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### Innovation Advantage

#### Big pharma has used disparagement – a series of misleading, false claims about the effectiveness of a competitor’s product – to create a monopoly on drug pricing. This dooms pharmaceutical innovation and harms consumers by crushing the manufacturing and development of more affordable biosimilar drugs

Carrier 2020, Michael A. Carrier Rutgers Law School Distinguished Professor (Northwestern Law Review 2020 “DON’T DIE! HOW BIOSIMILAR DISPARAGEMENT VIOLATES ANTITRUST LAW” https://papers.ssrn.com/sol3/papers.cfm?abstract\_id=3595785)//ellie

In the small-molecule setting, disparagement is not a concern. Brands are not likely to falsely injure near-identical generics, which garner sales not from advertising campaigns but from state laws that allow—and in many cases require—pharmacists to substitute generic versions of brand-name prescriptions.39 In contrast, the education of stakeholders is critical to the marketing of biologics and biosimilars,40 which has tempted biologic firms to engage in disparagement. There are four related categories of statements and omissions that biologic firms have made against biosimilars, none of which is consistent with the statute. The first category is the most dramatic. A January 2019 Washington Post article quotes Philip Schneider, chairman of the Alliance for Safe Biologic Medicines’ international advisory board, as suggesting caution in a move to unbranded biologics “so we don’t end up with another thalidomide [which famously caused birth defects]” or “all the other things that happen when safety isn’t considered.”41 Offering another example in the fearmongering category, the article further quotes a patient advocate affiliated with the group, who stated that a switch from one drug to another “disrupts your continuity of care,” as “[y]ou could end up in an emergency room, or be[] hospitalized, or try[] other, less efficient treatments,” all of which “can exacerbate or flare your disease, bring[ing] it out of remission.”42 The second group of assertions claims that the biosimilar acts differently from the reference product. In an Amgen YouTube video quoted in Pfizer’s citizen petition raising awareness of this issue, the company states that the two products “can behave differently in the body.”43 Amgen also tweeted: “Biologics or biosimilars? It’s not just apples to apples. While #biosimilars may be highly similar to their #biologic reference products, there’s still a chance that patients may react differently.”44 Janssen Biotech provides a similar, albeit more subtle, example. In a patient brochure, the company states that a patient “may be asked to switch to a biosimilar that works in a similar way to REMICADE,” but that “you and your doctor did a lot of fine tuning to get where you are now,” so “if your REMICADE® treatment is still working for you, talk to your doctor about staying on it.”45 The third category is based on claims that the biosimilar is not identical to the reference product. The Amgen video mentioned above states that “no two biologic medicines are identical.”46 Similarly, Genentech’s website, again as discussed in the Pfizer citizen petition, states that “FDA requires a biosimilar to be highly similar, but not identical” to the reference product.47 The fourth group emphasizes that biosimilars do not satisfy the standard of interchangeability. In the brochure mentioned above, Janssen states that “[e]ven though infliximab biosimilars are very similar to REMICADE®, that doesn’t mean they are interchangeable with REMICADE®.” Janssen also warned (in bolded statements) that “no infliximab biosimilar has been proven to be interchangeable with REMICADE®” and that “[t]he infliximab biosimilars are not approved as interchangeable with REMICADE®.”48 Each of these four categories can constitute disparagement. The first— consisting of threatening comparisons to Thalidomide and warnings of trips to the emergency room—needs no explanation. But each of the other categories also runs afoul of the statute’s requirements. The second category—that the biosimilar acts differently—fails to mention that the FDA only approves a biosimilar when it is “highly similar” to and has “no clinically meaningful differences” from the biologic product.49 In other words, the biologic and biosimilar products are required to have the same safety and effectiveness profile.50 As the FDA explained in Draft Guidance issued in February 2020, “representations or suggestions that create an impression that a biosimilar is not highly similar to its reference product are likely to be false or misleading.”51 Evidence from Europe, which has witnessed robust biosimilar market entry, has confirmed that more than “700 million patient days of treatment” demonstrated that “clinical outcomes with biosimilars match the outcomes of the reference biologics.”52 This evidence also has revealed that “patient[s] switching from the reference biologic to the biosimilar . . . is not of concern” since more than 14,000 switches resulted in “[n]o change in clinical outcomes.”53 As discussed below,54 disparaging statements, even if not completely false, are, at a minimum, deceptive in conveying the misleading interpretation that biosimilars have “clinically meaningful differences” from their reference biologics.55 The third category—claiming that the biosimilar is not identical— focuses on an issue that is irrelevant; in fact, it is “normal and expected within the manufacturing process” for even batches of biologic products themselves to reveal “[s]light differences.”56 In the Draft Guidance mentioned above, the FDA “remind[ed] firms that a biosimilar product is not required to be identical to the reference product” but that it need only be “highly similar to the reference product notwithstanding minor differences in clinically inactive components and that there are no clinically meaningful differences . . . in terms of safety, purity, and potency.”57 Finally, for the fourth category, a biosimilar’s failure to attain interchangeability does not mean that it is less safe. For starters, this status only makes sense for biosimilars that will be dispensed at the pharmacy counter (where substitution takes place), but each of the 15 biosimilars that has entered the U.S. market is dispensed in a hospital or infusion center.58 More fundamentally, as Pfizer pointed out in its citizen petition, its biosimilar “demonstrated that a single switch does not result in different safety or efficacy.”59 As the statement from the global regulatory authorities explained, “[a] full clinical development program[] is not necessary when extensive laboratory testing has demonstrated that the biosimilar is highly similar to the originator.”60 And as Boehringer Ingelheim explained in supporting Pfizer’s petition, “an FDA interchangeability designation is irrelevant” for “the majority of biologics . . . administered to the patient by the physician who has written the prescription,” with “misinformation . . . generated” to “impl[y] that interchangeable biologics are ‘better biosimilars’ . . . rather than the same biosimilar on which additional data has been generated.”61 II. REGULATORY SETTING How should courts analyze the antitrust effects of biologic firms’ disparagement of biosimilars? This Part sets the stage for the antitrust analysis by discussing the importance of the regulatory regime, showing the regime’s ineffectiveness, and highlighting the significant barriers to entry facing biosimilars. By brief way of background, the antitrust framework that applies to a single firm acting unilaterally is monopolization. This offense requires a showing of monopoly power and exclusionary conduct.62 Monopoly power is “the power to control prices or exclude competition.”63 Biologic firms that disparage biosimilars are likely to satisfy this element because of their ability to charge and sustain supracompetitive prices in a market characterized by significant barriers to entry.64 In contrast to monopoly power, the caselaw on exclusionary conduct is less clear. Courts often distinguish between the “willful acquisition or maintenance of [monopoly] power” and “growth or development as a consequence of a superior product, business acumen, or historic accident.”65 Considering the regulatory regime can shed critical light on the issue of exclusionary conduct. A. Regulatory Regime As the Supreme Court explained in Verizon Communications v. Trinko, the starting point for antitrust analysis is the regulatory regime. The Court stated that antitrust analysis must take “careful account” of “the pervasive federal and state regulation characteristic of the industry” and “recognize and reflect the distinctive economic and legal setting of the regulated industry to which it applies.”66 The Court in Trinko considered not just the existence of a regulatory regime, but also its effectiveness. In Trinko, the regime was working: phone companies providing local service were required to “be on good behavior” and not to discriminate in providing access before entering the long-distance market.67 Firms that did not satisfy these conditions were subject to financial penalties, weekly reporting requirements, or the suspension or revocation of long-distance approval.68 In contrast, regulatory abuse has prevented the biologics regime from operating as intended. The combination of ineffective FDA regulation and high barriers to entry ensures a role for antitrust.69 B. Ineffective Regulation Biosimilar competition in the United States is far from robust. In Europe, 59 biosimilars have received approval.70 In the United States, 27 biosimilars have been approved (with more than half the approvals occurring since July 2018).71 In addition, U.S. biosimilars have offered savings of only 15% to 35% (typically on the lower end), far less than the more significant (often 70%) discounts in Europe.72 The weak U.S. biosimilar market is not the consequence of the FDA’s lack of effort. In its citizen petition, Pfizer pointed to “various initiatives” the agency had undertaken “aimed at encouraging and facilitating the development and approval of biosimilars.”73 Such activities included “the numerous biosimilar-related guidance documents FDA has issued, the Agency’s development and distribution of educational materials . . . , the Agency’s Biosimilar User Fee Act performance goals, and the . . . Biosimilars Action Plan.”74 Despite these efforts, FDA officials have expressed frustration with the lack of biosimilar competition. In 2018, Former Commissioner Scott Gottlieb “worried” that the market for biosimilars “still isn’t established” and that “[t]he ability for these products to penetrate clinical practice, and gain acceptance, is still not firm.”75 In addition, Gottlieb lamented that biosimilar competition is “anemic” and that “the real savings” from biosimilars have been “just a fraction of even the most conservative initial estimates.”76 In fact, the agency found that “if Americans had the opportunity to purchase successfully marketed, FDA-approved biosimilar prescription drugs, they could have saved more than $4.5 billion in 2017.”77 Such savings, however, will not come to fruition if biologic companies “unfairly delay or derail the entry of biosimilar competitors” through conduct (discussed in the next Part) such as patent thickets and anticompetitive contracts.78 Gottlieb expressed further concern “that the biosimilar manufacturers may pull out” if biologics “are able to lock up markets even in cases where there’s a fully interchangeable competitor.”79 Even more on point, Gottlieb “worried” that “there are either deliberate or unintentional efforts by branded companies to create confusion” about biosimilars’ safety and effectiveness.80 These messages “can potentially undermine consumer confidence in biosimilars in ways that are untrue” and “negatively impact a patient’s judgment about an otherwise safe and effective product.”81 The FDA and FTC reiterated these concerns in a joint statement in February 2020 in which they explained that they “support competitive markets for biologics” and “have serious concerns about false or misleading statements and their negative impacts on public health and competition.”82

#### False advertisement wrecks biosimilars---maintaining competition with antitrust is key.

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An example illustrates our framework. The pharmaceutical industry is marked by high barriers to entry. It is expensive to enter the market, and there are significant hurdles such as receiving approval from the FDA. These barriers are even higher in the biologics setting. Compared to the “small molecule” drugs that have made up the pharmaceutical market for the past several decades, biologic products are more complex and less predictable. As a result, unlike the near-identical relationship between brand and generic drugs, the connection between biologics and “follow-on biosimilars” is not as direct.171 The relevant statute, the Biologics Price Competition and Innovation Act (“BPCIA”),172 requires a biosimilar to be “highly similar to” the biologic and have “no clinically meaningful differences” in relation to “safety, purity, and potency.”173 But the uncertainty surrounding the products has resulted in biologic manufacturers stating or implying that biosimilars are unsafe, sometimes by omitting relevant information about their functional equivalence with the reference biologics.174 In a setting in which even the most minute differences between products could be enough to dissuade patients from trying new medications, the assertions at least implied dissimilarities that could have significant safety effects. For example, Genentech noted on its “Examine Biosimilars” website that “FDA requires a biosimilar to be highly similar, but not identical to the [reference product].”175 More explicitly, Amgen tweeted: “Biologics or biosimilars? It’s not just apples to apples. While #biosimilars may be highly similar to their #biologic reference products, there’s still a chance that patients may react differently.”176 Given the context of life-saving medications, it’s easy to imply dire consequences. For example, Amgen created a YouTube video asserting that a switch “carries risks, given that no two biologic medicines are identical,” which suggests that they “can behave differently in the body.”177 Amgen also cautioned that “[s]witching drugs is not a good idea if your medicine is working for you” and that “an inadvertent substitution . . . is not appropriate care.”178 Finally, some biologic manufacturers have warned that patients could face “additional risks” by taking biosimilars or even “could end up in the emergency room.”179 These claims raise several concerns. Most significant, the statements at issue imply that biosimilars create serious risks, failing to disclose that the FDA approves a biosimilar only when “there are no clinically meaningful differences [from] the biologic product.”180 To the contrary, biologic and biosimilar products are required to have the same safety and effectiveness profile.181 Evidence from Europe, which has witnessed robust biosimilar entry, has confirmed that “over 700 million patient days of treatment” demonstrated “that clinical outcomes with biosimilars match the outcomes of the reference biologics.”182 This evidence also has revealed that “patient switching from the reference biologic to the biosimilar . . . is not of concern” since the more than 14,000 switches from biologic to biosimilar resulted in “[n]o change in clinical outcomes.”183 Given significant development costs, regulatory barriers, thickets of dozens of (or even more than 100) patents,184 and exclusive contractual arrangements,185 biologic manufacturers are likely to have monopoly power.186 Taking the absence of clinically meaningful differences in FDAapproved biosimilars as a given, plaintiffs challenging false statements are likely to satisfy our presumption if they can show that, under false advertising law, the statements (or omissions) are false and material, and therefore are likely to deceive consumers and cause harm. False advertising principles establish that biologic manufacturers will not be liable unless their statements are false or mislead substantial numbers of relevant consumers. But, if falsity or misleadingness are established, they are not likely to be able to rebut the presumption of anticompetitive conduct given the significance of health risk claims to consumers. Even for attempted monopolists, as long as a plaintiff establishes falsity or misleadingness, the factors would seem to favor liability. Given the lack of biosimilar entry to date, in many cases biosimilars will be seeking to enter the market. The statements, which focus directly on risk, pose significant barriers to entry, as doctors and consumers are not likely to take a chance on drugs that have even the possibility of safety concerns. It is hard to think of examples that would more concretely affect consumers than warnings that drug products are potentially unsafe. In fact, the FTC recently issued warning letters to a number of plaintiff-side law firms for advertising that linked FDAapproved drugs with serious side effects, potentially frightening patients away from useful medications.187 In addition, a biologic manufacturer’s disparagement of a biosimilar rival may be part of a broader range of anticompetitive conduct. For example, disparagement could entrench barriers to entry that convince insurance companies to favor biologics through potentially anticompetitive exclusive dealing, bundling, and rebates.188 In short, false advertising law provides useful tools for determining if substantial numbers of relevant consumers are being misled to their detriment. And our framework would likely find that a biologic manufacturer’s proven false advertising that raises safety concerns against a biosimilar constitutes monopolization.

#### Biosimilar competition via antitrust is vital to check health care costs – it’s the fastest-growing internal

Carrier, 20 – Michael, Professor of Law at Rutgers, *Don’t Die! How Biosimilar Disparagement Violates Antitrust Law*, 115 Nw. U. L. Rev. Online 119, p. Nexis – Iowa

ABSTRACT

Competition is the key to low prices in the pharmaceutical industry. For decades, Americans have benefitted from affordable generic versions of brand-name drugs. But now, we stand poised on the wave of a revolution. Biologics, which include lifesaving, cancer-treating drugs, can cost hundreds of thousands of dollars per year and are forecast to be the "fastest growing segment of drug spending" in coming years.

The hope, then, is that just like generic drugs, competition from follow-on products known as biosimilars will lower prices. But the fear is that they will not. Why? One main reason is disparagement.

Biosimilars are nearly the same as biologics. In fact, they are required to be "highly similar" to, and have "no clinically meaningful differences" from, biologics. Despite this, biologic manufacturers have raised ominous warnings that biosimilars are not the same as biologics but have differences that pose grave safety consequences. Doctors are getting the message loud and clear and are refusing to prescribe appropriate--and more affordable--biosimilars. It thus comes as no surprise that government agencies have serious concerns about the behavior of biologic companies.

This Essay addresses biologic manufacturers' disparagement of biosimilars. It sketches the background of the industry and introduces the unique regulatory setting. It then sets forth the caselaw and explains how disparagement can violate antitrust law.

