographies. This is the case in even the most seemingly stereotypical news reports of suffering in the developing world, and in even the most outlandish Hollywood disaster epics as well.

True, the focus on individual acts of heroism in films like 2012 often shifts attention away from the suffering multitudes, and for this they have been rightly criticized. But the seemingly impossible odds that the protagonists of such disaster epics must overcome also serve to highlight our shared vulnerability to risk. By imagining ourselves in Jackson Curtis’s shoes, we recognize that we might not be so lucky, and likely not survive at all. Similar sentiments are aroused when we watch the evening news, or a documentary about survivors of some terrible real-life tragedy. Such sentiment should be cultivated, not condemned.

In disaster porn, for all its flaws, publics are at least implicitly asked to struggle with the social significance of the suffering of others.

Encouraging an awareness of the vicissitudes of fate helps to combat the common tendency to blame victims of chance and inequality for their own misfortunes, and to view one’s own good fortune as the result of special individual talents unaffected by larger social forces or privileges. In this way, so-called disaster porn may prove itself to be more of a virtue than a vice.

#### Scenario analysis is pedagogically valuable.

Naazneen Barma et al. 16. May 2016, [Advance Publication Online on 11/6/15], Barma, PhD in Political Science from UC-Berkeley, Assistant Professor of National Security Affairs at the Naval Postgraduate School, Brent Durbin, PhD in Political Science from UC-Berkeley, Professor of Government at Smith College, Eric Lorber, JD from UPenn and PhD in Political Science from Duke, Gibson, Dunn & Crutcher, Rachel Whitlark, PhD in Political Science from GWU, Post-Doctoral Research Fellow with the Project on Managing the Atom and International Security Program within the Belfer Center for Science and International Affairs at Harvard, “‘Imagine a World in Which’: Using Scenarios in Political Science,” International Studies Perspectives 17 (2), pp. 1-19, <http://www.naazneenbarma.com/uploads/2/9/6/9/29695681/using_scenarios_in_political_science_isp_2015.pdf>

