# 1AC NDT

## Innovation Advantage

#### Disparagement dooms biosimilar innovation---antitrust is key.

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

#### 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.

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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.

#### Zombie viruses wreck all their defense

Lippi and Cervellin 2021, Giuseppe Lippi,Section of Clinical Biochemistry, University of Verona, Verona, Italy, and Gianfranco Cervellin, Academy of Emergency Medicine and Care, Pavia, Italy (NCBI 2/4/2021 “Updates on Rabies virus disease: is evolution toward “Zombie virus” a tangible threat?” https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7975959/#\_\_ffn\_sectitle)//ellie

Could Rabies virus become a “Zombie virus”? The term “rabies” most likely derives from the old Indian root word “rabh”, which stands for “making violence” (21). It is hence not surprising that the most devastating phenotype of encephalitic (“furious”) rabies disease is that of an individual displaying hypersalivation, hydrophobia, paranoia, hyperactivity, hyperirritability and abnormal aggressiveness (4). Interesting evidence has recently been published by a team of scientists from the University of Alaska Fairbanks (22), who demonstrated that a specific sequence within the Rabies virus glycoprotein, which has partial homology with snake toxins, is capable to inhibit the nAchR in the CNS, thus modifying animal behaviours and triggering high excitability and hostility. The hypothesis of viral infection as primary cause of a “Zombie” transformation (i.e., “zombification”) is not new, since it has already been proposed in both the “Resident Evil” movie series and by “Walking Dead” comics, nearly 20 years ago (23). In the former case, the so-called “Tyrant Virus” (also known as “T-Virus”) was originally developed by the imaginary pharmaceutical company “Umbrella Corporation” in the late 1970s, with the primary scope of eradicating some genetic diseases. Nevertheless, the innate characteristics of the T-Virus persuaded some scientists to promote its conversion into a biological weapon, whereby the pathogen would have been capable to almost irreversibly damage the CSF (especially neurons in frontal lobe, somatosensory cortex and hypothalamus), thus generating a dramatic decline in intelligence and motor functions in the host, but preserving many elementary function, reducing pain responsiveness and amplifying psychotic rage, persistent hunger, and increased aggressiveness (i.e., “zombification”) (17). Some intriguing cases of “pseudo-zombification” have also been reported in the scientific literature, mostly occurring in Haiti (where the original term “Zombie” was coined), as result of tetrodotoxin and/or Datura stramonium intake (24), or more recently in the US, after mass intoxication with synthetic cannabinoids such as AMB-FUBINACA (25). The risk of a “Zombie emergency” has also been seriously contemplated by the US Centers for Disease Control and Prevention (CDC), issuing an official manual entitled “Preparedness 101: Zombie Pandemic” (26) (Fig. 5), which aims to prepare healthcare and civil resources to handle epidemic threats, among which Zombie infestation is perhaps the most paradigmatic example. This document has then been followed by another guide, endorsed by the US Government, and specifically called “Counter-Zombie Dominance” (27). This second document contains the thoughtful description of how a military strategy shall be established for defending the nation against an imaginable Zombie alert, thus encompassing detailed information on biological characteristics of “enemy force”, on available means for preventing pathogen transmission, as well as on conceivable strategies that shall be planned for preventing collapse of civilized society (27). Therefore, some discernible questions would follow. Specifically, how much human rabies disease overlaps with “zombification”? And, would it be possible that a mutated Rabies virus epidemics (or pandemic) will transform mankind into Zombies? The first important aspect is defining the risk of human-to-human transmission, the mainstay of the imaginary Zombie contagion (28). It has been previously highlighted that bloodborne transmission is very unlikely for rabies disease, whereby viraemia does not seemingly occur with this type of infection. The survival of Rabies virus outside the host is also frankly poor, so that the most probable means of human-to-human transmission would need direct inoculation of the pathogen through bites from infected people (13). Rabies virus detection in saliva of infected humans has been reported as being the highest 2-3 days after the onset of symptoms, remains apparently stable for 2-7 days afterwards, and then apparently declines (29). Throughout the contagious window, it shall hence be assumed that patients with overt rabies disease would be so aggressive against their own kind to feel the uncontrollable instinct to bite them. Although there is only sporadic evidence of rabid patients biting other humans (e.g., a 41-year-old woman died of rabies disease after being bitten by her 5-year-old son, who in turn had developed the pathology after being bitten by a rabid dog) (9), this possibility cannot be straightforwardly excluded. The real incidence of human bites is largely underestimated due to under-reporting, and also because affected people tend to avoid medical care. Nevertheless, current evidence suggests that mammalian bites would account for almost 1% of all emergency department visits, up to 20% of which are attributable to human bites (i.e., 0.2% of all emergency department admission) (30). Therefore, the suggestion that extremely aggressive rabid patients would suffer from an incontrollable instinct to bite other humans, and thus transmitting the infection, remains actual. Interestingly, the Advisory Committee on Immunization Practices of the CDC suggests that post-exposure prophylaxis shall be planned for all people with mucous membranes or non-intact skin exposure to potentially infectious body fluids from rabid patients (31), thus implicitly confirming that the risk of human-to-human transmission of rabies disease is not irrelevant. The comparison of the current image of a Zombie with that of a rabid patient is a second import aspect that needs to be accurately scrutinized. As already emphasized, conventional Zombies, as depicted in comics and movies (23), share some similar behaviours with patients infected by Rabies virus. Both undergo a variable degree of consciousness deterioration, which tends to be almost identical in the last stages of rabies disease. Both individuals display also fearful facial expressions, increased hyperirritability and aggressiveness, which can be both substantially accentuated by external stimuli (thirst, fear, light and noise) in rabid patients (Figure 4), and may ultimately evolve toward violent and ferocious behaviours. That said, it is now widely acknowledged that many viruses are characterized by naturally occurring high mutation rates, which induce constant changes as reliable means for escaping host defences or facilitating their transmission to other susceptible hosts. Rabies virus makes no exception to this rule, as recently described by Wang et al (32), who found a vast array (up to 100) of antigenic variants of this pathogen in a wide range of animal hosts and geographic locations. Notably, even single amino acid mutations in the proteins of Rabies virus can considerably alter its biological characteristics, for example increasing its pathogenicity and viral spread in humans, thus making the mutated virus a tangible menace for the entire mankind (33). Beside the natural evolution of Rabies virus, an equal threat may come from the science of genetic engineering, which would reproduce the theatrical scenario depicted in the movies of the Resident Evil saga (23), and more recently advocated also for COVID-19. By means of genetic engineering, scientists have already developed innovative biological weapons, which would appear more powerful and destructive than their natural counterparts (34). The outbreak of severe acute respiratory syndrome (SARS) in 2003, in China, is perhaps the most paradigmatic example (35), whereby many biological features of the pathogen have led some eminent scientists to conclude that the SARS virus might have been produced under laboratory conditions (36). Would a mutated Rabies virus, bearing one or more mutations such as those described by Hueffer et al (22), and hence characterized by facilitated human-to-human transmission, faster incubation, enhanced neurotoxicity and predisposing towards aggressive highly behaviours, become the most lethal biological agent that humans have ever faced? Conclusions The Rabies virus, like the vast majority of other pathological microorganisms, attempts to perpetuate itself with general and reservoir host-specific mechanisms, which ultimately confer a considerable epidemiological plasticity. The pace and phenotype of rabies infection are mostly written in the virus genome, whilst transmission is strongly favoured by aggressive behaviours (i.e., a biting inclination) of rabid hosts (37). Despite incidence and mortality of rabies disease have both markedly declined during the past three decades (Fig. 1), and irrespective of whether the genetic code of Rabies virus can be naturally (i.e., by ecological opportunities and viral adaptation) or artificially (i.e., by genetic engineering) modified, we need to think “out-of-the-box”, in that the generation of a “Zombie virus” cannot be firmly excluded according to the currently available biological evidence (38). Wavefront velocity of rabies disease propagation has been calculated in wild animals (e.g., foxes, skunks, raccoons and vampire bats) at around 10-40 km per year (37). However, in densely populated towns, where natural landscape barriers would be minimal, the human-to-human contagion may increase by several orders of magnitude, thus easily assuming apocalyptic proportions and creating a new generation of pseudo-human creatures, who have completely unleashed their already existing part of zombie within (39). In keeping with this conjecture, an interesting simulation of an imaginary Zombie outbreak reveals that most of the US population would turn into Zombies within one week from appearance of the first case, whilst only some remotes zones in Montana and Nevada would remain infestation-free one month afterwards (40).