I. BIOLOGICS The relationship between biologics and biosimilars differs from that between brand-name drugs and their generic counterparts. This Part sketches these differences and discusses the relevant statute for biologics and biosimilars, as well as biologic companies' disparagement of biosimilars. A. Scientific Differences The science underlying biologics and small-molecule (brand) drugs is different. Small molecules are created through a series of chemical reactions known as chemical synthesis. 14The process is predictable, which allows generics to cheaply imitate brand drugs. 15Put another way, brands and generics can put the same pieces of a puzzle together in the same way to create the same image. Biologics, in contrast, emphasize not the individual pieces of the puzzle but the way the puzzle is constructed. Because "the product is the process," and the use of living cells to create biologics is inherently sensitive, there is higher variability in the product's final form. 16 This variability presents challenges to biosimilar manufacturers. Even if these entities can rely on patent disclosures and other materials in the public domain, they will lack access to critical information that is protected as a trade secret. 17Because biologics are "so closely defined by their manufacturing process," this secrecy blocks competition. 18All of these [\*123] development difficulties minimize the price reductions that biosimilars can unleash in comparison to generics. B. Statutory Framework The framework statute for biologics, the Biologics Price Competition and Innovation Act (BPCIA), 19was designed to encourage innovation and competition. To foster innovation, it provides biologic drugs with two exclusivity periods. 20The first period begins when the biologic (known as the reference product) is approved and lasts for four years. 21During this period, the FDA will not accept an application from a biosimilar manufacturer. 22In the second period, even after the FDA can accept a biosimilar application, it cannot grant approval until twelve years after the date the biologic was first licensed. 23This 12-year exclusivity period gives biologic products strong protection in the marketplace. The BPCIA fosters follow-on competition through an abbreviated approval pathway for biosimilars. 24To gain approval as a biosimilar under the BPCIA, an applicant must show that the biological product is highly similar to the reference product notwithstanding minor differences in clinically inactive components; and [] there are no clinically meaningful differences between the biological product and the reference product in terms of the safety, purity, and potency of the product. 25 A biosimilar manufacturer can show that its product is highly similar to the reference product by "extensively analyzing . . . the structure and function" of both products. 26The FDA has made it clear that "[m]inor differences . . . in clinically inactive components are acceptable," with the agency "carefully evaluat[ing]" such disparities to ensure that the biosimilar "meets FDA's high approval standards." 27In fact, "slight differences" are expected during the manufacturing process, not only for biosimilars but also [\*124] for biologics. As one company has explained, "most biologics vary and . . . in fact are not identical batch-to-batch. . . ." 28 A biosimilar manufacturer's ability to make these showings assuages fears that its product is not as safe as the biologic. A coalition of nearly thirty pharmaceutical regulators from around the world has explained that biosimilars demonstrate similarity through "extensive laboratory comparability studies." 29These studies use "highly sensitive state-of-the-art analytical technology that allows robust and extensive examination and comparison of the biosimilar and originator molecules." 30 The benefits of obtaining follow-on approval under the BPCIA differ from those under the Hatch-Waxman Act, Congress's framework statute for competition and innovation in the small-molecule, or brand-drug, setting. 31Unlike the Hatch-Waxman regime, in which the first generic manufacturer to file what is known as a "Paragraph IV" certification (claiming that the brand's patent is invalid or not infringed 32) is eligible for a 180-day period of exclusivity, the first to file a biosimilar does not benefit from such protection. 33Rather, exclusivity is granted only to the first biosimilar that clears the higher threshold of interchangeability. 34 To attain interchangeability status, the applicant must show that the follow-on version (1) "is biosimilar to the reference product" and (2) "can be expected to produce the same clinical result as the reference product in any given patient." 35For products administered more than once to an individual, the follow-on maker must show that the risk of switching between products is not greater than the risk of not switching. 36If the applicant seeking interchangeability can meet this standard, it will receive exclusivity, which expires (if certain other litigation or approval thresholds are not [\*125] reached earlier) one year after commercial marketing. 37The FDA has not yet approved an interchangeable biosimilar. 38 C. Disparagement In the small-molecule setting, disparagement is not a concern. Brands are not likely to falsely injure near-identical generics, which garner sales not from advertising campaigns but from state laws that allow--and in many cases require--pharmacists to substitute generic versions of brand-name prescriptions. 39In contrast, the education of stakeholders is critical to the marketing of biologics and biosimilars, 40which has tempted biologic firms to engage in disparagement. There are four related categories of statements and omissions that biologic firms have made against biosimilars, none of which is consistent with the statute. The first category is the most dramatic. A January 2019 Washington Post article quotes Philip Schneider, chairman of the Alliance for Safe Biologic Medicines' international advisory board, as suggesting caution in a move to unbranded biologics "so we don't end up with another thalidomide [which famously caused birth defects]" or "all the other things that happen when safety isn't considered." 41Offering another example in the fearmongering category, the article further quotes a patient advocate affiliated with the group, who stated that a switch from one drug to another "disrupts your continuity of care," as "[y]ou could end up in an emergency room, or be[] hospitalized, or try[] other, less efficient treatments," all of which "can exacerbate or flare your disease, bring[ing] it out of remission." 42 [\*126] The second group of assertions claims that the biosimilar acts differently from the reference product. In an Amgen YouTube video quoted in Pfizer's citizen petition raising awareness of this issue, the company states that the two products "can behave differently in the body." 43Amgen also tweeted: "Biologics or biosimilars? It's not just apples to apples. While #biosimilars may be highly similar to their #biologic reference products, there's still a chance that patients may react differently." 44Janssen Biotech provides a similar, albeit more subtle, example. In a patient brochure, the company states that a patient "may be asked to switch to a biosimilar that works in a similar way to REMICADE," but that "you and your doctor did a lot of fine tuning to get where you are now," so "if your REMICADE(R) treatment is still working for you, talk to your doctor about staying on it." 45 The third category is based on claims that the biosimilar is not identical to the reference product. The Amgen video mentioned above states that "no two biologic medicines are identical." 46Similarly, Genentech's website, again as discussed in the Pfizer citizen petition, states that "FDA requires a biosimilar to be highly similar, but not identical" to the reference product. 47 The fourth group emphasizes that biosimilars do not satisfy the standard of interchangeability. In the brochure mentioned above, Janssen states that "[e]ven though infliximab biosimilars are very similar to REMICADE(R), that doesn't mean they are interchangeable with REMICADE(R)." Janssen also warned (in bolded statements) that "no infliximab biosimilar has been proven to be interchangeable with REMICADE(R)" and that "[t]he infliximab biosimilars are not approved as interchangeable with REMICADE(R)." 48 Each of these four categories can constitute disparagement. The first--consisting of threatening comparisons to Thalidomide and warnings of trips to the emergency room--needs no explanation. But each of the other categories also runs afoul of the statute's requirements. The second category--that the biosimilar acts differently--fails to mention that the FDA only approves a biosimilar when it is "highly similar" to and has "no clinically meaningful differences" from the biologic product. 49In other words, the biologic and biosimilar products are required to have the same [\*127] safety and effectiveness profile. 50As the FDA explained in Draft Guidance issued in February 2020, "representations or suggestions that create an impression that a biosimilar is not highly similar to its reference product are likely to be false or misleading." 51 Evidence from Europe, which has witnessed robust biosimilar market entry, has confirmed that more than "700 million patient days of treatment" demonstrated that "clinical outcomes with biosimilars match the outcomes of the reference biologics." 52This evidence also has revealed that "patient[s] switching from the reference biologic to the biosimilar . . . is not of concern" since more than 14,000 switches resulted in "[n]o change in clinical outcomes." 53As discussed below, 54disparaging statements, even if not completely false, are, at a minimum, deceptive in conveying the misleading interpretation that biosimilars have "clinically meaningful differences" from their reference biologics. 55 The third category--claiming that the biosimilar is not identical--focuses on an issue that is irrelevant; in fact, it is "normal and expected within the manufacturing process" for even batches of biologic products themselves to reveal "[s]light differences." 56In the Draft Guidance mentioned above, the FDA "remind[ed] firms that a biosimilar product is not required to be identical to the reference product" but that it need only be "highly similar to the reference product notwithstanding minor differences in clinically inactive components and that there are no clinically meaningful differences . . . in terms of safety, purity, and potency." 57 Finally, for the fourth category, a biosimilar's failure to attain interchangeability does not mean that it is less safe. For starters, this status only makes sense for biosimilars that will be dispensed at the pharmacy [\*128] counter (where substitution takes place), but each of the 15 biosimilars that has entered the U.S. market is dispensed in a hospital or infusion center. 58More fundamentally, as Pfizer pointed out in its citizen petition, its biosimilar "demonstrated that a single switch does not result in different safety or efficacy." 59As the statement from the global regulatory authorities explained, "[a] full clinical development program[] is not necessary when extensive laboratory testing has demonstrated that the biosimilar is highly similar to the originator." 60And as Boehringer Ingelheim explained in supporting Pfizer's petition, "an FDA interchangeability designation is irrelevant" for "the majority of biologics . . . administered to the patient by the physician who has written the prescription," with "misinformation . . . generated" to "impl[y] that interchangeable biologics are 'better biosimilars' . . . rather than the same biosimilar on which additional data has been generated." 61 II. REGULATORY SETTING How should courts analyze the antitrust effects of biologic firms' disparagement of biosimilars? This Part sets the stage for the antitrust analysis by discussing the importance of the regulatory regime, showing the regime's ineffectiveness, and highlighting the significant barriers to entry facing biosimilars. By brief way of background, the antitrust framework that applies to a single firm acting unilaterally is monopolization. This offense requires a showing of monopoly power and exclusionary conduct. 62Monopoly power is "the power to control prices or exclude competition." 63Biologic firms that disparage biosimilars are likely to satisfy this element because of their ability [\*129] to charge and sustain supracompetitive prices in a market characterized by significant barriers to entry. 64 In contrast to monopoly power, the caselaw on exclusionary conduct is less clear. 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In Trinko, the regime was working: phone companies providing local service were required to "be on good behavior" and not to discriminate in providing access before entering the long-distance market. 67Firms that did not satisfy these conditions were subject to financial penalties, weekly reporting requirements, or the suspension or revocation of long-distance approval. 68 In contrast, regulatory abuse has prevented the biologics regime from operating as intended. The combination of ineffective FDA regulation and high barriers to entry ensures a role for antitrust. 69 [\*130] B. Ineffective Regulation Biosimilar competition in the United States is far from robust. In Europe, 59 biosimilars have received approval. 70In the United States, 27 biosimilars have been approved (with more than half the approvals occurring since July 2018). 71In addition, U.S. biosimilars have offered savings of only 15% to 35% (typically on the lower end), far less than the more significant (often 70%) discounts in Europe. 72 The weak U.S. biosimilar market is not the consequence of the FDA's lack of effort. In its citizen petition, Pfizer pointed to "various initiatives" the agency had undertaken "aimed at encouraging and facilitating the development and approval of biosimilars." 73Such activities included "the numerous biosimilar-related guidance documents FDA has issued, the Agency's development and distribution of educational materials . . . , the Agency's Biosimilar User Fee Act performance goals, and the . . . Biosimilars Action Plan." 74 Despite these efforts, FDA officials have expressed frustration with the lack of biosimilar competition. In 2018, Former Commissioner Scott Gottlieb "worried" that the market for biosimilars "still isn't established" and that "[t]he ability for these products to penetrate clinical practice, and gain acceptance, is still not firm." 75In addition, Gottlieb lamented that biosimilar [\*131] competition is "anemic" and that "the real savings" from biosimilars have been "just a fraction of even the most conservative initial estimates." 76In fact, the agency found that "if Americans had the opportunity to purchase successfully marketed, FDA-approved biosimilar prescription drugs, they could have saved more than $ 4.5 billion in 2017." 77Such savings, however, will not come to fruition if biologic companies "unfairly delay or derail the entry of biosimilar competitors" through conduct (discussed in the next Part) such as patent thickets and anticompetitive contracts. 78Gottlieb expressed further concern "that the biosimilar manufacturers may pull out" if biologics "are able to lock up markets even in cases where there's a fully interchangeable competitor." 79 Even more on point, Gottlieb "worried" that "there are either deliberate or unintentional efforts by branded companies to create confusion" about biosimilars' safety and effectiveness. 80These messages "can potentially undermine consumer confidence in biosimilars in ways that are untrue" and "negatively impact a patient's judgment about an otherwise safe and effective product." 81The FDA and FTC reiterated these concerns in a joint statement in February 2020 in which they explained that they "support competitive markets for biologics" and "have serious concerns about false or misleading statements and their negative impacts on public health and competition." 82 Compounding the regulatory regime's inability to effectuate robust biosimilar competition is the FDA's failure to (1) approve an interchangeable or (2) explain the lack of safety consequences from the absence of an interchangeability designation. 83As the disparagement examples above show, 84this vacuum has led to assumptions that biosimilars are unsafe as none have attained the highest standard of substitutability. This misunderstanding fails to recognize that--even if not as much data is [\*132] generated--a finding of biosimilarity is sufficient for patients to have complete confidence that the product is safe and will work as effectively as the reference biologic. For if a biosimilar was any less safe or effective, the FDA never would have approved it in the first place. C. Barriers to Entry Exacerbating the regulatory regime's ineffectiveness are multiple barriers to entry that have limited the number of U.S. biosimilars, including development costs, patent thickets, anticompetitive contracts, and established patients. The first barrier to entry is the cost of developing biosimilars. As discussed above, 85biosimilar manufacturers face significant development hurdles. Not only are the products complex, but key inputs are also hidden behind trade secrets and opaque manufacturing processes. As a result, unlike generics, which cost an average of $ 5 million to bring to market, biosimilar development involves more intensive and uncertain research and development, which could result in costs of at least $ 100 million. 86 A second hurdle involves vast patent thickets that biologic companies have put together. For example, AbbVie has more than 100 patents covering anti-inflammatory-treating Humira, including more than 50 obtained in 2015 and 2016 combined, just before the patent on the medicine's active ingredient expired. 87Similarly, Johnson & Johnson (J&J) has more than 100 patents covering the anti-inflammatory medication Remicade. 88Biosimilar manufacturers are not able to get around such massive portfolios. 89 A third barrier involves an array of conduct by which biologic firms have bundled products, employed exclusive dealing, and used rebates to make it harder for rivals to obtain a foothold in the market. Pfizer described this conduct in its lawsuit challenging J&J's protection of its biologic [\*133] Remicade at the expense of Pfizer's rival Inflectra. 90Pfizer challenged J&J's exclusive contracts, made up of (1) "express terms that would exclude biosimilars" from "medical policies and drug formularies" and (2) "fail first" provisions, which "require a patient to first try and fail on Remicade before the insurance company would reimburse Inflectra or another biosimilar." 91Pfizer also claimed that J&J "bundled rebates across multiple products," forcing insurers to "pay a higher price on other [J&J] products" if they "refuse[d] to grant exclusivity to Remicade." 92 The fourth and final barrier is presented by established patients. These "incontestable patients" "represent inelastic demand" as they are "'highly unlikely' to [switch] to a biosimilar," even in response to a price increase. 93For that reason, Pfizer challenged J&J's "all-or-nothing" program, which "bundles the base of existing Remicade patients with new patients." 94By "premising rebates on this incontestable population," J&J sought to use a "rebate trap," forcing insurers to "exclude Inflectra from competing for new patients." 95 \* \* \* The combined effect of these entry barriers exacerbates the problem. The cost of development limits the universe of biosimilars, and patent thickets make it extremely difficult to enter many markets. Existing patients are difficult to move to new medicines--even when they are more affordable. Rebates, bundling, and exclusive dealing threaten to link existing and new patients together. And on top of these existing barriers, disparagement dissuades the remaining new patients, taking away what should be the most receptive segment of the market: those not locked into existing regimens. Before determining if disparagement violates antitrust law, the next Part analyzes the approaches courts have applied to this conduct. III. CASELAW In analyzing the antitrust effects of disparagement, courts have adopted one of three approaches. This Part discusses the three: no-liability, de minimis, and case-by-case analyses. [\*134] A. No-Liability The first approach, which has been applied by the Fifth and Seventh Circuits, reasons that false statements enhance competition in advertising markets and thus that disparagement-based antitrust claims are not actionable. For example, the Fifth Circuit has drawn a distinction between "business torts, which harm competitors, and truly anticompetitive activities, which harm the market." 96It has also stated that "absent a demonstration that a competitor's false advertisements had the potential to eliminate, or did in fact eliminate, competition, an antitrust lawsuit will not lie." 97Similarly, the Seventh Circuit stated bluntly that "[c]ommercial speech is not actionable under the antitrust laws." 98In particular, this court asserted that "[a]ntitrust law condemns practices that drive up prices by curtailing output," distinguishing "[f]alse statements about a rival's goods [that] do not curtail output in either the short or long run," but instead "just set the stage for competition in a different venue: the advertising market." 99 This hands-off approach is not persuasive. There is not such a "rigid distinction" between "business torts, which harm competitors, and truly anticompetitive activities, which harm the market." 100Deceptive statements could depress demand for the criticized product, thereby reducing output and increasing price. 101Many false statements are made about the defendant's own products, with false superiority claims discouraging consumers from using any competitor's products. 102More fundamentally, misleading advertising forces competitors to fight back on unfair ground, expending resources defending truth against falsehood instead of investing them elsewhere, harming their overall ability to compete. And as Professor Rebecca Tushnet has written, "corrective advertising, especially by an [\*135] inherently-less-credible-because-self-interested competitor, is unlikely to fix all the damage of false advertising." 103 By engaging in deception, a company--in particular, a monopolist--could entrench its position in the market. And this conduct could (based on the dichotomy drawn in a leading Supreme Court monopolization case) resemble more the "willful acquisition or maintenance of [monopoly] power" than a "superior product, business acumen, or historic accident." 104Or the deception, applying another landmark case, could be viewed as "tend[ing] to impair the opportunities of rivals" and "not further[ing] competition on the merits." 105 B. De Minimis The second approach, represented by the Second, Sixth, Ninth, Tenth, and Eleventh Circuits, applies a presumption that the exclusionary effects of disparagement are de minimis. 106The plaintiff can rebut such a presumption by showing that the alleged anticompetitive conduct is (1) clearly false, (2) clearly material, (3) clearly likely to induce reasonable reliance, (4) made to buyers without knowledge of the subject matter, (5) continued for prolonged periods, and (6) not readily susceptible to neutralization or other offsets by rivals. 107Courts are not consistent on whether a plaintiff must show each of the six factors. 108 In creating such strict requirements, the framework ensures that the vast majority of false advertising, perpetuated by firms lacking market power, does not automatically violate antitrust law. But it overshoots the mark in making it nearly impossible to find antitrust liability even for monopolists bringing about substantial competitive harm. [\*136] In assessing the appropriateness of the de minimis factors, it is worth considering false advertising law, which offers a ready-made template for assessing the harmful effects of false and misleading advertising. For an advertisement to be actionable, it must contain false or misleading statements that are material, that deceive or are likely to deceive consumers, and that cause or are likely to cause harm to the plaintiff. 109 Considering false advertising law raises questions about the propriety of the factors making up the de minimis framework. For example, a clear falsity requirement does not reflect false advertising's concern with misleading statements, which could be literally true or ambiguous but still induce consumers to reach false conclusions. 110In fact, "[c]onsumers are less likely to argue against associations they came up with themselves, and more likely to remember and act on them." 111Additionally, reasonable reliance duplicates false advertisement's materiality factor while overemphasizing the fraud-like idea--not present in false advertising law--of "reasonable" reliance. Nor do the other factors in the de minimis test capture the reality of false advertising, which is not readily susceptible to neutralization and which can still be effective even if directed to buyers with knowledge of the subject matter. In short, in departing from the basics of false advertising law, the de minimis framework raises questions. 112Despite these shortcomings, because it represents the state of the law in many courts, I take the de minimis test as a given in this piece. A case from the medical device industry, Lenox MacLaren Surgical Corp. v. Medtronic, 113provides one potential guidepost for analysis based on the de minimis approach. In that case, Lenox, a manufacturer of bone mills used in spinal-fusion surgery, 114entered into an agreement by which Medtronic distributed the product to hospitals. 115After the agreement broke down, Lenox alleged that Medtronic engaged in disparagement that [\*137] constituted monopolization by telling potential customers that its device was dangerous and helping to initiate a recall. 116Applying the six-factor test, the Tenth Circuit found that Lenox offered evidence to rebut the presumption of a de minimis impact on competition. 117 The court's discussion of three of the six factors is instructive. 118For the fourth factor, whether the alleged statement was made to buyers without knowledge of the subject matter, the court found that "even sophisticated consumers [like hospitals and group purchasing organizations] would rely on Medtronic's false statements." 119For the fifth factor, whether the false statement continued for prolonged periods, the court found that the continued listing of Lenox's device on the FDA's website as recalled was enough to show a prolonged period. 120And the court found the sixth factor, whether the plaintiff could show that it could not readily neutralize the disparaging statement, was satisfied from "worries involving malpractice liability," which resulted in "hospitals [being] unwilling to purchase" recalled products. 121The Lenox case offers a roadmap for how a plaintiff can satisfy this framework. C. Case-by-Case A third group of courts, led by the Third, Eighth, and D.C. Circuits, takes a case-by-case approach in assessing whether the alleged disparagement violates antitrust law. For example, the Third Circuit has explained that "anticompetitive conduct can include . . . making false statements about a rival to potential investors and customers" and that "defamation, which plainly is not competition on the merits, can give rise to antitrust liability, especially when it is combined with other anticompetitive acts." 122Similarly, the D.C. Circuit has recognized that "fraudulent misrepresentations" are "well within" the universe of anticompetitive conduct. 123And the Eighth Circuit has explained that an alleged monopolist's "full frontal attack" that "(1) used false, misleading and deceptive advertising and (2) was directed at (a) consumers and (b) travel agents" [\*138] demonstrated an unreasonable restraint because of its "purpose of preventing any effective competition." 124 Courts applying the case-by-case approach have appreciated that anticompetitive conduct takes "too many different forms, and is too dependent upon context, for any court or commentator ever to have enumerated all the varieties." 125Under this approach, one relevant factor could be the role the conduct plays in a competitor's ability to finance high expenses. In one case, for example, the Third Circuit determined that false statements to investors about a competitor's financial health caused the rival to pay inflated financing costs on its debt and, in combination with other actions, demonstrated anticompetitive conduct sufficient to survive a motion to dismiss. 126 A second factor that courts have analyzed under the case-by-case approach is the extent to which false statements lock in decision-making. In United States v. Microsoft Corp., for example, the D.C. Circuit found that deceptive statements to Java-based software developers about the interoperability of Windows-based systems with other platforms resulted in the inadvertent development of software compatible only with Windows and demonstrated anticompetitive conduct. 127 Though courts have considered the two factors mentioned above, the case-by-case analyses apply a totality of the circumstances approach. By analyzing conduct as a whole without requiring a showing exceeding de minimis harm, this approach offers flexibility for biosimilar manufacturers bringing disparagement claims. \* \* \* In sum, antitrust courts apply three very different frameworks when considering deception-based claims. The first, unjustifiable approach, abandons antitrust liability. The other two, considered more fully in the next Part, apply the strict standards of the de minimis framework and the more flexible standards of the case-by-case approach.