Over the past decade, the “cult of irrelevance” in political science scholarship has been lamented by a growing chorus (Putnam 2003; Nye 2009; Walt 2009). Prominent scholars of international affairs have diagnosed the roots of the gap between academia and policymaking, made the case for why political science research is valuable for policymaking, and offered a number of ideas for enhancing the policy relevance of scholarship in international relations and comparative politics (Walt 2005,2011; Mead 2010; Van Evera 2010; Jentleson and Ratner 2011; Gallucci 2012; Avey and Desch 2014). Building on these insights, several initiatives have been formed in the attempt to “bridge the gap.”2 Many of the specific efforts put in place by these projects focus on providing scholars with the skills, platforms, and networks to better communicate the findings and implications of their research to the policymaking community, a necessary and worthwhile objective for a field in which theoretical debates, methodological training, and publishing norms tend more and more toward the abstract and esoteric. Yet enhancing communication between scholars and policymakers is only one component of bridging the gap between international affairs theory and practice. Another crucial component of this bridge is the generation of substantive research programs that are actually policy relevant—a challenge to which less concerted attention has been paid. The dual challenges of bridging the gap are especially acute for graduate students, a particular irony since many enter the discipline with the explicit hope of informing policy. In a field that has an admirable devotion to pedagogical self-reflection, strikingly little attention is paid to techniques for generating policy-relevant ideas for dissertation and other research topics. Although numerous articles and conference workshops are devoted to the importance of experiential and problem-based learning, especially through techniques of simulation that emulate policymaking processes (Loggins 2009; Butcher 2012; Glasgow 2012; Rothman 2012; DiCicco 2014), little has been written about the use of such techniques for generating and developing innovative research ideas. This article outlines an experiential and problem-based approach to developing a political science research program using scenario analysis. It focuses especially on illuminating the research generation and pedagogical benefits of this technique by describing the use of scenarios in the annual New Era Foreign Policy Conference (NEFPC), which brings together doctoral students of international and comparative affairs who share a demonstrated interest in policy-relevant scholarship.3 In the introductory section, the article outlines the practice of scenario analysis and considers the utility of the technique in political science. We argue that scenario analysis should be viewed as a tool to stimulate problem-based learning for doctoral students and discuss the broader scholarly benefits of using scenarios to help generate research ideas. The second section details the manner in which NEFPC deploys scenario analysis. The third section reflects upon some of the concrete scholarly benefits that have been realized from the scenario format. The fourth section offers insights on the pedagogical potential associated with using scenarios in the classroom across levels of study. A brief conclusion reflects on the importance of developing specific techniques to aid those who wish to generate political science scholarship of relevance to the policy world. What Are Scenarios and Why Use Them in Political Science? Scenario analysis is perceived most commonly as a technique for examining the robustness of strategy. It can immerse decision makers in future states that go beyond conventional extrapolations of current trends, preparing them to take advantage of unexpected opportunities and to protect themselves from adverse exogenous shocks. The global petroleum company Shell, a pioneer of the technique, characterizes scenario analysis as the art of considering “what if” questions about possible future worlds. Scenario analysis is thus typically seen as serving the purposes of corporate planning or as a policy tool to be used in combination with simulations of decision making. Yet scenario analysis is not inherently limited to these uses. This section provides a brief overview of the practice of scenario analysis and the motivations underpinning its uses. It then makes a case for the utility of the technique for political science scholarship and describes how the scenarios deployed at NEFPC were created. The Art of Scenario Analysis We characterize scenario analysis as the art of juxtaposing current trends in unexpected combinations in order to articulate surprising and yet plausible futures, often referred to as “alternative worlds.” Scenarios are thus explicitly not forecasts or projections based on linear extrapolations of contemporary patterns, and they are not hypothesis-based expert predictions. Nor should they be equated with simulations, which are best characterized as functional representations of real institutions or decision-making processes (Asal 2005). Instead, they are depictions of possible future states of the world, offered together with a narrative of the driving causal forces and potential exogenous shocks that could lead to those futures. Good scenarios thus rely on explicit causal propositions that, independent of one another, are plausible—yet, when combined, suggest surprising and sometimes controversial future worlds. For example, few predicted the dramatic fall in oil prices toward the end of 2014. Yet independent driving forces, such as the shale gas revolution in the United States, China’s slowing economic growth, and declining conflict in major Middle Eastern oil producers such as Libya, were all recognized secular trends that—combined with OPEC’s decision not to take concerted action as prices began to decline—came together in an unexpected way. While scenario analysis played a role in war gaming and strategic planning during the Cold War, the real antecedents of the contemporary practice are found in corporate futures studies of the late 1960s and early 1970s (Raskin et al. 2005). Scenario analysis was essentially initiated at Royal Dutch Shell in 1965, with the realization that the usual forecasting techniques and models were not capturing the rapidly changing environment in which the company operated (Wack 1985; Schwartz 1991). In particular, it had become evident that straight-line extrapolations of past global trends were inadequate for anticipating the evolving business environment. Shell-style scenario planning “helped break the habit, ingrained in most corporate planning, of assuming that the future will look much like the present” (Wilkinson and Kupers 2013, 4). Using scenario thinking, Shell anticipated the possibility of two Arab-induced oil shocks in the 1970s and hence was able to position itself for major disruptions in the global petroleum sector. Building on its corporate roots, scenario analysis has become a standard policymaking tool. For example, the Project on Forward Engagement advocates linking systematic foresight, which it defines as the disciplined analysis of alternative futures, to planning and feedback loops to better equip the United States to meet contemporary governance challenges (Fuerth 2011). Another prominent application of scenario thinking is found in the National Intelligence Council’s series of Global Trends reports, issued every four years to aid policymakers in anticipating and planning for future challenges. These reports present a handful of “alternative worlds” approximately twenty years into the future, carefully constructed on the basis of emerging global trends, risks, and opportunities, and intended to stimulate thinking about geopolitical change and its effects.4 As with corporate scenario analysis, the technique can be used in foreign policymaking for long-range general planning purposes as well as for anticipating and coping with more narrow and immediate challenges. An example of the latter is the German Marshall Fund’s EuroFutures project, which uses four scenarios to map the potential consequences of the Euro-area financial crisis (German Marshall Fund 2013). Several features make scenario analysis particularly useful for policymaking.5 Long-term global trends across a number of different realms—social, technological, environmental, economic, and political—combine in