IV. ANTITRUST VIOLATION

Biologic manufacturers' disparagement of biosimilars can violate antitrust law. This Part shows how biologics typically have monopoly power. It then applies the two primary judicial approaches to the conduct, finding that monopolization is likely under both the de minimis and case-by-case approaches. 128

As an initial matter, as applied to monopolists' deceptive conduct, antitrust law offers unique advantages over false advertising law. 129For example, as compared to false advertising law, antitrust offers more powerful remedies of treble damages, automatic (as opposed to exceptional) attorneys' fees, 130 and injunctive relief preventing the behavior's continuation, 131 as well as a more expansive universe of potential plaintiffs, all of which promise to provide robust deterrence.

A. Monopoly Power A monopolization case consists of monopoly power and exclusionary conduct. 132The first element is monopoly power, which courts have defined as "the power to control prices or exclude competition." 133Monopoly power can be shown in one of two ways. First, it can be proved indirectly by examining a defendant's market share along with barriers to entry that could entrench that market position. 134Courts regularly hold that a 90% market share supports monopoly power, with some courts finding a 75% share to be sufficient. 135 [\*140] Second, a plaintiff can prove monopoly power directly, 136such as when a brand firm is able to "maintain the price of [a] drug . . . at supracompetitive levels without losing substantial sales . . . ." 137Direct proof of monopoly power can also consist of observable effects on the market such as a price increase or output reduction. 138 The Supreme Court has held that a market can consist of a single product. 139Lower courts have also found that a single drug can constitute its own market, which has led naturally to the conclusion that a single drug can have monopoly power. 140Where potential purchasers have no alternative to using a drug, monopoly power is likely. Biologics are likely to have monopoly power. There has been very limited entry of biosimilars in the United States. Biologics make up 7 of the top 10 highest-selling drugs in the country. 141And manufacturers charge astronomical prices, as much as hundreds of thousands of dollars per year for a product. 142Even though biologics make up less than 2% of the market, they represent 40% of prescription drug spending. 143Pfizer offered one example of monopoly power in its lawsuit against J&J, claiming that J&J's 10% price increase did not affect its 96% market share, with 90% of providers refusing to stock Pfizer's competing product. 144 Given biologics' control over markets and ability to charge high prices without suffering losses, a plaintiff should be able to demonstrate that the [\*141] products have monopoly power. 145Having satisfied monopoly power, the next element is exclusionary conduct. As discussed above, 146the Fifth and Seventh Circuits would not find liability under the first approach. But that is only because they abandon antitrust analysis. That is not a justifiable approach. Disparagement could cement a biologic's status as an unchallenged monopolist. And as confirmed by the various barriers to entry discussed above, 147the biologic would not easily lose that monopoly position. B. De Minimis The Second, Sixth, Ninth, Tenth, and Eleventh Circuits apply the de minimis framework to deception-based conduct. As discussed above, 148courts applying this framework presume that the exclusionary effects of disparagement are de minimis. The plaintiff can rebut such a presumption by showing that the alleged anticompetitive conduct is (1) clearly false, (2) clearly material, (3) clearly likely to induce reasonable reliance, (4) made to buyers without knowledge of subject matter, (5) continued for prolonged periods, and (6) not readily susceptible to neutralization or other offsets by rivals. 149The remainder of this Section applies the framework. 150 The first factor requires clear falsity. It is unclear exactly what counts as "clearly false." But the relevant underlying law, false advertising, targets not only false, but also misleading, conduct. 151And, given that the FTC is the government agency most directly focused on challenging or misleading deceptive conduct, its analysis is particularly instructive. In a policy statement, the FTC explained that deception can involve "omission of material information, the disclosure of which is necessary to prevent the claim . . . from being misleading." 152Ensuring a robust interpretation, the FTC made clear that when a seller's representation "conveys more than one meaning to reasonable consumers, one of which is false, the seller is liable [\*142] for the misleading interpretation." 153"[I]t can be deceptive," the FTC explained, "to tell only half the truth, and to omit the rest." 154Such a situation "may occur where a seller fails to disclose qualifying information" needed to prevent an "affirmative statement[] from creating a misleading impression." 155 These types of omissions and half-truths have appeared in the biologic setting. Genentech, Amgen, and Janssen each have made assertions that implied differences between biologics and biosimilars, warning that the products were "not identical," that "patients may react differently" to biosimilars, that biologics "cannot be copied exactly," that switches "carr[y] risks, given that no two biologic medicines are identical," that "[s]witching drugs is not a good idea if your medicine is working for you," and that a failure to achieve interchangeability threatens safety. 156At a minimum (and applying a conservative analysis), these assertions result in at least one interpretation to a reasonable consumer that there are clinically meaningful differences between the biologic and the biosimilar. But this innuendo is false. And to the sophisticated actors at the biologic companies, this is not likely to be an oversight. 157 Turning to the second factor, the statements would be clearly material. The FTC has defined a "material" misrepresentation as "one which is likely to affect a consumer's choice" of product. 158Such an assertion targets "information that is important to consumers." 159The FTC presumes that even implied claims "are material if they pertain to the central characteristics of the product, such as its safety. . . ." 160Similarly, "omissions [are] material if they significantly involve health. . . ." 161To state the obvious, denigrating a biosimilar product is material. It is hard to imagine a statement more material than one warning of health concerns with a competitor's product. Third, biologic manufacturers' statements would clearly be likely to induce reasonable reliance. A representation about a biosimilar's safety is exceedingly likely to discourage the patient from purchasing the product. At [\*143] the same time, doctors also would be less likely to prescribe the biosimilar and payors would be less likely to reimburse biosimilars. And not only would there be reliance, but it would also be reasonable given the unparalleled consequences of taking unsafe medications. 162 Fourth, the statements would be made to buyers without knowledge of the subject matter. Doctors rely on the pharmaceutical industry, "the most typical source of information about biosimilars," with prescriptions based on information disseminated by the industry. 163In fact, doctors "report being unsure how to go about explaining biosimilars to patients, which further restricts their use." 164This is unfortunate, as "positive framing can improve patients' perceptions of biosimilars and increase their hypothetical willingness to switch to a biosimilar from a biologic treatment." 165Perhaps it is not a surprise then that patients "hold concerns about biosimilars, particularly relating to safety, efficacy, manufacturing and clinical trials that need to be addressed to improve acceptability." 166 The Lenox case discussed above 167supports a finding that the fourth factor is satisfied. That court found that "even sophisticated consumers [like hospitals and group purchasing organizations] would rely on false statements." 168Here, it does not take a lot in the way of innuendo to dissuade patients from taking, and doctors from prescribing, biosimilars. Again, doctors rely on the pharmaceutical industry as "the most typical source of information about biosimilars." 169Given doctors' obligations to keep abreast of industry standards and avoid prescribing products with safety concerns, it is concerning that "the information disseminated by the pharmaceutical industry affects [doctors'] prescription decisions." 170 [\*144] Fifth, the statements' effect would likely last for prolonged periods. In the Lenox case, the court found that the continued listing of Lenox's device on the FDA's website as recalled was enough to show a prolonged period. 171Biologic companies have control over the market, and this factor would seem to be easily satisfied as they would be likely to promulgate the assertions for lengthy periods of time to maintain their monopolies. Sixth, the plaintiff would not be able to readily neutralize the disparaging statements. Once a safety concern is raised, it is particularly difficult to rebut. Consumers taking, and doctors prescribing, follow-on products that are not exactly the same as the original would tend to shy away from products with safety concerns. Given the dire consequences of drugs operating differently, it is natural to err on the side of avoiding biosimilars. At its core, the Lenox court emphasized the effect of potential liability concerns in secondary markets. Similarly, the central issue confronting doctors in prescribing biosimilars would be whether they are convinced the product operates in a similar manner to the biologic, or instead threatens patients' safety or diminishes efficacy of treatment. Lenox provides a useful guidepost to future courts in emphasizing liability fears as a factor that can overcome the presumption of a de minimis impact on competition. In short, a plaintiff challenging a biologic firm's disparagement of a biosimilar would likely satisfy the second through sixth factors of the de minimis test. A court applying a high standard for the first factor might find that the conduct, although misleading, is not "clearly false." In applying the factors, courts should consider false advertising law and the FTC's consideration of the issue, which would recommend liability. And, at a minimum, for courts that do not require each of the factors to be satisfied, 172liability would most likely be found based on the presence of at least five of the six factors. C. Case-by-Case The case-by-case approach would be even more likely to find liability. By analyzing conduct as a whole without requiring a showing exceeding de minimis harm, the case-by-case approach offers flexibility that increases the likelihood of successful disparagement claims. This flexible framework would allow courts to consider the regulatory setting and the FDA's lack of success in fostering robust biosimilar competition. It would also recognize the irreversible and lasting effects of locking new patients into biologics because they do not trust biosimilars. And, finally, it would consider the [\*145] effects of disparagement in cementing the multiple barriers to entry that entrench the biologic's power. Cases that have applied this approach offer building blocks for liability. Like the Third Circuit case mentioned earlier involving false statements impacting a rival's financing costs, 173disparagement could adversely affect a biosimilar company's ability to finance already-high expenses. Moreover, like the D.C. Circuit case, which found that deceptive statements resulted in anticompetitive conduct, 174false statements could lock in physician decisionmaking. 175 The case-by-case approach could also allow plaintiffs to demonstrate that parties with monopoly power have satisfied the elements of the false advertising offense. 176Given the "near certainty" of anticompetitive effects in this setting, Professor Rebecca Tushnet and I have suggested that courts should adopt a presumption of monopolization when the elements at the core of false advertising law are satisfied. 177 Through its less regimented analysis, the case-by-case approach increases the likelihood that biologic companies would be found liable for monopolistic conduct. The approach would more likely consider the factors highlighted in Part II above (such as significant barriers to entry and the FDA's ineffectiveness in bringing about robust biosimilar competition), allowing plaintiffs to show how these factors exacerbate anticompetitive effects of increased price and reduced output, and it would enable plaintiffs to illustrate how disparagement offers no legitimate procompetitive justifications.

CONCLUSION

Biologics are the wave of the future, promising to unleash revolutionary health benefits. But their price tag is staggering. And if biologic manufacturers can stifle more affordable biosimilars in their cradle by ominously implying false safety concerns, patients will suffer. Recognizing an antitrust cause of action for disparagement promises to enhance competition and help U.S. consumers afford life-saving medicines.

#### Antitrust and biosimilar competition is make or break for the future of pharma

Marmaro, 21 – Morgan, Editor-in-Chief, Colum. J.L. & Soc. Probs., 2020-2021. J.D. Candidate 2021, Columbia Law School. Molecule Size Doesn't Matter: The Case for Harmonizing Antitrust Treatment of Pay-for-Delay Agreements, 54 Colum. J.L. & Soc. Probs. 169, Winter, p. Nexis – Iowa

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." 31 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 [\*177] 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. A class action, In re Humira (Adalimumab) Antitrust Litigation, 46alleges 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 [\*179] advantages" derived from the current regulatory system. 47The 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. 48But 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, 49this 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 [\*180] procedures, 51recent 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. 52Some commentators, however, have advocated a narrow interpretation of Actavis to apply only to small molecule drugs 53because the Court only discusses the relevant regulatory framework for small molecule drugs in that case. 54They argue that the Actavis result was founded and based on the language and intent of the Hatch-Waxman Act. 55Just as the courts then spent years litigating whether Actavis only implicated cash-only "payments," 56savvy 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 [\*181] 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.

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

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As key actors in the healthcare innovation landscape, pharmaceutical and life sciences companies have been called on to develop medicines, vaccines and diagnostics for pressing public health challenges. The COVID-19 crisis is one such challenge, but there are many others. For example, MERS, SARS, Ebola, Zika and avian and swine flu are also infectious diseases that represent public health threats. Infectious agents such as anthrax, smallpox and tularemia could present threats in a bioterrorism context. The general threat to public health that is posed by antimicrobial resistance is also well-recognised as an area in need of pharmaceutical innovation. Innovating in response to these challenges does not always align well with pharmaceutical industry commercial models, shareholder expectations and competition within the industry. However, the expertise, networks and infrastructure that industry has within its reach, as well as public expectations and the moral imperative, make pharmaceutical companies and the wider life sciences sector an indispensable partner in the search for solutions that save lives. This perspective argues for the need to establish more sustainable and scalable ways of incentivising pharmaceutical innovation in response to infectious disease threats to public health. It considers both past and current examples of efforts to mobilise pharmaceutical innovation in high commercial risk areas, including in the context of current efforts to respond to the COVID-19 pandemic. In global pandemic crises like COVID-19, the urgency and scale of the crisis – as well as the spotlight placed on pharmaceutical companies – mean that contributing to the search for effective medicines, vaccines or diagnostics is essential for socially responsible companies in the sector. It is therefore unsurprising that we are seeing industry-wide efforts unfold at unprecedented scale and pace. Whereas there is always scope for more activity, industry is currently contributing in a variety of ways. Examples include pharmaceutical companies donating existing compounds to assess their utility in the fight against COVID19; screening existing compound libraries in-house or with partners to see if they can be repurposed; accelerating trials for potentially effective medicine or vaccine candidates; and in some cases rapidly accelerating in-house research and development to discover new treatments or vaccine agents and develop diagnostics tests. Pharmaceutical companies are collaborating with each other in some of these efforts and participating in global R&D partnerships (such as the Innovative Medicines Initiative effort to accelerate the development of potential therapies for COVID-19) and supporting national efforts to expand diagnosis and testing capacity and ensure affordable and ready access to potential solutions. The primary purpose of such innovation is to benefit patients and wider population health. Although there are also reputational benefits from involvement that can be realised across the industry, there are likely to be relatively few companies that are ‘commercial’ winners. Those who might gain substantial revenues will be under pressure not to be seen as profiting from the pandemic. In the United Kingdom for example, GSK has stated that it does not expect to profit from its COVID-19 related activities and that any gains will be invested in supporting research and long-term pandemic preparedness, as well as in developing products that would be affordable in the world’s poorest countries. Similarly, in the United States AbbVie has waived intellectual property rights for an existing combination product that is being tested for therapeutic potential against COVID-19, which would support affordability and allow for a supply of generics. Johnson & Johnson has stated that its potential vaccine – which is expected to begin trials – will be available on a not-for-profit basis during the pandemic. Pharma is mobilising substantial efforts to rise to the COVID-19 challenge at hand. However, we need to consider how pharmaceutical innovation for responding to emerging infectious diseases can best be enabled beyond the current crisis. Many public health threats (including those associated with other infectious diseases, bioterrorism agents and antimicrobial resistance) are urgently in need of pharmaceutical innovation, even if their impacts are not as visible to society as COVID-19 is in the immediate term. The pharmaceutical industry has responded to previous public health emergencies associated with infectious disease in recent times – for example those associated with Ebola and Zika outbreaks. However, it has done so to a lesser scale than for COVID-19 and with contributions from fewer companies. Similarly, levels of activity in response to the threat of antimicrobial resistance are still low. There are important policy questions as to whether – and how – industry could engage with such public health threats to an even greater extent under improved innovation conditions.

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

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

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

#### Extinction outweighs

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UNDERSTANDING EXISTENTIAL RISK

Humanity’s future is ripe with possibility. We have achieved a rich understanding of the world we inhabit and a level of health and prosperity of which our ancestors could only dream. We have begun to explore the other worlds in the heavens above us, and to create virtual worlds completely beyond our ancestors’ comprehension. We know of almost no limits to what we might ultimately achieve.

Human extinction would foreclose our future. It would destroy our potential. It would eliminate all possibilities but one: a world ~~bereft~~ [lacking] of human flourishing. Extinction would bring about this failed world and lock it in forever—there would be no coming back.

The philosopher Nick Bostrom showed that extinction is not the only way this could happen: there are other catastrophic outcomes in which we lose not just the present, but all our potential for the future.

Consider a world in ruins: an immense catastrophe has triggered a global collapse of civilization, reducing humanity to a pre-agricultural state. During this catastrophe, the Earth’s environment was damaged so severely that it has become impossible for the survivors to ever reestablish civilization. Even if such a catastrophe did not cause our extinction, it would have a similar effect on our future. The vast realm of futures currently open to us would have collapsed to a narrow range of meager options. We would have a failed world with no way back.

Or consider a world in chains: in a future reminiscent of George Orwell’s Nineteen Eighty-Four, the entire world has become locked under the rule of an oppressive totalitarian regime, determined to perpetuate itself. Through powerful, technologically enabled indoctrination, surveillance and enforcement, it has become impossible for even a handful of dissidents to find each other, let alone stage an uprising. With everyone on Earth living under such rule, the regime is stable from threats, internal and external. If such a regime could be maintained indefinitely, then descent into this totalitarian future would also have much in common with extinction: just a narrow range of terrible futures remaining, and no way out.

[FIGURE 2.1 Omitted]

Following Bostrom, I shall call these “existential catastrophes,” defining them as follows: 3

An existential catastrophe is the destruction of humanity’s longterm potential.

An existential risk is a risk that threatens the destruction of humanity’s longterm potential.

These definitions capture the idea that the outcome of an existential catastrophe is both dismal and irrevocable. We will not just fail to fulfill our potential, but this very potential itself will be permanently lost. While I want to keep the official definitions succinct, there are several areas that warrant clarification.

First, I am understanding humanity’s longterm potential in terms of the set of all possible futures that remain open to us. 4 This is an expansive idea of possibility, including everything that humanity could eventually achieve, even if we have yet to invent the means of achieving it. 5 But it follows that while our choices can lock things in, closing off possibilities, they can’t open up new ones. So any reduction in humanity’s potential should be understood as permanent. The challenge of our time is to preserve our vast potential, and to protect it against the risk of future destruction. The ultimate purpose is to allow our descendants to fulfill our potential, realizing one of the best possible futures open to us.

While it may seem abstract at this scale, this is really a familiar idea that we encounter every day. Consider a child with high longterm potential: with futures open to her in which she leads a great life. It is important that her potential is preserved: that her best futures aren’t cut off due to accident, trauma or lack of education. It is important that her potential is protected: that we build in safeguards to make such a loss of potential extremely unlikely. And it is important that she ultimately fulfills her potential: that she ends up taking one of the best paths open to her. So too for humanity.

Existential risks threaten the destruction of humanity’s potential. This includes cases where this destruction is complete (such as extinction) and where it is nearly complete, such as a permanent collapse of civilization in which the possibility for some very minor types of flourishing remain, or where there remains some remote chance of recovery. 6 I leave the thresholds vague, but it should be understood that in any existential catastrophe the greater part of our potential is gone and very little remains.

Second, my focus on humanity in the definitions is not supposed to exclude considerations of the value of the environment, other animals, successors to Homo sapiens, or creatures elsewhere in the cosmos. It is not that I think only humans count. Instead, it is that humans are the only beings we know of that are responsive to moral reasons and moral argument—the beings who can examine the world and decide to do what is best. If we fail, that upward force, that capacity to push toward what is best or what is just, will vanish from the world.

Our potential is a matter of what humanity can achieve through the combined actions of each and every human. The value of our actions will stem in part from what we do to and for humans, but it will depend on the effects of our actions on non-humans too. If we somehow give rise to new kinds of moral agents in the future, the term “humanity” in my definition should be taken to include them.

My focus on humanity prevents threats to a single country or culture from counting as existential risks. There is a similar term that gets used this way—when people say that something is “an existential threat to this country.” Setting aside the fact that these claims are usually hyperbole, they are expressing a similar idea: that something threatens to permanently destroy the longterm potential of a country or culture.

Third, any notion of risk must involve some kind of probability. What kind is involved in existential risk? Understanding the probability in terms of objective long-run frequencies won’t work, as the existential catastrophes we are concerned with can only ever happen once, and will always be unprecedented until the moment it is too late. We can’t say the probability of an existential catastrophe is precisely zero just because it hasn’t happened yet.

Situations like these require an evidential sense of probability, which describes the appropriate degree of belief we should have on the basis of the available information. This is the familiar type of probability used in courtrooms, banks and betting shops. When I speak of the probability of an existential catastrophe, I will mean the credence humanity should have that it will occur, in light of our best evidence.9

There are many utterly terrible outcomes that do not count as existential catastrophes.

One way this could happen is if there were no single precipitous event, but a multitude of smaller failures. This is because I take on the usual sense of catastrophe as a single, decisive event, rather than any combination of events that is bad in sum. If we were to squander our future simply by continually treating each other badly, or by never getting around to doing anything great, this could be just as bad an outcome but wouldn’t have come about via a catastrophe.

Alternatively, there might be a single catastrophe, but one that leaves open some way for humanity to eventually recover. From our own vantage, looking out to the next few generations, this may appear equally bleak. But a thousand years hence it may be considered just one of several dark episodes in the human story. A true existential catastrophe must by its very nature be the decisive moment of human history—the point where we failed.

Even catastrophes large enough to bring about the global collapse of civilization may fall short of being existential catastrophes. While colloquially referred to as “the end of the world,” a global collapse of civilization need not be the end of the human story. It has the required severity, but may not be permanent or irrevocable.

In this book, I shall use the term civilization collapse quite literally, to refer to an outcome where humanity across the globe loses civilization (at least temporarily), being reduced to a pre-agricultural way of life. The term is often used loosely to refer merely to a massive breakdown of order, the loss of modern technology, or an end to our culture. But I am talking about a world without writing, cities, law, or any of the other trappings of civilization.

This would be a very severe disaster and extremely hard to trigger. For all the historical pressures on civilizations, never once has this happened— not even on the scale of a continent.10 The fact that Europe survived losing 25 to 50 percent of its population in the Black Death, while keeping civilization firmly intact, suggests that triggering the collapse of civilization would require more than 50 percent fatality in every region of the world.11

Even if civilization did collapse, it is likely that it could be reestablished. As we have seen, civilization has already been independently established at least seven times by isolated peoples.12 While one might think resource depletion could make this harder, it is more likely that it has become substantially easier. Most disasters short of human extinction would leave our domesticated animals and plants, as well as copious material resources in the ruins of our cities—it is much easier to re-forge iron from old railings than to smelt it from ore. Even expendable resources such as coal would be much easier to access, via abandoned reserves and mines, than they ever were in the eighteenth century. 13 Moreover, evidence that civilization is possible, and the tools and knowledge to help rebuild, would be scattered across the world.

There are, however, two close connections between the collapse of civilization and existential risk. First, a collapse would count as an existential catastrophe if it were unrecoverable. For example, it is conceivable that some form of extreme climate change or engineered plague might make the planet so inhospitable that humanity would be irrevocably reduced to scattered foragers.14 And second, a global collapse of civilization could increase the chance of extinction, by leaving us more vulnerable to subsequent catastrophe.

One way a collapse could lead to extinction is if the population of the largest remaining group fell below the minimum viable population—the level needed for a population to survive. There is no precise figure for this, as it is usually defined probabilistically and depends on many details of the situation: where the population is, what technology they have access to, the sort of catastrophe they have suffered. Estimates range from hundreds of people up to tens of thousands.15 If a catastrophe directly reduces human population to below these levels, it will be more useful to classify it as a direct extinction event, rather than an unrecoverable collapse. And I expect that this will be one of the more common pathways to extinction.

We rarely think seriously about risks to humanity’s entire potential. We encounter them mostly in action films, where our emotional reactions are dulled by their overuse as an easy way to heighten the drama.16 Or we see them in online lists of “ten ways the world could end,” aimed primarily to thrill and entertain. Since the end of the Cold War, we rarely encounter sober discussions by our leading thinkers on what extinction would mean for us, our cultures or humanity. 17 And so in casual contexts people are sometimes flippant about the prospect of human extinction.

But when a risk is made vivid and credible—when it is clear that billions of lives and all future generations are actually on the line—the importance of protecting humanity’s longterm potential is not, for most people, controversial. If we learned that a large asteroid was heading toward Earth, posing a greater than 10 percent chance of human extinction later this century, there would be little debate about whether to make serious efforts to build a deflection system, or to ignore the issue and run the risk. To the contrary, responding to the threat would immediately become one of the world’s top priorities. Thus our lack of concern about these threats is much more to do with not yet believing that there are such threats, than it is about seriously doubting the immensity of the stakes.

Yet it is important to spend a little while trying to understand more clearly the different sources of this importance. Such an understanding can buttress feeling and inspire action; it can bring to light new considerations; and it can aid in decisions about how to set our priorities.

### Plan

#### The United States federal government should substantially increase prohibitions on false advertising by applying a presumption that monopolists engaging in false advertising violate antitrust law and are subject to Penalty Offense Authority enforcement by the Federal Trade Commission.

### FTC Advantage – 1AC

#### **FTC failure to prohibit false advertising is an existential threat to the agency. Invoking market-wide Section 5 penalty offense authority (POA) restores FTC credibility and boosts fraud deterrence against big business**

Lee, 21 – Bethany, J.D. Candidate, University of Pennsylvania Law School. “Reviving the Power of the FTC,” The Regulatory Review, May 17, <https://www.theregreview.org/2021/03/17/lee-reviving-power-of-ftc/> -- Iowa

The Federal Trade Commission (FTC) may face an existential threat to its ability to hold corporate lawbreakers accountable. A pending U.S. Supreme Court case threatens the FTC’s ability to seek monetary relief from wrongdoers, while mounting public concerns about the adequacy of the FTC’s enforcement have led to a crisis of confidence in the agency.

The solution to this urgent crisis involves restoring a key FTC authority, according to a new paper by FTC Commissioner Rohit Chopra and his attorney advisor Samuel Levine.

After tracing the history of the FTC’s enforcement tools and explaining their current inadequacy, Chopra and Levine argue that reviving the FTC’s Penalty Offense Authority will improve the FTC’s effectiveness and regain public confidence by increasing deterrence and ensuring fairness for honest firms.

Established by the FTC Act, the FTC has a mission to “protect consumers and competition by preventing anticompetitive, deceptive, and unfair business practices.” Chopra and Levine, however, highlight the FTC’s concerning track record in fulfilling this mission.

In the 1980s, the FTC’s leadership viewed markets as self-correcting, and the agency shifted its focus from market-wide abuses to “small-scale criminal fraud.” Seeking to avoid the derisive label of a “national nanny,” the FTC began to disarm the administrative state by halving the agency’s staff, reversing rulemakings, and adopting policies restricting the agency’s own authority.

The FTC’s ideology of the 1980s had lasting consequences, according to Chopra and Levine. In the 1990s, the agency failed to challenge tobacco advertising directed at children. In the 2000s, the FTC took minimal enforcement action to prevent the mortgage meltdown, remaining largely idle as subprime lenders sold loans structured to fail. Congress responded by stripping the FTC of major authorities over the financial sector, such as rulemaking on mortgages and debt collection.

Chopra and Levine argue that the agency’s inaction over several decades has resulted in “massive harm for consumers, small businesses, and the economy.” They call for a shift toward “systematic efforts to combat widespread harms.”

A key step, say Chopra and Levine, involves resurrecting the agency’s Penalty Offense Authority. Codified in Section 5 of the FTC Act, this provision allows the FTC to correct and deter harmful practices.

Currently, the FTC largely relies on Section 13(b) of the FTC Act, which allows the agency to seek preliminary and permanent relief in federal court. But the use of Section 13(b) has been challenged in multiple cases, including in a pending U.S. Supreme Court case challenging the FTC’s authority to seek equitable monetary relief.

Even if courts uphold the use of Section 13(b), argue Chopra and Levine, this enforcement tool remains inadequate in correcting and deterring widespread harms. To seek monetary relief under Section 13(b), the FTC must approximate harms or unjust gains—a potentially difficult and costly calculation. As a result, the FTC often resorts to no-money settlements that do not adequately deter wrongdoing. In addition, corporate wrongdoers tend to be undeterred by equitable relief sought under Section 13(b) since the worst consequence merely involves returning their earnings.