often-unexpected ways to produce unforeseen challenges. Yet the ability of decision makers to imagine, let alone prepare for, discontinuities in the policy realm is constrained by their existing mental models and maps. This limitation is exacerbated by well-known cognitive bias tendencies such as groupthink and confirmation bias (Jervis 1976; Janis 1982; Tetlock 2005). The power of scenarios lies in their ability to help individuals break out of conventional modes of thinking and analysis by introducing unusual combinations of trends and deliberate discontinuities in narratives about the future. Imagining alternative future worlds through a structured analytical process enables policymakers to envision and thereby adapt to something altogether different from the known present. Designing Scenarios for Political Science Inquiry The characteristics of scenario analysis that commend its use to policymakers also make it well suited to helping political scientists generate and develop policy-relevant research programs. Scenarios are essentially textured, plausible, and relevant stories that help us imagine how the future political-economic world could be different from the past in a manner that highlights policy challenges and opportunities. For example, terrorist organizations are a known threat that have captured the attention of the policy community, yet our responses to them tend to be linear and reactive. Scenarios that explore how seemingly unrelated vectors of change—the rise of a new peer competitor in the East that diverts strategic attention, volatile commodity prices that empower and disempower various state and nonstate actors in surprising ways, and the destabilizing effects of climate change or infectious disease pandemics—can be useful for illuminating the nature and limits of the terrorist threat in ways that may be missed by a narrower focus on recognized states and groups. By illuminating the potential strategic significance of specific and yet poorly understood opportunities and threats, scenario analysis helps to identify crucial gaps in our collective understanding of global politicaleconomic trends and dynamics. The notion of “exogeneity”—so prevalent in social science scholarship—applies to models of reality, not to reality itself. Very simply, scenario analysis can throw into sharp relief often-overlooked yet pressing questions in international affairs that demand focused investigation. Scenarios thus offer, in principle, an innovative tool for developing a political science research agenda. In practice, achieving this objective requires careful tailoring of the approach. The specific scenario analysis technique we outline below was designed and refined to provide a structured experiential process for generating problem-based research questions with contemporary international policy relevance.6 The first step in the process of creating the scenario set described here was to identify important causal forces in contemporary global affairs. Consensus was not the goal; on the contrary, some of these causal statements represented competing theories about global change (e.g., a resurgence of the nation-state vs. border-evading globalizing forces). A major principle underpinning the transformation of these causal drivers into possible future worlds was to “simplify, then exaggerate” them, before fleshing out the emerging story with more details.7 Thus, the contours of the future world were drawn first in the scenario, with details about the possible pathways to that point filled in second. It is entirely possible, indeed probable, that some of the causal claims that turned into parts of scenarios were exaggerated so much as to be implausible, and that an unavoidable degree of bias or our own form of groupthink went into construction of the scenarios. One of the great strengths of scenario analysis, however, is that the scenario discussions themselves, as described below, lay bare these especially implausible claims and systematic biases.8 An explicit methodological approach underlies the written scenarios themselves as well as the analytical process around them—that of case-centered, structured, focused comparison, intended especially to shed light on new causal mechanisms (George and Bennett 2005). The use of scenarios is similar to counterfactual analysis in that it modifies certain variables in a given situation in order to analyze the resulting effects (Fearon 1991). Whereas counterfactuals are traditionally retrospective in nature and explore events that did not actually occur in the context of known history, our scenarios are deliberately forward-looking and are designed to explore potential futures that could unfold. As such, counterfactual analysis is especially well suited to identifying how individual events might expand or shift the “funnel of choices” available to political actors and thus lead to different historical outcomes (Nye 2005, 68–69), while forward-looking scenario analysis can better illuminate surprising intersections and sociopolitical dynamics without the perceptual constraints imposed by fine-grained historical knowledge. We see scenarios as a complementary resource for exploring these dynamics in international affairs, rather than as a replacement for counterfactual analysis, historical case studies, or other methodological tools. In the scenario process developed for NEFPC, three distinct scenarios are employed, acting as cases for analytical comparison. Each scenario, as detailed below, includes a set of explicit “driving forces” which represent hypotheses about causal mechanisms worth investigating in evolving international affairs. The scenario analysis process itself employs templates (discussed further below) to serve as a graphical representation of a structured, focused investigation and thereby as the research tool for conducting case-centered comparative analysis (George and Bennett 2005). In essence, these templates articulate key observable implications within the alternative worlds of the scenarios and serve as a framework for capturing the data that emerge (King, Keohane, and Verba 1994). Finally, this structured, focused comparison serves as the basis for the cross-case session emerging from the scenario analysis that leads directly to the articulation of new research agendas. The scenario process described here has thus been carefully designed to offer some guidance to policy-oriented graduate students who are otherwise left to the relatively unstructured norms by which political science dissertation ideas are typically developed. The initial articulation of a dissertation project is generally an idiosyncratic and personal undertaking (Useem 1997; Rothman 2008), whereby students might choose topics based on their coursework, their own previous policy exposure, or the topics studied by their advisors. Research agendas are thus typically developed by looking for “puzzles” in existing research programs (Kuhn 1996). Doctoral students also, understandably, often choose topics that are particularly amenable to garnering research funding. Conventional grant programs typically base their funding priorities on extrapolations from what has been important in the recent past—leading to, for example, the prevalence of Japan and Soviet studies in the mid-1980s or terrorism studies in the 2000s—in the absence of any alternative method for identifying questions of likely future significance. The scenario approach to generating research ideas is grounded in the belief that these traditional approaches can be complemented by identifying questions likely to be of great empirical importance in the real world, even if these do not appear as puzzles in existing research programs or as clear extrapolations from past events. The scenarios analyzed at NEFPC envision alternative worlds that could develop in the medium (five to seven year) term and are designed to tease out issues scholars and policymakers may encounter in the relatively near future so that they can begin thinking critically about them now. This timeframe offers a period distant enough from the present as to avoid falling into current events analysis, but not so far into the future as to seem like science fiction. In imagining the worlds in which these scenarios might come to pass, participants learn strategies for avoiding failures of creativity and for overturning the assumptions that prevent scholars and analysts from anticipating and understanding the pivotal junctures that arise in international affairs.