Instead of overreliance on Section 13(b), Chopra and Levine advocate greater use of the Penalty Offense Authority under Section 5 of the FTC Act. Under this authority, the FTC can seek civil penalties if the agency issued a final cease-and-desist order determining that a practice is unfair or deceptive and if a party subsequently engaged in that practice, knowing that the practice was unfair or deceptive.

Chopra and Levine note that the Penalty Offense Authority provides “strong due process protections for defendants.” For example, parties cannot be held liable unless shown to have actual knowledge of the FTC’s determination. Defendants can also challenge the FTC’s prior determination that the conduct was unlawful.

Previously, the FTC deployed its Penalty Offense Authority to target whole industries, in a manner that one FTC commissioner described as “extremely effective and efficient.” Nevertheless, the agency’s use of this tool rapidly declined in the 1980s, and it was used only once in the last decade.

Calling for renewed use of the Penalty Offense Authority, Chopra and Levine outline three key benefits of such a resurrection. First, compared to equitable relief, civil penalties would more effectively punish and deter wrongdoers. Second, the use of the Penalty Offense Authority would reduce litigation risk for the FTC. Current overreliance on Section 13(b) creates uncertainty as court cases challenge the program, and seeking monetary relief under Section 13(b) requires risky and expensive attempts to quantify harm. Finally, the Penalty Offense Authority provides market-wide impact. By providing notice to firms across an industry, the FTC can correct market-wide practices—increasing compliance and reducing the need to bring similar enforcement actions repeatedly.

Chopra and Levine specifically advocate the use of the Penalty Offense Authority in areas where a harmful practice has been condemned by an FTC order but not forbidden by an agency rule. They identify five areas where the FTC could deploy the Penalty Offense Authority based on existing orders: for-profit college fraud, false earnings claims targeted at workers, online disinformation, deceptive data harvesting, and illegal targeted marketing.

Ultimately, Chopra and Levine call on the FTC to shed its “self-inflicted paralysis” by drawing on a broader set of tools to protect the public.

#### The FTC approach to antitrust for false ads is incoherent – only the aff’s presumption against monopolists solves

Tushnet and Carrier, 21 – Rebecca Tushnet is a Professor at Harvard Law School and former NDT Finalist. Michael Carrier is a Professor at Rutgers Law School. *An Antitrust Framework for False Advertising*, May, 106 Iowa L. Rev. 1841, p. Nexis – Iowa

Federal law presumes that false advertising harms competition. Federal law also presumes that false advertising is harmless or even helpful to competition. Contradiction is not unknown to the law, of course. This contradiction, though, is acute. For not only are both regimes at issue designed to protect competition, but they are both enforced by the same agency: the Federal Trade Commission, which targets "unfair competition" through antitrust and consumer protection enforcement.

Courts' treatment of false advertising in antitrust cases makes no sense. While courts have reasonably evidenced concern that not all false advertising violates antitrust law, the remedy is not to abandon the false advertising/antitrust interface. Instead, the solution is to focus on the actors most likely to harm the market: monopolists and attempted monopolists.

This Essay proposes an antitrust framework for false advertising claims. It introduces a presumption that monopolists engaging in false advertising violate antitrust law and a rebuttal if the false advertising is ineffective. The framework also applies to attempted monopolization by incorporating factors such as falsity, materiality, and harm inherent in false advertising law, along with competition-centered issues like targeting new market entrants.

Antitrust has dismissed false advertising that entrenches monopoly power for too long. This Essay seeks to resolve the contradiction in the law by showing how false advertising threatens the proper functioning of markets. Such an approach promises benefits for false advertising law, antitrust law, and consumers.

#### Section 5 credibility is vital to fraud crackdowns

Olsen & Schultze 21, Christopher Olsen is a partner in the privacy and cybersecurity practice at Wilson Sonsini and Vice Chair of the Privacy and Information Security Committee of the ABA Antitrust Law Section, and former Deputy Director of the FTC’s Bureau of Consumer Protection; Stephen Schultze is an Associate in the privacy and cybersecurity practice at Wilson Sonsini, “FTC Authority Under Siege: Monetary and Injunctive Relief at Risk in Courts as Congress Contemplates a Response,” The Antitrust Source, April 2021, ABA

It is hard to imagine a favorable outcome for the FTC after this oral argument. The Court will probably limit 13(b) relief to injunctions, requiring the Commission to resort to cumbersome administrative proceedings to get any monetary relief. That would dramatically undermine the Commission’s work over several decades to build a robust fraud program.40 It would leave Section 5 and 19 as the only avenues for monetary relief under the FTC’s general consumer protection authority. Under Section 5, the Commission may impose monetary civil penalties under some limited circumstances.41 Under Section 19, the Commission may obtain monetary consumer redress or disgorgement but only after obtaining a final cease-and-desist order through administrative litigation and only after demonstrating that “a reasonable man would have known under the circumstances [that the conduct] was dishonest or fraudulent.”42 Moreover, Section 19 includes a statute of limitations whereas Section 13(b) does not.43 Thus, the FTC has strongly favored Section 13(b) actions. At oral argument, the FTC conceded that going directly to court is “more attractive in certain instances” and that the Commission brings “far more [consumer protection] cases” in court than through its own administrative proceedings.

#### **Halting fraud is a decision rule – big business disproportionately preys on Black and Latino communities who experience fraud at the highest rates but are protected from fraud at the lowest rates – the FTC has a duty to ramp up surveys, outreach, data, and enforcement**

Rich, 21 – Jessica, Distinguished Fellow - Institute for Technology Law and Policy, Georgetown University Law Center. "Five reforms the FTC can undertake now to strengthen the agency," Brookings, <https://www.brookings.edu/blog/techtank/2021/03/01/five-reforms-the-ftc-can-undertake-now-to-strengthen-the-agency/> -- Iowa

Fraud can have a disproportionate effect on certain communities, such as seniors, veterans, African Americans, and Latinos. As a result, during my tenure at the FTC, we created and scaled up an ambitious project called Every Community, the goal of which was to ensure that the agency was reaching and protecting the diverse communities victimized by fraud.

The project included consumer surveys, outreach to community organizations, and data analysis by BE. Among BE’s findings was that Black and Latino communities experienced fraud at higher rates than white communities but reported fraud to the FTC at lower rates—in other words, they were underreporting fraud, highlighting a key challenge for the FTC in reaching and protecting these communities. In making its findings, BE staff had to perform a detailed analysis of fraud and census data, since the FTC’s complaint database contained very limited demographic data.

The FTC should expand this program, especially in light of the recent Executive Order on racial equity and underserved communities, Acting Chairwoman Rebecca Slaughter’s commitment to these issues, and the enhanced data protection mission proposed above. As part of this expanded program, the FTC should collect more demographic data (with appropriate safeguards) to enable the type of analysis discussed above, and task BE with additional studies of the FTC’s reach and impact on different communities. The FTC also should consider hiring experts on racial equity and inclusion to assist with this important work.

#### FTC enforcement authority is vital to countering algorithmic bias

James V. Fazio 21. Special counsel in the Intellectual Property Practice Group at Sheppard, Mullin, Richter & Hampton LLP, with Liisa M. Thomas, 3/11. “What Is FTC’s Course Under Biden?” https://www.natlawreview.com/article/what-ftc-s-course-under-biden

The new acting FTC chair, Rebecca Kelly Slaughter, recently signaled that the FTC may increase enforcement and penalties in the privacy and data security realm. Slaughter pointed to several areas of focus for the FTC this year, which companies will want to keep in mind: Notifying Consumers About FTC Allegations: Slaughter referred favorably to two recent cases: (1) the Everalbum biometric settlement from earlier this year (which we wrote about at the time); and (2) the Flo Health settlement over alleged deceptive data sharing practices (which we also wrote about at the time). In drawing on these two cases, Slaughter indicated that in future cases the FTC intends to include as part of any settlement a requirement to notify customers of any FTC allegations. This, she said, would allow consumers to “vote with their feet” and help them decide whether to recommend their services to others. FTC Intent to Plead All Relevant Violations: According to Slaughter, another lesson the FTC is taking from the Flo case is to include in the cases it brings all potentially applicable violations of all relevant privacy-related laws. In the Flo case, Slaughter said the FTC should have pleaded a violation of the Health Breach Notification Rule, which requires that vendors of personal health records notify consumers of data breaches. Focus on Ed Tech and COPPA: Given the explosive growth of education technology during COVID-19, the FTC is conducting an industry sweep of the industry. Related to this, the FTC is reviewing its Children’s Online Privacy Protection Act Rule. This goes beyond the refresh the agency did of their FAQs earlier in the pandemic (which we wrote about at the time). For now, Slaughter reminds companies that parental consent is needed before collecting information online from children under the age of 13. Examination of Health Apps: The FTC will take a closer look at health apps, including telehealth and contact tracing apps, as more and more consumers are relying on such apps to manage their health during the pandemic. Overlap Between Competition and Privacy: Slaughter also indicated that it is worth looking at situations where there may be not only privacy concerns, but antitrust as well. Because the FTC has a dual mission (consumer protection and competition) she notes that it has a “structural advantage” over other regulators in that it can look at these issues, especially since -she states- “many of the largest players in digital markets are as powerful as they are because of the breadth of their access to and control over consumer data.” Racial Equality and AI/Biometrics/Geotracking: Slaughter noted that COVID-19 is exacerbating racial inequities. She pointed to the unequal access to technology, as well as algorithmic discrimination (the idea that discrimination offline becomes embedded into algorithmic system logic). The FTC intends to focus on algorithmic discrimination, as well as on the discrimination potentially embedded into facial recognition technologies. (This mirrors concerns that gave rise to the recent Portland facial recognition law, which we recently wrote about). Finally, Slaughter commented on the use of location data to identify characteristics of Black Lives Matter protesters, and said she is concerned about the misuse of location data to track Americans engaged in constitutionally protected speech. Putting it Into Practice: Companies that operate health apps, that are in the education technology space, or that use algorithms or facial recognition tools will want to keep in mind that these are areas of focus for the FTC. And for everyone, keep in mind that the FTC has indicated it will beef up privacy law penalties and will ask for more notification to injured consumers.

#### Algorithmic bias causes extinction and even if some elements of inequality, surveillance, and suffering are inevitable, algorithmic bias makes them much worse

Mike Thomas 20. Quoting AI experts including MIT Physics Professors, Senior Features Writer for BuiltIn. THE FUTURE OF ARTIFICIAL INTELLIGENCE: 7 ways AI can change the world for better ... or worse, Updated: April 20, 2020, <https://builtin.com/artificial-intelligence/artificial-intelligence-future>

Klabjan also puts little stock in extreme scenarios — the type involving, say, murderous cyborgs that turn the earth into a smoldering hellscape. He’s much more concerned with machines — war robots, for instance — being fed faulty “incentives” by nefarious humans. As MIT physics professors and leading AI researcher Max Tegmark put it in a 2018 TED Talk, “The real threat from AI isn’t malice, like in silly Hollywood movies, but competence — AI accomplishing goals that just aren’t aligned with ours.” That’s Laird’s take, too. “I definitely don’t see the scenario where something wakes up and decides it wants to take over the world,” he says. “I think that’s science fiction and not the way it’s going to play out.” What Laird worries most about isn’t evil AI, per se, but “evil humans using AI as a sort of false force multiplier” for things like bank robbery and credit card fraud, among many other crimes. And so, while he’s often frustrated with the pace of progress, AI’s slow burn may actually be a blessing. “Time to understand what we’re creating and how we’re going to incorporate it into society,” Laird says, “might be exactly what we need.” But no one knows for sure. “There are several major breakthroughs that have to occur, and those could come very quickly,” Russell said during his Westminster talk. Referencing the rapid transformational effect of nuclear fission (atom splitting) by British physicist Ernest Rutherford in 1917, he added, “It’s very, very hard to predict when these conceptual breakthroughs are going to happen.” But whenever they do, if they do, he emphasized the importance of preparation. That means starting or continuing discussions about the ethical use of A.G.I. and whether it should be regulated. That means working to eliminate data bias, which has a corrupting effect on algorithms and is currently a fat fly in the AI ointment. That means working to invent and augment security measures capable of keeping the technology in check. And it means having the humility to realize that just because we can doesn’t mean we should. “Our situation with technology is complicated, but the big picture is rather simple,” Tegmark said during his TED Talk. “Most AGI researchers expect AGI within decades, and if we just bumble into this unprepared, it will probably be the biggest mistake in human history. It could enable brutal global dictatorship with unprecedented inequality, surveillance, suffering and maybe even human extinction. But if we steer carefully, we could end up in a fantastic future where everybody’s better off—the poor are richer, the rich are richer, everybody’s healthy and free to live out their dreams.”

#### FTC penalty authority deters cyber attacks on critical infrastructure

Holland, 10-8-2021 – Mackenzie, citing Edward Felten, professor of computer science and public affairs at Princeton and former chief technologist at the FTC. "Senators want FTC to enforce a federal data security standard," SearchSecurity, <https://searchsecurity.techtarget.com/news/252507933/Senators-want-FTC-to-enforce-a-federal-data-security-standard> -- Iowa

U.S. Senators want to empower the Federal Trade Commission to become a stronger protector and enforcer of consumer data privacy and security.

During the second in a series of hearings focused on the importance of federal standards for data privacy and security, the U.S. Senate Committee on Commerce, Science and Transportation listened to experts who recommended development of a data security standard for businesses that's enforced by the FTC. The first hearing explored the creation of a federal data privacy law as well as creation of a data privacy bureau within the FTC.

The call for federal data privacy and security standards follows attacks on critical infrastructure companies, including the 2021 attack on Colonial Pipeline. That attack, which caused fuel shortages, was cited by committee chair Sen. Maria Cantwell, D-Wash., as a reason necessitating federal standards.

Cantwell and Sen. Roger Wicker, R-Miss., have introduced two separate bills that would set U.S. privacy and security standards for businesses: the Consumer Online Privacy Rights Act and the Setting an American Framework to Ensure Data Access, Transparency and Accountability (Safe Data) Act. The legislation would also give the FTC and state attorneys general the ability to enforce the standards.

"We believe that these companies don't invest enough for the fact that they have oversight of our precious data and information," Cantwell said. "We know that a stronger FTC will help, but we need to give the FTC the resources they need to do their job."

Experts make data security standard recommendations

James Lee, chief operating officer at San Diego-based nonprofit Identity Theft Resource Center, echoed Cantwell's concern that the U.S. needs a federal data security standard and to better outline national cybersecurity best practices.

Lee said a federal data security standard should require companies to address small but preventable flaws that lead to data breaches, such as unpatched software, as well as minimize consumer data that can be collected and stored by companies. Additionally, Lee said stronger enforcement measures would be necessary for companies that fail to meet the data security standard.

"Without enforceable minimal standards, there are no broad incentives beyond trying to avoid headlines or post-breach litigation to get people to actually make broad organizational changes," Lee said.

"We need better enforcement," he said. The FTC is "best equipped to be that enforcement agency."

Indeed, Jessica Rich, counsel at law firm Kelley Drye and Warren LLP and former director of the FTC Bureau of Consumer Protection, said current law fails to set clear standards for data security or provide adequate remedies.

"Most of the FTC's data security efforts are based on the FTC Act, a law that leaves wide gaps in protection and doesn't authorize penalties for first-time violations," she said. "While there are sector-specific laws with a data security component, and half the states now have their own data security laws, it's a messy and confusing patchwork."

Rich recommended a standard that's scalable to different types and sizes of companies and the volume and sensitivity of the data they collect. Otherwise the law could impose requirements ill-suited and unattainable for small business, she said. Rich also supported data minimization incentives or requirements.

Rich said to ensure accountability and deterrence, the data security standard should authorize strong remedies such as civil penalties and redress to businesses that fail to meet the data security standard.

Edward Felten, Robert E. Kahn professor of computer science and public affairs at Princeton University and former chief technologist at the FTC, said the FTC currently doesn't have the tools it needs to address today's data security enforcement challenges.

To further empower the FTC, Felten voiced support for allowing civil penalties for first-time violations of certain statutes within the FTC Act, such as Section 5, which states that unfair or deceptive practices affecting commerce are unlawful. The lack of first-time penalties makes the FTC Act a "weak deterrent," he said.

Additionally, Felten said Congress could authorize data security rulemaking so the FTC can clarify what is expected of companies, as well as funnel additional resources to the FTC for data security and technology initiatives.

"The successful FTC of the future is one that has stronger authority, increased resources and greater technological capability," Felten said.

#### Cyber attacks on critical infrastructure go nuclear and are uncontrollable

Orlov 20 [Vladimir, Founder & Director of the PIR Center, President of the Trialogue Club International, Head of the Center for Global Trends and International Organizations at the Diplomatic Academy, Ministry of Foreign Affairs of the Russian Federation, Co-Founder and Academic Supervisor of the International Dual Degree MA Program in Nonproliferation and Global Security Studies, MGIMO University, Professor at MGIMO University, author (or coauthor) of more than a dozen books and monographs and more than three hundred research papers, articles, and essays, publishes his views in Russian and foreign periodicals, “‘No Holds Barred’ and the New Vulnerability: Are We in for a Re-Run of the Cuban Missile Crisis in Cyberspace?,” SSRN Scholarly Paper, ID 3538078, Social Science Research Network, 02/14/2020, papers.ssrn.com, doi:10.2139/ssrn.3538078]

Not hundred per cent of the dialogue has been frozen, fortunately. Certain informal, mostly offthe-record, meetings of US and Russian experts on cyber agenda continue taking place, both through Track 2 and Track 1.5. One of the most intellectually stimulating meetings, with frank exchanges, took place in Vienna in December 2018. The report produced after the meeting stressed “the significant risk […] that cyber-attacks could conceivably lead to a military escalation that may further trigger a nuclear weapons exchange, a fact that became more explicit with the adoption of the current Nuclear Posture Review. This issue gets complicated given that third parties may have the capabilities to invoke a cyber conflict between Russia and the United States. Whether a country or a non-state actor, they could put the two countries on the verge of an armed conflict by attacking critical infrastructure of either of them and making it look as if the aggressor were the other one”[22]. However, one should have no illusion: such informal meetings may be fully fruitful only when their reports and policy recommendations are utilized by the governments. And for that, a warmer climate in bilateral relations is a must. So far, we see exactly the opposite: mercury falling to freezing levels.

Risk of cyber clashes growing into a chaotic global cyber war has been emphasized by the UN Secretary-General Antonio Guterres in his Agenda for Disarmament: “Malicious acts in cyberspace are contributing to diminishing trust among States… States should implement the recommendations elaborated under the auspices of the General Assembly, which aim at building international confidence and greater responsibility in the use of cyberspace.[23]” However, as the members of the US-Russian Track 1.5 working group on strategic stability recently concluded, “without a constructive dialogue on cyber issues between the United States and Russia, the world would most likely fail to agree on any norms of responsible behavior of states in cyber space”[24].

Do we really have to survive a cyber equivalent of the Cuban Missile Crisis to realize the importance of achieving some kind of agreement on cyber issues, and on the broader agenda of international information security?[25] Or is that kind of talk plain old alarmism?

I don’t want to sound a fatalist, but I am even less keen on sounding like an ostrich that’s buried its head in the sand. We cannot ignore the obvious: whether the world’s most powerful actors like it or not, the world is sliding to another major crisis like the one in 1962. The cyber war is already raging. There are no rules of engagement in that war. The uncertainty is high. The spiral of tension is getting out of control. The cyber arms race is gaining momentum. And there are no guarantees that the next crisis will be controllable, or that it will result in a catharsis as far as international information security regulation is concerned. There’s no telling what will happen once the cyber genie is out of the bottle.

#### Vote aff to challenge the decisions by private actors to stockpile economic dominance – antitrust has no root cause, it’s entirely the product of contingent legal decisions. Our re-framing of the analytic of antitrust renders visible how economic domination was naturalized, opening new forms of economic coordination that challenge exploitation

Sanjukta Paul 20, assistant Professor of Law at Wayne State Law School, “Antitrust As Allocator of Coordination Rights,” UCLA Law Review, Vol. 67, No. 2, 2020, https://papers.ssrn.com/sol3/Papers.cfm?abstract\_id=3337861

INTRODUCTION

The central function of antitrust law is to allocate economic coordination rights. This means that private decisions to engage in economic coordination are always subject to public approval, which antitrust law grants either expressly or tacitly. Currently, its methods for accomplishing this function have the effect of anointing control and concentrated power as the preferred form of economic coordination, and to frown upon forms of economic coordination in which power and decisionmaking are more broadly dispersed. Antitrust law’s current methods for allocating coordination rights include what I call its firm exemption, as well as its preference for vertical over horizontal coordination beyond firm boundaries. Antitrust’s methods of allocating coordination rights are ultimately indigenous, and cannot be explained away by external referents: neither by other areas of law, nor by putatively neutral conclusions of social science. They are also historically contingent, and have shifted over time.

Practically speaking, the reigning antitrust paradigm authorizes large, powerful firms as the primary mechanisms of economic and market coordination, while largely undermining others: from workers’ organizations to small business cooperation to democratic regulation of markets. While deploying the legal concept of competition to undermine disfavored forms of economic coordination, antitrust law also quietly underwrites certain major exceptions to principles of competition, notably, the business firm itself. In surfacing the firm exemption, this Article also isolates the underlying, largely unexamined decision criteria for allocating coordination rights that it employes.

The current paradigm for thinking and decisionmaking within antitrust law has a professed commitment to implementing the insights of neoclassical economic theory in legal decisionmaking.1 According to that framework, the aggregate of individual market transactions, rather than direct coordination, will result in an optimal allocation of society’s resources. But this process of market allocation, which the law is supposed to facilitate but not displace, itself has no existence independent of prior legal allocations of economic coordination rights. Those coordination rights are shaped by numerous areas of law—from property to corporate law to labor law to antitrust, among others. This Article focuses on antitrust law, where this function is rarely acknowledged. Although the law and economics paradigm has enormous institutional sticking power in current antitrust law, the basic purposes and methods of antitrust law are also up for debate today in a way that they have not been in decades. Recent contributions to the antitrust revival have emphasized the law’s traditional concerns with corporate power and fairness, which were largely written out of antitrust law in the Chicago School revolution. 2 Dissenting voices asserted these as legitimate antitrust concerns even prior to the current challenge. 3 Mirroring the reformist call to put some limits upon the broad coordination rights of the powerful, a growing chorus of scholarship has emphasized the need to expand the coordination rights of small players to some extent or another, beginning with the question of workers and microenterprises caught between labor and antitrust regulation.4

However, proposals to reform antitrust, or to reconceptualize it, have thus far generally stopped short of questioning the basic premise that its primary function is to promote competition. At least officially, if increasingly uneasily, competition is still king. To be sure, many posit that antitrust performs this stated function badly, or does not perform it at all in certain markets.5 Even when reintroducing values such as fairness and deconcentrating power, for the most part the reform camp has characterized those values as flowing from—or at least coextensive with—promoting or protecting competition. Thus, the political debate over antitrust has been characterized by all sides claiming the idea of competition and defining what it means to promote competition in different ways.

In the current moment of paradigm instability,6 this Article aims to serve a clarifying role. Defenders of Chicago School antitrust tend to view reformers’ concerns—for example, fairness or deconcentrating corporate power—are extraneous to the fundamental function of antitrust law. That view, however, relies upon the idea that the function of antitrust law is to promote competition and that the law does so by following the independent guidance of economics. But neither of these things is true. Antitrust law decides where competition will be required and where coordination will be permitted. And in accomplishing that task, its most fundamental judgments are not ultimately derived from a neutral external referent, such as economic theory. Meanwhile, as the opposition to antitrust’s targeting of small players’ economic cooperation builds, some have begun to respond that this opposition evinces an inconsistency within the antitrust reform program, which otherwise generally favors increased antitrust enforcement. But, again, this objection only makes sense if one assumes that antitrust’s purpose is to promote competition, full stop. By showing that antitrust in fact already allocates coordination rights, I also show that a conscious reallocation would not constitute a special exemption from a general principle. Instead, it would simply be a different allocation of coordination rights, requiring justification no more and no less than the current one. By reframing antitrust law as this Article does, we can clarify what we are actually debating: what criteria should antitrust law use to allocate economic coordination rights? What forms of economic coordination should it permit or even promote, and what forms of economic coordination should it discourage or even prohibit?

Part I of the Article sets out the doctrinal and logical argument that a core function of antitrust law is to allocate economic coordination rights, that its disfavor of horizontal coordination beyond firm boundaries is an example of this function, and that this function cannot be reduced to the operation of other areas of law. Part II then shows how antitrust’s firm exemption, as embodied in Supreme Court case law, involves the concentration of economic coordination rights—a preference that is mirrored in other aspects of antitrust doctrine as well.

Part III briefly describes how these criteria for allocating coordination rights—preferring control over cooperation, and naturalizing the coordination embodied in hierarchically organized business firms— resulted from a historically contingent process within the development of antitrust law itself. Part IV addresses the contention that this allocation of coordination rights can be rationalized and justified by reference to economic theory, focusing on a now-foundational argument articulated by Robert Bork.

I. ANTITRUST LAW’S OVERALL ALLOCATION OF ECONOMIC COORDINATION RIGHTS

Antitrust law’s core function is to allocate coordination rights to some economic actors and deny them to others. This makes private decisions to engage in economic coordination subject to public approval, which antitrust law grants either expressly or tacitly. Importantly, this reframing is an analytic claim that redescribes existing reality; it is not a normative claim about what antitrust law ought to do. That said, reframing antitrust law this way renders visible economic coordination that has been naturalized and invites us to consider anew forms of economic coordination that have been presumed illegitimate. Ultimately, transparency about antitrust law’s core function should lead to transparency in performing it—that is, in articulating and defending the criteria by which coordination rights are allocated. Currently, those criteria are often obscure and implicit; where they are acknowledged at all, they are often presumed, incorrectly, to be derived from the independent conclusions of social science.

Economic coordination is always either authorized by antitrust law, or not. For any given instance of economic coordination, and certainly for any instance of economic coordination implicating prices, antitrust asks—either explicitly or implicitly—whether that coordination is justified, and then answers that question one way or the other. Moreover, the answers that antitrust gives to these questions are not derivable from property, contract, or corporate law—though its answers interact with each of these.

Currently, antitrust law tends to allocate coordination rights, across doctrinal areas, according to criteria that systematically prefer concentrated control over dispersed coordination or cooperation. If we envision antitrust’s approach to allocating economic coordination rights as a three-legged stool, its conception of the firm is one leg. The other two are its treatment of horizontal coordination beyond firm boundaries and its treatment of vertical coordination beyond firm boundaries. In deciding how to evaluate interfirm coordination, antitrust law first decides whether that coordination is horizontal (between competitor firms in the same market) or vertical(between firms in adjacent markets, such as supplier or distributor relationships). Antitrust law’s stark preference for coordination accomplished through vertical contracting over horizontal interfirm coordination mirrors the criteria according to which the firm exemption itself is applied. Both preferences embody the preference for control over cooperation, which is to say, for the concentration of economic coordination in fewer rather in many hands. This Article focuses primarily on the firm exemption because it is the most obscure of the three legs, and because both vertical interfirm coordination and horizontal coordination beyond firm boundaries are dealt with in greater detail in other work.7 For context, I briefly summarize the doctrinal content of the other two legs of the stool, and their relationship to the firm exemption. I also briefly describe the role of the Chicago School revolution in establishing this overall allocation of coordination rights, although this Article does not provide an exhaustive account of historical origins or etiology of current doctrine.8

#### There’s also no sweeping theory that can explain every detail of a given American policy decision—you should defer instead to testable predictions backed by solutions

Rose, 21—editor of Foreign Affairs (Gideon, “Foreign Policy for Pragmatists,” Foreign Affairs, March/April 2021, dml)

Theories of history, fundamental beliefs about how the world works, are usually assumed rather than argued and rarely get subjected to serious scrutiny. Yet these general ideas set the parameters for all the specific policy choices an administration makes. Know an administration’s theory of history, and much of the rest is easy to fill in.

There are a lot of possible theories of history, but they tend to fall, like Bush’s and Trump’s, into two main camps: optimistic and pessimistic. Thus, the Clinton administration followed its own version of happy directionality—think of it as Bush with less muscular Christianity. And there have been earlier believers in Trump’s dark and stormy night, as well.

Unfortunately, given the stakes of the question, no one really knows whether the optimists or the pessimists have the better case. Political theorists have fought about that for centuries, with neither side winning. A few generations ago, modern social scientists joined in, generating and testing lots of theories in lots of ways, but still, neither camp bested the other. And then, in the last few years, history got interesting again and erased some of the few things the scholars thought they had learned.

As individuals, presidents have had strong views on these matters. As a group, they have not. American foreign policy is notorious for its internal tensions. Its fits and starts and reversals do not fit easily into any single theoretical framework. Yet this pluralism has proved to be a feature, not a bug. Precisely because it has not embraced any one approach to foreign policy consistently, Washington has managed to avoid the worst aspects of all. Blessed with geopolitical privilege, it has slowly stumbled forward, moving over the centuries from peripheral obscurity to global hegemony. Its genius has been less strategic insight than an ability to cut losses.

By now, it seems fair to say that the debate between the optimists and the pessimists will never be settled conclusively, since each perspective knows something big about international politics. Instead of choosing between them, the new administration should keep both truths in its pocket, taking each out as appropriate.

Learning in U.S. foreign policy has come largely across administrations. President Joe Biden’s goal should be to speed up the process, allowing it to happen within an administration. Call it the Bayesian Doctrine: rather than being wedded to its priors, the administration should constantly update them.

The way to do so is to make theorists, not principals, the administration’s true team of rivals, forcing them to make real-world predictions, and to offer testable practical advice, and then seeing whose turn out to be better in real time. In this approach, searching intellectual honesty is more important than ideology; what people think matters less than whether they can change their minds. Constantly calculating implied odds won’t always win pots. But it will help the administration fold bad hands early, increasing its winnings over time.

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## Case

#### Even a tiny risk of extinction vastly outweighs – it’s permanent and irreversible

Baum and Barrett, 15- \*co-director of the Global Catastrophic Risk Institute with a PhD from Penn State in geography , \*\*director of research at the Global Catastrophic Risk Institute with a PhD in engineering and public policy form Carnegie Mellon (\*Seth D. Baum, \*\*Anthony M. Barrett, 2015, “The Most Extreme Risks: Global Catastrophes,” published in “The Gower Handbook of Extreme Risk,” edited by Vicki Bier, published by Ashgate Publishing, <http://sethbaum.com/ac/fc_Extreme.pdf>)

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

## K

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Using Sagan’s 500 trillion lives estimate, it follows that reducing the probability of global catastrophe by a mere one-in-500-trillion chance is of the same significance as saving one human life. Phrased differently, society should try 500 trillion times harder to prevent a global catastrophe than it should to save a person’s life. Or, preventing one million deaths is equivalent to a one-in- 500-million reduction in the probability of global catastrophe. This suggests society should make extremely large investment in GCR reduction, at the expense of virtually all other objectives. Judge and legal scholar Richard Posner made a similar point in monetary terms (Posner 2004). Posner used $50,000 as the value of a statistical human life (VSL) and 12 billion humans as the total loss of life (double the 2004 world population); he describes both figures as significant underestimates. Multiplying them gives $600 trillion as an underestimate of the value of preventing global catastrophe. For comparison, the United States government typically uses a VSL of around one to ten million dollars (Robinson 2007). Multiplying a $10 million VSL with 500 trillion lives gives $5x1021 as the value of preventing global catastrophe. But even using “just" $600 trillion, society should be willing to spend at least that much to prevent a global catastrophe, which converts to being willing to spend at least $1 million for a one-in-500-million reduction in the probability of global catastrophe. Thus while reasonable disagreement exists on how large of a VSL to use and how much to count future generations, even low-end positions suggest vast resource allocations should be redirected to reducing GCR. This conclusion is only strengthened when considering the astronomical size of the stakes, but the same point holds either way. The bottom line is that, as long as something along the lines of the standard risk equals-probability-times-magnitude framework is being used, then even tiny GCR reductions merit significant effort. This point holds especially strongly for risks of catastrophes that would cause permanent harm to global human civilization. The discussion thus far has assumed that all human lives are valued equally. This assumption is not universally held. People often value some people more than others, favoring themselves, their family and friends, their compatriots, their generation, or others whom they identify with. Great debates rage on across moral philosophy, economics, and other fields about how much people should value others who are distant in space, time, or social relation, as well as the unborn members of future generations. This debate is crucial for all valuations of risk, including GCR. Indeed, if each of us only cares about our immediate selves, then global catastrophes may not be especially important, and we probably have better things to do with our time than worry about them. While everyone has the right to their own views and feelings, we find that the strongest arguments are for the widely held position that all human lives should be valued equally. This position is succinctly stated in the United States Declaration of Independence, updated in the 1848 Declaration of Sentiments: “We hold these truths to be self-evident: that all men and women are created equal”. Philosophers speak of an agent-neutral, objective “view from nowhere” (Nagel 1986) or a “veil of ignorance” (Rawls 1971) in which each person considers what is best for society irrespective of which member of society they happen to be. Such a perspective suggests valuing everyone equally, regardless of who they are or where or when they live. This in turn suggests a very high value for reducing GCR, or a high degree of priority for GCR reduction efforts.