As students entrenched in Academia it is imperative that we look to scenario analysis so that when we join the workplace/public policy space that we are able to make the world a better place in the future. Avoidance of scenario analysis leaves unscientific policy analysis that can be rooted in bias and flawed thinking.

#### Predictive understanding are key to rational decisionmaking outside debate and generates better policy and activists

Ward 16 (Michael D, Duke University Professor of Political Science, “Can We Predict Politics? Toward What End?”, 2/10, Journal of Global Security Studies, 1.1, 80-91) DB

The main pro is that the predictive enterprise helps us evaluate how well we are doing so that we can improve our understanding of the world. It is the gold standard of a scientific approach. We do not yet have an experimental framework for many important subjects. As a result, it is important to make sure we can get the same kind of results with new information that we got with the data we began investigating. That means we have to either save some data back (a great idea), use the future to see how well our modeled understandings perform, or preferably both. There are only nascent traditions of this in the social sciences at present. Keeping track of your success is not collecting significant coefficients. Keeping track matters. One consequence is that we cannot just keep using the same data over and over. And over. One reason that many hate predictions is that talking heads make many predictions in the media, but few of them ever keep track of how well they are doing. Their goal is somewhat akin to a venture capitalist’s make enough bets that eventually one of them is correct enough that you get to make a lot more bets. Ascher (1979) long ago showed that the talking heads were most often wrong. This is still true. You would think that they would get better over time, but there is little evidence that this is the case.¶ We also will be driven into making more precise investigations once we start to predict. We will not be satisfied with annual data for most things. Nor will we necessarily be satisfied with national-level information because it becomes even more apparent in the predictive domain that the world is neither flat nor homogeneous. As a result, we should get more precise understandings of how things play out in our social world. At the same time, we have to recognize that our predictions are probabilistic and contain a large amount of uncertainty, more so than in other endeavors.¶ As a result of these two aspects, better and more precise understandings of our social world, it is possible to be more relevant to decision makers at all levels. This does not mean just inside the beltway. It also means decision makers at CDC (Centers for Disease Control) as well as those in non-governmental organizations around the world.¶ What are the cons? Several arguments are usually brought to the fore.¶ The world is inherently unpredictable. But we are studying it anyway. Go figure. The refrain to this litany is often “but I know what is going to happen in this instance.” Maybe, but let us keep track and find out if you are right. This is the talking heads premise, and it is demonstrably false. Making cause and effect statements about politics does imply that politics is in part, at least, predictable.¶ This will empower the establishment and impoverish those without power. Actually, it might. But at the same time, it provides ways in which those outside the capitals can also affect the future. Why will prediction be more valuable to the establishment than it is to the rest of society? Is the same thing true of explanation and substantive knowledge? Western society is based in part on the idea that knowledge is a valuable thing for all. It is true that some take more advantage of it than others. But having open and available knowledge can be important for many diverse groups. As an example, we might think that clandestine organizations can benefit from open knowledge, even precise actionable knowledge, but as we think these thoughts, most of us might not be thinking about transnational activist networks but rather large governmental organizations. However, it is clear that non-governmental actors are also consumers of knowledge.¶ It is possible to predict things without true understanding or knowledge. Sure, but rarely is this true for any but the simplest of systems. I am reminded of the wonderful essay by Calvin Trillin describing the chicken on Mott Street in New York’s Chinatown that played and always won Tic-Tac-Toe. The chicken did not understand the game. But the chicken always won.6 It is ridiculous to suggest that we have models that predict as accurately as the (now gone) Mott Street chicken but have the same understanding of the “chicken” game. Even if it were the case (and I repeat it is not), could the opposite really be true? If you have deep understanding of the world, should you not be able to generate accurate predictions of how it will work in situations you have not seen before? Will proximate effects lead us toward distant causes much like proximate causes can lead us to distant effects?¶ We will disrupt the space-time continuum. If we can predict conflict, for example, we will be able to prevent it. Or start it where we want. And then we will no longer be able to predict conflict. One of my models attempts to predict where there will be coups de état and other types of irregular regime changes on a monthly level. Maybe if Muhammadu Buhari, who assumed the presidency of Nigeria at the end of May 2015, sees our manuscript, he might be able to prevent any irregular leadership change from occurring in the next six months. And maybe that would be bad. Or good. But in any case, I am pretty sure that the Nigerian president is already aware of the fragility of the Nigerian political landscape. This is a frequent type of criticism of forecasting. I think we can wait for this to become a real problem before we stop trying to develop better understandings of the world.¶ Real social effects occur glacially. Predictions will be focused on epiphenomenal changes that won’t matter in the long run. How do you know?¶ In summary, we need less theory because most theory is an attempt to rescue or adapt extant theory. We need more predictions in order to keep track of how well we understand the world around us. They will tell us how good our theories are and where we need better explanations. Predictions are like cell phones. First, they seem arcane and bizarre. Then, in a few short years, there is no one around who remembers life without cell phones and your kids use them in ways you don’t understand. The 2012 US presidential election was the first that was famously and accurately predicted. But it will be the first of many. All future voters will vote in an era in which accurately predicting the election will be the norm, not the exception, though as in the UK in 2015, there will be exceptions. This will have consequences for democracy. In the same way that having a product recommended to us on the web is now normal, this will become the new normal. Data science (and more data) will guide us to a better understanding of our future than we have now. Whether you are involved with commercial organizations, local government, non-governmental organizations (NGOs), the federal government, or international organizations, prediction will be part of the daily ebb and flow of information, and we shall become used to seeing accurate predictions about a wide variety of political phenomena.¶ But, as we get more accurate, will we be able to begin manipulating outcomes? Engineer results? It may not seem like it to everyone, but political beliefs are malleable. In fact, survey researchers are feigning shock at discovering that political surveys tend to politicize respondents. Republicans can turn into Democrats, and vice versa. Will we get equally adept at predicting what kinds of information, interactions, and initiatives will turn the tide in a particular election? Facebook and Google—and many other less famous firms—think so, and are gearing up for the 2016 election with tools that go way beyond surveys that can be used for that purpose.¶ What do we expect to see in the global security system? First, we know that a wider variety of actors will be consuming and generating data on their activities. Indeed, we know that a wider variety of national and non-state actors are using predictive models of behavior that might broadly be considered in the realm of political violence, ranging from strikes and protests to attacks and casualties. China, Russia, the European Union, and the UK, as well as the United States and the United Nations and the North Atlantic Treaty Organization, all have substantial forecasting capabilities in the global realm. Some of these forecasts are made on a weekly basis, and others are more long term, looking out a couple of decades. But the fact that predictive heuristics are now part and parcel of normal statecraft is important and recent. Moreover, non-state actors are not to be left out and are beginning to evolve toward greater foresight. Consider that an International Red Cross that is able to predict domestic conflicts will be better able to pre-position supplies and expertise to deal with the human toll of such conflicts. A monitoring of violent government actions that can predict the safest time to remove NGO personnel in conflict zones is another example of a predictive tool that can affect the global security system in new and beneficial ways.¶ The global security system is complicated, multilayered, unknown, and changing. In some ways, it is exactly like the solar system. However, it may change more quickly but maybe less dramatically.7 By developing explanations and subjecting them to critical evaluations, we learned more. We can learn more again. We can build Antikythera Mechanisms. Though they may or may not tell us about the next sociopolitical eclipse in the international security system, they are likely to help us get rid of bad ideas.