#### Capitalism is sustainable---recent data proves we’re entering the golden age

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The past 30 years have seen immense progress in improving the quality of life for much of humanity. Extreme poverty — the number of people living on less than $1.90 per day — has fallen by nearly two-thirds, from 1.9 billion to around 650 million. Life expectancy has risen in most of the world, along with literacy and access to education, while infant mortality has fallen. Despite perceptions to the contrary, the average person born today is likely to have access to more opportunities and have a better quality of life than at any other point in human history. Much of this increase in human wellbeing has been propelled by rapid economic growth driven largely by state-led industrial policy, particularly in poor-to-middle income countries. However, this growth has come at a cost: between 1990 and 2019, global emissions of CO2 increased by 56%. Historically, economic growth has been closely linked to increased energy consumption — and increased CO2 emissions in particular — leading some to argue that a more prosperous world is one that necessarily has more impacts on our natural environment and climate. There is a lively academic debate about our ability to “absolutely decouple” emissions and growth — that is, the extent to which the adoption of clean energy technology can allow emissions to decline while economic growth continues. Over the past 15 years, however, something has begun to change. Rather than a 21st century dominated by coal that energy modelers foresaw, global coal use peaked in 2013 and is now in structural decline. We have succeeded in making clean energy cheap, with solar power and battery storage costs falling 10-fold since 2009. The world produced more electricity from clean energy — solar, wind, hydro, and nuclear — than from coal over the past two years. And, according to some major oil companies, peak oil is upon us — not because we have run out of cheap oil to produce, but because demand is falling and companies expect further decline as consumers increasingly shift to electric vehicles. The world has long been experiencing a relative decoupling between economic growth and CO2 emissions, with the emissions per unit of GDP falling for the past 60 years. This is the case even in countries like India and China that have been undergoing rapid economic growth. But relative decoupling alone is inadequate in a world where global CO2 emissions need to peak and decline in the next decade to give us any chance at limiting warming to well below 2℃, in line with Paris Agreement targets. Thankfully, there is increasing evidence that the world is on track to absolutely decouple CO2 emissions and economic growth — with global CO2 emissions potentially having peaked in 2019 and unlikely to increase substantially in the coming decade. While an emissions peak is just the first and easiest step towards eventually reaching the net-zero emissions required to stop the world from continuing to warm, it demonstrates that linkages between emissions and economic activity are not an immutable law, but rather simply a result of our current means of energy production. In recent years we have seen more and more examples of absolute decoupling — economic growth accompanied by falling CO2 emissions. Since 2005, 32 countries with a population of at least one million people have absolutely decoupled emissions from economic growth, both for terrestrial emissions (those within national borders) and consumption emissions (emissions embodied in the goods consumed in a country). This includes the United States, Japan, Mexico, Germany, United Kingdom, France, Spain, Poland, Romania, Netherlands, Belgium, Portugal, Sweden, Hungary, Belarus, Austria, Bulgaria, El Salvador, Singapore, Denmark, Finland, Slovakia, Norway, Ireland, New Zealand, Croatia, Jamaica, Lithuania, Slovenia, Latvia, Estonia, and Cyprus. Figure 1, below, shows the declines in territorial emissions (blue) and increases in GDP (red). To qualify as having experienced absolute decoupling, we require countries included in this analysis to pass four separate filters: a population of at least one million (to focus the analysis on more representative cases), declining territorial emissions over the 2005-2019 period (based on a linear regression), declining consumption emissions, and increasing real GDP (on a purchasing power parity basis, using constant 2017 international $USD). We chose not to include 2020 in this analysis because it is not particularly representative of longer-term trends, and consumption and territorial emissions estimates are not yet available for many countries. There is a wide range of rates of economic growth between 2005-2019 among countries experiencing absolute decoupling. Somewhat counterintuitively, there is no significant relationship between the rate of economic growth and the magnitude of emissions reductions within the group. While it is unlikely that there is not at least some linkage between the two factors, there are plenty of examples of countries (e.g., Singapore, Romania, and Ireland) experiencing both extremely rapid economic growth and large reductions in CO2 emissions. One of the primary criticisms of some prior analyses of absolute decoupling is that they ignore leakage. Specifically, the offshoring of manufacturing from high-income countries over the past three decades to countries like China has led to “illusory” drops in emissions, where the emissions associated with high-income country consumption are simply shipped overseas and no longer show up in territorial emissions accounting. There is some truth in this critique, as there was a large increase in emissions embodied in imports from developing countries between 1990 and 2005. After 2005, however, structural changes in China and a growing domestic market led to a reversal of these trends; the amount of emissions “exported” from developed countries to developing countries has actually declined over the past 15 years. This means that, for many countries, both territorial emissions and consumption emissions (which include any emissions “exported” to other countries) have jointly declined. In fact, on average, consumption emissions have been declining slightly faster than territorial emissions since 2005 in the 32 countries we identify as experiencing absolute decoupling. Figure 2, below, shows the change in consumption emissions (teal) and GDP (red) between 2005 and 2019. There is a pretty wide variation in the extent to which these countries have reduced their territorial and consumption emissions since 2005. Some countries — such as the UK, Denmark, Finland, and Singapore – have seen territorial emissions fall faster than consumption emissions, while the US, Japan, Germany, and Spain (among others) have seen consumption emissions fall faster. Figure 3 shows reductions in consumption and territorial emissions for each country, with the size of the dot representing the size of the population in 2019. Absolute decoupling is possible. There is no physical law requiring economic growth — and broader increases in human wellbeing — to necessarily be linked to CO2 emissions. All of the services that we rely on today that emit fossil fuels — electricity, transportation, heating, food — can in principle be replaced by near-zero carbon alternatives, though these are more mature

#### Transition causes an immediate spike in warming – only capitalism solves – otherwise, exitinction

Crownshaw et al 18 (Timothy Crownshaw, Department of Natural Resource Sciences, McGill University, Caitlin Morgan, Food Systems Graduate Program, University of Vermont, Alison Adams, Rubenstein School of the Environment, University of Vermont, Martin Sers, Faculty of Environmental Studies, York University, Natália Britto dos Santos, Faculty of Environmental Studies, York University, Alice Damiano, Department of Natural Resource Sciences, McGill University, Laura Gilbert, Department of Natural Resource Sciences, McGill University, Gabriel Yahya Haage, Department of Natural Resource Sciences, McGill University, and Daniel Horen Greenford, Department of Geography, Planning and Environment, Concordia University, “Over the horizon: Exploring the conditions of a post-growth world”, The Anthropocene Review) DB

Near-term impacts to the climate system originating from macroeconomic disruptions remains a relatively unexplored topic, as the climate change research community typically assumes a continuation of economic growth and stability in their scenarios (for example, IPCC, 2014b, and UNEP, 2014b). However, industrial emissions will be significantly diminished during a period of economic contraction following the end of growth. This will bring local environmental benefits in the form of reduced air pollution but also a partial loss of the aerosol-induced cooling effect.3 The IPCC’s best estimate of the magnitude of aerosol cooling is approximately half that of the warming from carbon dioxide in the atmosphere (IPCC, 2013); clearly a significant counterbalance to the warming potential of GHGs. Contraction and deindustrialization of the global economy will curtail these cooling emissions, and thus complicate climate change policy and mitigation efforts. Owing to the short residence time of aerosols in the atmosphere (Textor et al., 2006), an increase in warming could manifest rapidly following a decline in industrial activity. Changes in the rate and global distribution of industrial aerosol emissions have already caused significant shifts in localized cooling effects (IPCC, 2013; Kühn et al., 2014). Several studies have highlighted a potential increase in global warming as aerosol emissions are gradually reduced via pollution control measures, finding that average temperatures will rise approximately an additional 1°C by 2100 as a consequence (Smith and Bond, 2014; Westervelt et al., 2015). While the magnitude is uncertain (Lewis and Curry, 2015; Rosenfeld et al., 2013), this additional warming may occur earlier and at a much faster rate than expected due to falling emissions from industrial activities resulting from the end of growth and subsequent economic contraction. This outcome could enhance climate impacts non-linearly, as human and natural systems would have little time to adapt to a rapid change in the rate of warming (Smith et al., 2015). As such, a relatively sudden increase in the pace of climate change and associated impacts followed by a gradual long-term reduction may be a more realistic prospect than current assumptions of a rising emissions trend in line with economic growth, partially mitigated by technological innovation and declining emissions intensity of the global economy. Post-growth climate mitigation and systemic feedbacks A transient increase in warming following the end of growth has the potential to affect multiple components of the climate system, including albedo dynamics and natural GHG sources. Additional short-term warming will induce greater albedo changes in the climate system due to melting of more ice and snow cover, reducing the reflection of sunlight (IPCC, 2014c). This is significant as greater near-term warming increases risks of runaway feedback between albedo reduction and increased warming (Curry et al., 1995; Hall, 2004). An increase in short-term warming may also exacerbate the release of terrestrial and oceanic sources of GHG emissions, such as the permafrost in high-latitude and high-altitude regions around the world (IPCC, 2013; Schuur et al., 2015), and emissions from aquatic ecosystems and methane clathrate deposits (Hamdan and Wickland, 2016). Consideration of these climate system feedbacks enhances expectations of post-growth warming and invalidates prevailing estimations of the underlying risks associated with self-reinforcing processes. As such, the near-term risks associated with climate feedbacks in scenarios assuming continued economic growth, already underestimated as noted by Bloch-Johnson et al. (2015), will be further exacerbated in a post-growth context. The climate system will also be affected by changing patterns of economic activity and GHG emissions stemming from trade and transportation. Long-distance transportation is a key emitter (Karl et al., 2009); a decline in international trade stemming from economic contraction will diminish GHG emissions. Additionally, increased disruption of long-distance trade routes from weather-related climate change impacts (WTO and UNEP, 2009) will further reduce GHG emissions from transportation (Heinberg and Fridley, 2016). This effectively forms a stabilizing feedback loop as future warming and associated impacts on trade will partially limit future emissions. Climate mitigation and adaptation presents an unwieldy problem for capital-constrained, contracting societies, and may in fact be a major component of the contraction process because of the redirection of investment away from productive capital, as mentioned in the introduction. The IPCC (2014c) estimates that the necessary investments per year in low-carbon technology and infrastructure will rise by several hundreds of billions of dollars each year before 2030. As the assumptions used to calculate these investment estimates are not consistent with a scenario of long-term economic contraction, they must be treated critically in the context of a post-growth world. However, mitigation efforts will remain a prerequisite for remaining within acceptable climate conditions. Current approaches to climate change mitigation relying on capital-intensive technological solutions, including a global transition from fossil fuels to renewable energy, continued development and deployment of carbon capture and storage (CCS), and geoengineering projects, may be untenable in this context. Climate change mitigation through a large-scale switch to biofuels, or bioenergy with carbon capture and storage (BECCS) technology, will be additionally constrained by a limited supply of agricultural land subject to rising food demand in the near-term (Kraxner et al., 2013). Instead, feasible climate mitigation options may be practically limited to low-capital, demand-side behavioral responses and lifestyle changes. A decrease in energy demand, associated with a decline in aggregate demand, will be complicated both by declining EROI of our major fuels (Hall, 2017; Lambert et al., 2014; Murphy, 2014) and the issue of capital constraints. As energy demand falls, extraction of costly unconventional hydrocarbon resources with higher emissions intensities (NRDC, 2010) will become increasingly uneconomic. However, declining investment capacity implies that an ongoing conversion to lowcarbon renewables may be similarly constrained due to the vast material, energy and capital requirements involved, as described by Trainer (2010). As energy demand falls, economies may be forced to return to conventional low-cost fuels with acceptable EROI, such as remaining coal reserves (Hall et al., 2014), which are attractive because of compatibility with existing energy infrastructure but have detrimental consequences for GHG emissions. The net effect of the above factors on the climate system will depend on their relative magnitudes and the respective time lags involved. Provided the effects of stabilizing feedbacks outweigh reinforcing feedbacks, the end of growth may ultimately reduce human perturbance of the climate system. Conversely, if stabilizing economy–climate feedbacks are insufficient to counteract the consequences of a near-term spike in warming, the world may face significantly worse climate stress than is currently anticipated.

#### COVID induced restructuring that prevents catastrophic future fallouts

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Reimagination A shock of this scale will create a discontinuous shift in the preferences and expectations of individuals as citizens, as employees, and as consumers. These shifts and their impact on how we live, how we work, and how we use technology will emerge more clearly over the coming weeks and months. Institutions that reinvent themselves to make the most of better insight and foresight, as preferences evolve, will disproportionally succeed. Clearly, the online world of contactless commerce could be bolstered in ways that reshape consumer behavior forever. But other effects could prove even more significant as the pursuit of efficiency gives way to the requirement of resilience—the end of supply-chain globalization, for example, if production and sourcing move closer to the end user. The crisis will reveal not just vulnerabilities but opportunities to improve the performance of businesses. Leaders will need to reconsider which costs are truly fixed versus variable, as the shutting down of huge swaths of production sheds light on what is ultimately required versus nice to have. Decisions about how far to flex operations without loss of efficiency will likewise be informed by the experience of closing down much of global production. Opportunities to push the envelope of technology adoption will be accelerated by rapid learning about what it takes to drive productivity when labor is unavailable. The result: a stronger sense of what makes business more resilient to shocks, more productive, and better able to deliver to customers. Reform The world now has a much sharper definition of what constitutes a black-swan event. This shock will likely give way to a desire to restrict some factors that helped make the coronavirus a global challenge, rather than a local issue to be managed. Governments are likely to feel emboldened and supported by their citizens to take a more active role in shaping economic activity. Business leaders need to anticipate popularly supported changes to policies and regulations as society seeks to avoid, mitigate, and preempt a future health crisis of the kind we are experiencing today. In most economies, a healthcare system little changed since its creation post–World War II will need to determine how to meet such a rapid surge in patient volume, managing seamlessly across in-person and virtual care. Public health approaches, in an interconnected and highly mobile world, must rethink the speed and global coordination with which they need to react. Policies on critical healthcare infrastructure, strategic reserves of key supplies, and contingency production facilities for critical medical equipment will all need to be addressed. Managers of the financial system and the economy, having learned from the economically induced failures of the last global financial crisis, must now contend with strengthening the system to withstand acute and global exogenous shocks, such as this pandemic’s impact. Educational institutions will need to consider modernizing to integrate classroom and distance learning. The list goes on. The aftermath of the pandemic will also provide an opportunity to learn from a plethora of social innovations and experiments, ranging from working from home to large-scale surveillance. With this will come an understanding of which innovations, if adopted permanently, might provide substantial uplift to economic and social welfare— and which would ultimately inhibit the broader betterment of society, even if helpful in halting or limiting the spread of the virus.

#### Abandoning technocratic progressive IR and the western order writ large culminate in climate catastrophe and fascism

Tallis, 20—senior researcher, Institute for Peace Research and Security Policy, University of Hamburg (Benjamin, “Un-cancelling the future,” New Perspectives, OnlineFirst, July 8, 2020, dml)

Examples of this way of thinking are plentiful but, for convenience, one need to look no further than Jairus Grove’s scintillatingly pessimistic keynote at the Hamburg Sessions (forthcoming as an essay in NP and based on his 2019 book, Savage Ecology).3 It is not that Grove doesn’t make compelling critical arguments – he does and in brilliant, imaginative ways – but that they lack balance. And balance matters, whether we are reckoning with horrendous pasts or trying to boldly imaging new futures.

To see, or certainly to dwell on, only the bad in what we in the West have collectively done (however, Grove or anyone else defines who we are), over the entire course of our past and present is grossly unfair. It also amounts, in effect, to a counsel of despair, however much Grove protests to the contrary or claims to eschew nihilism. In his keynote, having written off our past and present, Grove also explicitly urged us in Europe and the West to stop imagining better, progressive futures, arguing that this has led to precisely the problems he identified. Grove’s critique thus not only leaves us out of time (without an avowable past, present or future) but also leaves us without space for contesting negative, regressive and repressive political trends. In his book, he laments the ‘debilitating stupor’ in which the work of thinkers like Theodor Adorno and Giorgio Agamben leaves us (Grove, 2019: 238). But Grove’s own pessimism, if we took it seriously, would leave Europeans without a political leg to stand on. It would leave us in just such a stupor – or worse – with no solid ground and no lever: no way to move the world and no platform for positive, progressive change.

Why bother, if everything we do only makes things worse?