#### Apocalyptic rhetoric is good

Baum, 2015- co-director of the Global Catastrophic Risk Institute with a PhD from Penn State in Geography (Seth D. Baum, September 2015, “The Far Future Argument for Confronting Catastrophic Threats to Humanity: Practical Significance and Alternatives,” published in Futures, vol. 72 pg. 86-96, http://sethbaum.com/ac/2015\_FarFuture.pdf, fg)

6. Far Future As Inspiration The paper thus far has focused on how to avoid appeals to the far future argument, in recognition of the fact that many people are not motivated by what will benefit the far future. But some GCR reduction actions can only be justified with reference to far future benefits. Additionally, some people are motivated to benefit the far future. Other people could be too. Tapping the inspirational power of the far future can enable more GCR reduction. There are at least two ways that the far future can inspire action: analytical and emotional. Both are consistent with the far future argument, but the argument is typically inspired by analytical considerations. The analytical inspiration is found in works analyzing how to maximize the good or achieve related objectives. Most of the scholarly works invoking the far future argument are of this sort.6 Such ideas have the potential to resonate not just with other scholars, but with people in other professions as well, and also the lay public. Thus there can be some value to disseminating analysis about the importance of the far future and its relation to GCR. Analytical inspiration can also come from analyzing specific actions in terms of their farfuture importance. Such analysis can help promote these actions, even if the actions could be justified without reference to the far future. However, the analysis should be careful to connect with actual decision makers, and not just evaluate hypothetically optimal actions that no one ever takes. For example, there has been now multiple decades of research analyzing what the optimal carbon tax should be (for an early work, see Nordhaus 1992), yet throughout this period, for most of the world, the actual carbon tax has been zero. Analytical inspiration has its limits. Research effort may be more productively spent on what policies and other actions people are actually willing to implement. The other far future inspiration is emotional. The destruction of human civilization can itself be a wrenching emotional idea. In The Fate of the Earth, Jonathan Schell writes “The thought of cutting off life’s flow, of amputating this future, is so shocking, so alien to nature, and so contradictory to life’s impulse that we can scarcely entertain it before turning away in revulsion and disbelief” (Schell 1982/2000, p.154). In addition, there is a certain beauty to the idea of helping shape the entire arch of the narrative of humanity, or even the universe itself. People often find a sense of purpose and meaning in contributing to something bigger than themselves— and it does not get any bigger than this. Carl Sagan’s (1994) Pale Blue Dot and James Martin’s (2007) The Meaning of the 21st Century both capture this well, painting vivid pictures of the special place of humanity in the universe and the special opportunities people today have to make a difference of potentially cosmic significance. This perspective says that humanity faces great challenges. It says that if these challenges are successfully met, then humanity can go on to some amazing achievements. It is a worthy perspective for integrating the far future into our lives, not just for our day-to-day actions but also for how we understand ourselves as human beings alive today. This may be worth something in its own right, but it can also have a practical value in motivating additional actions to confront catastrophic threats to humanity. 7. Conclusion The far future argument is sound. The goal of helping the far future is a very worthy one, and helping the far future often means helping reduce the risk of those global catastrophes that could diminish the far-future success of human civilization. However, in practical terms, reducing this risk will not always require attention to its far-future significance. This is important because many people are not motivated to help the far future, but they could nonetheless be motivated to take actions that reduce GCR and in turn help the far future. They may do this because the actions reduce the risk of near-future GCRs, or because the actions have co-benefits unrelated to GCRs and can be mainstreamed into established activities. This paper surveys GCRs and GCR-reducing actions in terms of how much these actions require support for the far future argument for confronting catastrophic threats to humanity. The analysis suggests that a large portion of total GCR, probably a large majority, can be reduced without reference to the far future and with reference to what people already care about, be it the near future or even more parochial concerns. These actions will often be the best to promote, achieving the largest GCR reduction relative to effort spent. On the other hand, some significant GCR reducing actions (especially those requiring large sacrifice) can only be justified with reference to their far-future benefits. For these actions in particular, it is important to emphasize how the far future can inspire action.

#### The K is a refusal to accept the same falsifiable review our evidence goes through – disproves their methodology, destroys academic debate, and causes extinction.

Coyne, 06 – Author and Writer for the Times (Jerry A., “A plea for empiricism”, FOLLIES OF THE WISE, Dissenting essays, 405pp. Emeryville, CA: Shoemaker and Hoard, 1 59376 101 5)

Supernatural forces and events, essential aspects of most religions, play no role in science, not because we exclude them deliberately, but because they have never been a useful way to understand nature. Scientific “truths” are empirically supported observations agreed on by different observers. Religious “truths,” on the other hand, are personal, unverifiable and contested by those of different faiths. Science is nonsectarian: those who disagree on scientific issues do not blow each other up. Science encourages doubt; most religions quash it. But religion is not completely separable from science. Virtually all religions make improbable claims that are in principle empirically testable, and thus within the domain of science: Mary, in Catholic teaching, was bodily taken to heaven, while Muhammad rode up on a white horse; and Jesus (born of a virgin) came back from the dead. None of these claims has been corroborated, and while science would never accept them as true without evidence, religion does. A mind that accepts both science and religion is thus a mind in conflict. Yet scientists, especially beleaguered American evolutionists, need the support of the many faithful who respect science. It is not politically or tactically useful to point out the fundamental and unbreachable gaps between science and theology. Indeed, scientists and philosophers have written many books (equivalents of Leibnizian theodicy) desperately trying to show how these areas can happily cohabit. In his essay, “Darwin goes to Sunday School”, Crews reviews several of these works, pointing out with brio the intellectual contortions and dishonesties involved in harmonizing religion and science. Assessing work by the evolutionist Stephen Jay Gould, the philosopher Michael Ruse, the theologian John Haught and others, Crews concludes, “When coldly examined . . . these productions invariably prove to have adulterated scientific doctrine or to have emptied religious dogma of its commonly accepted meaning”. Rather than suggesting any solution (indeed, there is none save adopting a form of “religion” that makes no untenable empirical claims), Crews points out the dangers to the survival of our planet arising from a rejection of Darwinism. Such rejection promotes apathy towards overpopulation, pollution, deforestation and other environmental crimes: “So long as we regard ourselves as creatures apart who need only repent of our personal sins to retain heaven’s blessing, we won’t take the full measure of our species-wise responsibility for these calamities”. Crews includes three final essays on deconstruction and other misguided movements in literary theory. These also show “follies of the wise” in that they involve interpretations of texts that are unanchored by evidence. Fortunately, the harm inflicted by Lacan and his epigones is limited to the good judgement of professors of literature. Follies of the Wise is one of the most refreshing and edifying collections of essays in recent years. Much like Christopher Hitchens in the UK, Crews serves a vital function as National Sceptic. He ends on a ringing note: “The human race has produced only one successfully validated epistemology, characterizing all scrupulous inquiry into the real world, from quarks to poems. It is, simply, empiricism, or the submitting of propositions to the arbitration of evidence that is acknowledged to be such by all of the contending parties. Ideas that claim immunity from such review, whether because of mystical faith or privileged “clinical insight” or the say-so of eminent authorities, are not to be countenanced until they can pass the same skeptical ordeal to which all other contenders are subjected.” As science in America becomes ever more harried and debased by politics and religion, we desperately need to heed Crews’s plea for empiricism.