However much harm we Europeans and Westerners have done, we haven’t done, don’t and won’t only do harm. The real danger of Grove’s type of timelessly pessimistic and literally hopeless critique is that (again, if taken seriously) it breeds only damaging inertia, inaction and resentment – its hopelessness makes it a debilitating critique; its timelessness offers no possibility of salvage, let alone progress. It cedes the ground of action to those who many of us (including Grove) would explicitly disagree with – whether to exponents of ‘traditional’ approaches to IR who are more than happy to offer policy advice or, worse, to authoritarians and populists in practical politics (as ably described in Johanna Sumuvuori’s essay in this issue). Critical scholars too rarely see it as their task to construct positive visions of better worlds. Instead, too often they content themselves (if no one else) with evermore thoroughgoing deconstructive critique – including of other critical academics. Whether totalising or parasitic, even some of its leading proponents admit that IR’s critical project has, thus far, had insufficient impact on the world at large (Austin, 2017, 2019).

Few critical scholars will thank me for this comparison, but, in their pessimistic, misanthropic zeal, they echo what French President Emmanuel Macron called the ‘sad passions’ of the author Michel Houellebecq4 (Carre`re, 2017). They may not share Houellebecq’s politics, but many critical scholars certainly share his exhaustive (and exhausting) disenchantment with contemporary (neo)liberal societies, the state of Europe and of the West. Too often they also share his miserabilist outlook on the impossibility of change for the better and the futility or harm of even trying to improve things.

Grove does propose several forms of political action: micro-kindnesses, however vague (e.g. ‘the impossible generosity and affirmation of deconstruction’, 2019: 231); resistant acts by brave individuals (e.g. ‘William ‘‘Fox’’ Fallon, who sacrificed his prestigious position as head of [US Military] Central Command because he would not go along with the plan to attack Iran’, 2019: 232); embracing entirely new ‘forms of life 5 ’; or welcoming apocalypse as driver of change (2019: 229–248). Grove will not be confused with Goldilocks anytime soon – these forms of action each seem either too little or (much) too much.

Few of us would question the value of and need for kindness and, indeed, the most hopeful part of Grove’s book is the touching introduction where he details many of the kindnesses he has himself benefitted from, mainly from people in the West where he has spent most of his life. There is also, clearly, a role for resistance and for the kinds of acts that Grove notes have prevented executions and even nuclear war. Yet without a wider programme, without a bigger positive vision, kindness and resistance cannot sufficiently change our world for the better. Apocalypse, on the contrary, changes too much, junks too much that is good and is rarely likely to be an appealing option, or something we can all get behind. The apocalyptic aspect of Grove’s position, like that of many critical scholars, seeks to inflict destructive harm on Western institutions rather than constructively reform them – something Houellebecq would also relish. Apocalyptic change also smacks of the recklessly callous, negative sides of early 20th-century futurism (Marinetti, 1909), as Grove acknowledges when asking ‘How do we go wild without the cruelty of indifference?’ (2019: 280). Again, a more balanced approach to boldness would help.

To be clear, major change is needed – that was the whole point of the Hamburg Sessions and the motivation behind giving it the theme of ‘Un-Cancelling the Future’. I’ve argued elsewhere that the kind of socio-economically regressive, technocratic, defensive liberalisms that have dominated large parts of the last 40 years in the West have a lot to answer for (Tallis, 2018). So too, of course, does the type of narrowly, teleological individually atomising (neo)liberalism that neither saw (Fukuyama, 1992) nor allowed (Fisher, 2009) alternative visions of politics, societies and economies. Mark Fisher (2009), echoing the artist Gerhard Richter (Elger, 2009), called this myopic liberalism ‘Capitalist Realism’. You don’t have to be a Marxist or even a leftist to see that a mandated lack of alternatives and a commensurate narrowing of possibilities and horizons is a bad thing. As noted above, both climate change and sociotechnical upheavals in the ways we work and live need bold visions to address the challenges they pose while also seizing the opportunities they present.

It is, however, eminently possible to recognise the full horrors of Europe’s (colonial) pasts and presents without immediately discounting the possibility of improvement coming from the West, from Europe. Similarly, one can recognise the myriad problems that Europeans have caused while also celebrating the many positive things they have also achieved. Moreover, it is possible to use those achievements as inspirations for better ways of doing things – as catalysts to new, progressive creativity and to positive visions of the future. Just as Kraftwerk did in the fragile yet fertile Germany of the second half of the 20th century when they acknowledged the abyss yet still sought a better future, including as atonement for that past.

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#### Always value in preserving life

Torbjörn **Tännsjö 11**. The Kristian Claëson Professor of Practical Philosophy at Stockholm University. 2011. “Shalt Thou Sometimes Murder? On the Ethics of Killing.” https://www.philosophy.su.se/polopoly\_fs/1.126012.1361890813!/menu/standard/file/thoushalt-inprogress.doc

I suppose it is correct to say that, if Schopenhauer is right, if life is never worth living, then according to utilitarianism we should all commit suicide and put an end to humanity. But this does not mean that, each of us should commit suicide. I commented on this in chapter two when I presented the idea that utilitarianism should be applied, not only to individual actions, but to collective actions as well.¶ It is a well-known fact that people rarely commit suicide. Some even claim that no one who is mentally sound commits suicide. Could that be taken as evidence for the claim that people live lives worth living? That would be rash. Many people are not utilitarians. They may avoid suicide because they believe that it is morally wrong to kill oneself. It is also a possibility that, even if people lead lives not worth living, they believe they do. And even if some may believe that their lives, up to now, have not been worth living, their future lives will be better. They may be mistaken about this. They may hold false expectations about the future.¶ From the point of view of evolutionary biology, it is natural to assume that people should rarely commit suicide. If we set old age to one side, it has poor survival value (of one’s genes) to kill oneself. So it should be expected that it is difficult for ordinary people to kill themselves. But then theories about cognitive dissonance, known from psychology, should warn us that we may come to believe that we live better lives than we do.¶ My strong belief is that most of us live lives worth living. However, I do believe that our lives are close to the point where they stop being worth living. But then it is at least not very far-fetched to think that they may be worth not living, after all. My assessment may be too optimistic.¶ Let us just for the sake of the argument assume that our lives are not worth living, and let us accept that, if this is so, we should all kill ourselves. As I noted above, this does not answer the question what we should do, each one of us. My conjecture is that we should not commit suicide. The explanation is simple. If I kill myself, many people will suffer. Here is a rough explanation of how this will happen: ¶ ... suicide “survivors” confront a complex array of feelings. Various forms of guilt are quite common, such as that arising from (a) the belief that one contributed to the suicidal person's anguish, or (b) the failure to recognize that anguish, or (c) the inability to prevent the suicidal act itself. Suicide also leads to rage, loneliness, and awareness of vulnerability in those left behind. Indeed, the sense that suicide is an essentially selfish act dominates many popular perceptions of suicide. ¶ The fact that all our lives lack meaning, if they do, does not mean that others will follow my example. They will go on with their lives and their false expectations — at least for a while devastated because of my suicide. But then I have an obligation, for their sake, to go on with my life. It is highly likely that, by committing suicide, I create more suffering (in their lives) than I avoid (in my life).

#### Psychoanalysis does not justify the immutability of settler colonial ontologies.

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Apprehending this history as what Jodi Byrd has called the “transit” over which the international “postwestern” cityscape of Las Vegas is realized leads us into a reading of a very different type of frontier than the one memorialized on Fremont Street (Transit xv). Read this way, as a site of Indigenous dispossession, the West cannot be seen as a dynamic site of pure possibility, as Gilles Deleuze and Félix Guattari have represented it, as “a rhizomatic West, with its Indians without ancestry, its ever- receding limit, its shifting and displaced frontiers” (19). The repetitive revisitation of frontier tropes recalls what critic Hamish Dalley calls “the frozen temporality of settler- colonial narrative,” which, “fixated on the moment of the frontier, recalls nothing so much as Freud’s description of the ‘repetition compulsion’ attending trauma” (Dalley). The “hyperreal West” in this context emerges as a fantasy (Lewis 194), in the sense that theorist Jacqueline Rose describes in her work on Israel/Palestine. “Never completely losing its grip, fantasy is always heading for the world it only appears to have left behind” (3).5 Of course settler colonialism is but one of the “secret histories of Las Vegas” that underwrite the postmodern wonderland visitors fi nd on Fremont Street and the strip, and but one of many structures of violence that shape life in the contemporary western United States.6 Nonetheless, it remains a structure central to the consideration of “westness.” As the postwestern critics argue, “westness” is neither contained by geography (as the popularity of the Western genre internationally attests), nor necessarily representative of cultural production being produced within the western United States (Kollin x– xi). When we speak of a cultural production as “Western,” we are speaking of a work that addresses the process and consequences of settler conquest, whether we are discussing a California memoir, an Australian novel, or an Italian fi lm.7 This is not to say that Western cultural production is always a result of settler colonial ideology, but rather that it is engaged with questions pertaining to it. Th e problem of the West is, in a crucial sense, the problem of settler colonialism. Imagining postwestern futures thus requires a critical outlook that is more than just inclusive in its politics, transnational in its scope, and poststructuralist in its methodology. Our movement toward the “post” in the conceptual space of the Western must be decolonial in its orientation. Such a critique would abandon unilateral settler attempts at postnational place-making in order to critique settler colonial structures of violence. Such a critique would not work to reify these structures as permanent or inevitable, but rather to probe their contradictions, and to promote the Indigenous intellectual traditions that have long been at work critiquing the settler colonial present in order to shape a decolonial future.8 We hope that this special issue of Western American Literature, which features critical readings of western American film and literature by three scholars from different fields and national backgrounds, can contribute toward this effort.

#### 2---Critiques of calculation are wrong---compassionate attempts to influence a situation don’t yield their impacts

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The first thing I want to do is to explore the notion of instrumentalization that is so important for Brintnall’s position. Brintnall says that compassion and sadism are “structurally analogous” to each other, because “both are bound up in a potentially instrumentalizing subject-object perspective on the world,” a perspective that is the “foundation” of violence. So in achieving an ecstatic relation to others that is not instrumentalizing, Bataille’s meditation “exerts great pressure to eradicate the dispositions that produce sadistic violence.” This is an important opinion and it bears not just on the study of Bataille but on the study of mysticism and morality in general, since many philosophers of mysticism take as paradigmatic a unitive experience that, similarly to Bataille, effaces the subject-object distinction.∂ However, I do not think that the instrumentalization/non- instrumentalization distinction has the ethical significance that Brintnall attributes to it, and I do not think, as Brintnall and Bataille do, that subject-object relations involve “inherently alienating violence.” Not all instrumentalization is ethically problematic or tends toward violence. We instrumentalize each other all the time and could not carry on our affairs without doing so. Many goods we rightly regard as valuable require instrumentalizing relations. What matters is that when we treat others as a means to an end, we simultaneously respect them as an end in themselves. We cannot treat them as a mere means. It is possible to regard someone as both a means and an end, in other words. This is what the Kantians tell us, and though I do not count myself among their number, they are on to something here. When we buy a head of lettuce at a farmer’s market, we treat the farmer as a means to our end, but the important thing is we do not treat her as merely a means. We must treat her in such a way that regards her as a means to our end (of obtaining salad ingredients) but also as someone who has her own ambitions, desires, concerns, attachments, and decision-making capacities. To give an extreme example: if we abducted her and kept her in captivity, forcing her to grow and provide food for us, then we would be treating her merely as a means. So the ethically relevant distinction is not between instrumentalizing and non-instrumentalizing relations with others, but rather between different types of instrumentalizing, subject-object relations.∂ This leads me to doubt that compassion and sadism are structurally analogous. If Brintnall is right that sadism is a teleological project centered on “mastering, controlling, and dominating,” then it is a teleological project that treats people as mere means. Compassion, however, does not have this feature. And I stress in saying this that not all actions that the agent (or some other party) deems compassionate actually are. People can and often do mistake their attempts to dominate others as compassion. The reverse is possible as well: the patient may regard an action that is actually compassionate as an attempt to dominate and master. But one cannot properly identify an action as compassionate and also regard it as an instance of treating someone as a mere means. Any plausible account of what a compassionate action is would rule out that such an action merely instrumentalizes the patient. In speaking of certain actions as being classifiable as compassionate or not, I do not mean to deny that, on the psychological level, motivations for actions are often complex and contradictory, and I do not mean to deny that one might be motivated to act in a certain way by a complex mixture of compassionate and domineering motives. But even so—even though compassion can coexist with the will to dominate—the will to dominate is not itself what compassion is about. Whatever else compassion is, it is a concern for suffering and vulnerable people that regards their well-being as an end. So I disagree with Brintnall when he says that compassion is often about mastery and domination.∂ Just as I think that relations that involve instrumentalization and the subject-object distinction come in good and bad varieties, so also I think that ecstatic relations come in good and bad varieties. I learned this from Bataille, in fact, and this is an important insight that he has to make against philosophers who unambiguously valorize unitive mystical experiences. Human sacrifice, for Bataille, is a non-instrumentalizing relationship (Bataille 1991, 45–61). One takes the slave or captive who could otherwise be a productive economic unit and slaughters him. The ecstatic loss of self can occur just as well in a frenzy of violent destruction— murder, torture, rape, and the like—as it can in solitary meditation or consensual sex. The wolf does not regard its prey as an object discontinuous with itself (Bataille 1989, 17–25). So too for the human: it is not necessarily the case that in ecstasy one opens to and encounters others in a symmetric and reciprocal relationship. One can ecstatically subordinate the other to oneself or be subordinated to the other.∂ To see this, we need to explore the relation between sadism and inner experience more fully. I am not sure that Brintnall is right that sadism transpires exclusively in the realm of project. Of course, it depends on what exactly we mean by sadism, and we could turn to various sources to delineate the term: common parlance, a literary analysis of Sade’s writings, psychoanalytic theory, and S/M practices, for example, would give us different conceptions of the idea. Bataille at one point described sadism as involving “the desire to hurt and to kill” (Bataille 1986, 183). These desires are not quite the same as the attempt or desire to master and control (one could conceivably exercise mastery and control without inflicting pain or killing), so it is not clear to me that the desire to hurt and kill requires or presupposes a sense of self versus object or of self-aggrandizement. Indeed, the orgiastic frenzies of which Bataille so often wrote consist simultaneously of violent assault and the ecstatic loss of self, such as when the maenads devour their children (Bataille 1986, 113). Of course what is most important to me about this is not, at the end of the day, whether the right label for such actions and passions is sadism, but that we reject any perspective that does not give us sufficient ethical resources to condemn such actions and counteract such passions.∂ So for me instrumentalization and non-instrumentalization do not fall on different sides of the moral dividing line. Rather, the line cuts through both categories. I will turn now to the final thing I want to say, and that is that Brintnall’s response to my essay tends to present things as though there are only two relevant options: actions that strive to master and control, and the inaction of Bataillean ecstasy. He worries that “intervention in the world on behalf of the other” too readily occurs as “mastery of the world.” However, attempts to influence a situation are not necessarily attempts to master or control it. For example, I might try to persuade my child of the choice I think is best for him, but forego means beyond persuasion and set myself to respect his decision whatever it turns out to be, whereas a desire to master or control him might resort to humiliation or coercion when persuasion fails. Influence without mastery involves a proper sense of the limits of its efforts, and it more readily acknowledges failure than mastery does. Influence without mastery involves a respect for the other that refuses both non-intervention and domination.∂ There is then a third way between apathetic disengagement and mastery, and in fact, some of the theologians who challenge and inspire me the most are in search of practices that exemplify this third way. Sarah Coakley, for example, advocates a form of vulnerability that she explicitly contrasts to a desire to control. Coakley is especially relevant to the present conversation because her vision of vulnerability is rooted in practices of contemplation and meditation, and also because she shares with Brintnall’s Ecce Homo an opposition to domineering masculinism. The vulnerability Coakley finds in contemplation is opposed to the will to dominate, but not to the will to influence one’s society and contest injustice: she sees a virtue in “prophetic resistance” and enjoins her readers to “meet the ambiguous forms of ‘worldly’ power in a new dimension, neither decrying them in se nor being enslaved to them, but rather facing, embracing, resisting or deflecting them with discernment” (Coakley 2002, xviii, 38). Coakley’s meditative practices have a connection to the ethical life, but they do not stand on their own as supreme authorities. They are teleological in nature, and so susceptible to criticism by the various authorities in the Christian tradition (which are themselves susceptible to criticism). To be sure, Coakley is a minority perspective in the Christian tradition, which has been and still is domineering and cruel all too often, as Brintnall rightly notes. But she gives an example of an option between apathetic disengagement and mastery, and she does so with resources to differentiate between cruelty and kindness and to articulate a preference for one over the other.