# 1AR

## K

#### They can’t establish causality for their impacts

Brian McConachie 7, Chair of Theatre Arts at the University of Pittsburgh, "Falsifiable Theories for Theatre and Performance Studies", Theatre Journal 59.4 (2007), 553-577, MUSE

Can the master theorists in our critical theory consensus make the same claim? All scientific assertions are potentially falsifiable through the use of the scientific method, but what experiments or logics would the master theorists accept as a basis for the falsifiability of their ideas? Looking at the theorists featured in Critical Theory and Performance, one might say that they represent a range of approaches that admit of greater or lesser degrees of falsifiability. At one end of the continuum, the theories of Bourdieu, Habermas, Gramsci, and Williams generally work within the falsifiability protocols of social science, which (though open to dispute) have been fairly well established for fifty years. When Raymond Williams's version of Gramsci's hegemony theory was gaining a curious audience among historians, its potential falsifiability was widely discussed.46 While social scientists, including historians, cannot apply falsifiability to their work with the same rigor as scientists who work with nonhuman subjects, their standards concerning evidence, economy, and consistency are high.47¶ Somewhere in the middle of the continuum of falsifiability, perhaps, are the psychoanalytic theories of Freud, their synthesis with semiotics in Lacan, and the many theorists who build their own ideas on some version of a psychoanalytic base. Their advocates often claim scientific validity for these theories. Most psychologists, however, have rejected psychoanalysis and its spin-offs as unfalsifiable. In her Psychoanalysis and Cognitive Science, for example, Wilma Bucci concludes that Freud's meta-psychology has not "been subject to the empirical evaluation and theory development that is necessary for a scientific field." Specifically, the type of systematic inference that is applied in cognitive science and in all modern science requires explicit definitions that limit the meaning of the concepts, correspondence rules mapping hypothetical constructs and intervening variables onto observable events, and means of assessing reliability of observation. Each of the indicators that analysts rely on to make inferences about the conscious and unconscious states of other persons (as [End Page 571] about one's own conscious states) must itself be independently validated as having the implications that are assumed.48¶ In defense, Freudians and Lacanians often claim that their theories are consonant with good science because their concepts have been scientifically validated in therapeutic sessions.49 But clinical success, however it is measured, is not the same as empirical verification. Just because "the talking cure" has been effective in some cases does not mean that Freud's or Lacan's explanation for why it worked is valid. Humans have had many explanations for fire over the centuries, but understanding why and how combustion really works must rely on recent physics and chemistry.¶ At the other end of the continuum are theorists such as Baudrillard, Derrida, Féral, and other poststructuralists, whose radical skepticism challenges the ability of science or any other discourse to provide a valid standard of falsifiability. The relativism of poststructuralism, including its challenges to empirical verification, defies any protocols that might stabilize knowledge based on the slippery signifiers provided by language. Despite what they take to be the inherent contradictions of textual assertions, poststructuralists from Lyotard to Derrida rely chiefly on logic and argumentation rather than scientific or historical evidence. Within the assumptions of poststructuralism, Derrida's gnomic remark, "There is nothing beyond the text," is simply unfalsifiable. The critic who wishes to rely on what Derrida might have meant in that statement, however, will have to ignore a great deal of good science in linguistics and evolutionary psychology to be able to assess the probable truth of Derrida's assertion.50¶ Brian Vickers challenges the weak scientific credentials of several of the master theorists that many humanist academics have embraced. As he points out with acerbity:¶ Freud's work is notoriously speculative, a vast theoretical edifice elaborated with a mere pretense of corroboration, citing "clinical observations" which turn out to be false, with contrary evidence suppressed, data manipulated, building up over a forty-year period a self-obscuring, self-protective mythology. The system of Derrida, although disavowing systematicity, is based on several unproven theses about the nature of language which are supported by a vast expanding web of idiosyncratic terminology. . . . Lacan's system, even more vastly elaborated . . . is a series of devices for evading accountability. . . . Foucault places himself above criticism.51¶ Whether all of Vickers's charges are valid may be less important than his general point: he presents suggestive evidence that these master theorists tried to place their ideas beyond the protocols of falsifiability.

#### Empiricism is the most useful form of knowledge for policymakers—useful in making theories to shape policy

**Walt, ‘5** – Prof, Kennedy School of Government @ Harvard (Stephen M., Annu. Rev. Polit. Sci. 2005. 8:23–48, pg. 25-26, “The Relationship Between Theory and Policy in International Relations,” http://www.iheid.ch/webdav/site/political\_science/shared/political\_science/3452/walt.pdf)

Policy decisions can be influenced by several types of knowledge. First, policy makers invariably rely on purely factual knowledge (e.g., how large are the opponent’s forces? What is the current balance of payments?). Second, decision makers sometimes employ “rules of thumb”: simple decision rules acquired through experience rather than via systematic study (Mearsheimer 1989).3 A third type of knowledge consists of typologies, which classify phenomena based on sets of specific traits. Policy makers can also rely on empirical laws. An empirical law is an observed correspondence between two or more phenomena that systematic inquiry has shown to be reliable. Such laws (e.g., “democracies do not fight each other” or “human beings are more risk averse with respect to losses than to gains”) can be useful guides even if we do not know why they occur, or if our explanations for them are incorrect. Finally, policy makers can also use theories. A theory is a causal explanation— it identifies recurring relations between two or more phenomena and explains why that relationship obtains. By providing us with a picture of the central forces that determine real-world behavior, theories invariably simplify reality in order to render it comprehensible. At the most general level, theoretical IR work consists of “efforts by social scientists. . .to account for interstate and trans-state processes, issues, and outcomes in general causal terms” (Lepgold & Nincic 2001, p. 5; Viotti & Kauppi 1993). IR theories offer explanations for the level of security competition between states (including both the likelihood of war among particular states and the warproneness of specific countries); the level and forms of international cooperation (e.g., alliances, regimes, openness to trade and investment); the spread of ideas, norms, and institutions; and the transformation of particular international systems, among other topics. In constructing these theories, IR scholars employ an equally diverse set of explanatory variables. Some of these theories operate at the level of the international system, using variables such as the distribution of power among states (Waltz 1979, Copeland 2000, Mearsheimer 2001), the volume of trade, financial flows, and interstate communications (Deutsch 1969, Ruggie 1983, Rosecrance 1986); or the degree of institutionalization among states (Keohane 1984, Keohane & Martin 2003). Other theories emphasize different national characteristics, such as regime type (Andreski 1980, Doyle 1986, Fearon 1994, Russett 1995), bureaucratic and organizational politics (Allison & Halperin 1972, Halperin 1972), or domestic cohesion (Levy 1989); or the content of particular ideas or doctrines (Van Evera 1984, Hall 1989, Goldstein & Keohane 1993, Snyder 1993). Yet another family of theories operates at the individual level, focusing on individual or group psychology, gender differences, and other human traits (De Rivera 1968, Jervis 1976, Mercer 1996, Byman&Pollock 2001, Goldgeier&Tetlock 2001, Tickner 2001, Goldstein 2003), while a fourth body of theory focuses on collective ideas, identities, and social discourse (e.g., Finnemore 1996, Ruggie 1998, Wendt 1999). To develop these ideas, IR theorists employ the full range of social science methods: comparative case studies, formal theory, large-N statistical analysis, and hermeneutical or interpretivist approaches.

#### Predictions avoid a state of permanent emergency. They allow us to reclaim our agency from passivity.

**Bindé ’00** (Jérôme, Dir. Analysis and Forecasting Office – UNESCO, Public Culture, “Toward an Ethics of the Future”, 12:1, Project Muse)

An ethics of the future is not an ethics in the future. If tomorrow is always too late, then today is often already very late. The disparities between North and South, and increasingly between North and North and between South and South, the growing rift within the very heart of societies, population growth, the threat of an ecological crisis on a planetary scale, and the way societies have lost control and surrendered to the hands of "anonymous masters" all call for a new paradoxical form of emergency, the emergency of the long term. To adopt, as quickly as possible, a constructive and preventive attitude means preserving future generations from the fever of immediacy, from reactive passivity, from refuge in artificial or virtual illusory paradises, and from omnipotent emergency. Through a forward-looking approach, we can be in a position to offer generations to come what we are deprived of today--a future. Institutions have the power to forecast or not to forecast. This is an awesome responsibility. By choosing not to forecast, they choose to postpone indefinitely their much needed long-term action for the sake of short-term emergency: They condemn themselves, literally, **to passivity, dependency, and, ultimately, to obsolescence and nonexistence**. **By choosing to forecast and by refusing to become purely reactive agents**, they will not only preserve their institutional independence but also send a strong message to other policymakers and decisionmakers worldwide that the first object of policy, and its first responsibility, is the future. Max Weber justly warned that "the proper business of the politician is the future and his responsibility before the future." The failure to use foresight, in other words, is not just a benign failure of intelligence: It is a culpable neglect of future generations. Is it not therefore surprising that, once foresight has been applied, once an issue has been recognised as a policy priority by all parties concerned, once international instruments have been signed that declare the commitment to act on this [End Page 56] foresight, we should fail so miserably to take the appropriate measures? Take development aid: In 1974, developed countries solemnly agreed to dedicate 0.7 percent of their GDP to development aid; nearly a quarter of a century later, in 1997, they contribute 0.22 percent of their GDP to development aid, and one superpower dedicates only 0.09 percent to it. 5 Take the issue of the global environment: Seven years after the 1992 Earth Summit in Rio, Agenda 21 remains, for the greater part, a dead letter, and the promising but timid advances made at the Kyoto Summit have since been all but forgotten. In both instances, foresight was exerted and solemn oaths taken to act on this foresight, in order to remedy pressing problems. In both instances, action has been delayed, and problems have been allowed to become more pressing. How long can we afford the luxury of inactivity? An ethics of the future, if it remains an ethics in the future, is an injustice committed against all generations, present and future. To paraphrase a common saying, the future delayed is the future denied.