#### Affirmative prohibition is critical to innovation---creates a presumption of antitrust liability.

Carrier and Tushnet 21, Michael A. Carrier Rutgers Law School Distinguished Professor, Rebecca Tushnet Harvard Law School Professor of Law (Iowa Law Review 2021 “An Antitrust Framework for False Advertising” https://papers.ssrn.com/sol3/papers.cfm?abstract\_id=3593914)//ellie

One concern courts have raised with making false advertising the basis for an antitrust violation is that much of this behavior does not affect the market as a whole. Courts are right that even if one company engages in this conduct, and even if an individual rival is harmed as a result, that does not mean that competition in the market as a whole is affected. But there is a simple solution to this concern: focus on the defendant’s market power. Of all the actors employing false advertising, monopolists are the most likely to affect the market, with those attempting to monopolize making up the second-most-likely category. Targeting these two categories of actors recognizes that Section 2 of the Sherman Act provides the appropriate—and in fact only—framework for antitrust liability for unilateral conduct such as false advertising. Focusing attention on only monopolists and attempted monopolists dramatically narrows the universe of false advertising/antitrust claims. Such an emphasis also is consistent with the approach taken in the Areeda/Hovenkamp treatise, which recognizes that antitrust may be appropriate when “the practice makes a durable contribution to the defendant’s market power.”131 The treatise crafts a de minimis presumption because of the relative unlikelihood that any given false claim would “lead[] to or perpetuat[e] durable market power.”132 But the treatise also recognizes that “misrepresentations and organized deception by a dominant firm may have Section 2 implications when used against a nascent firm just as it is entering the market.”133 Once we understand that the treatise’s concerns about overapplication of false advertising law are addressed by requiring monopoly (or, as discussed below, attempted monopoly) status, the treatise would lend support to liability when the defendant’s monopoly power makes false advertising especially likely to affect the market as a whole and harm competition. Our focus on monopolists and attempted monopolists also is consistent with antitrust injury doctrine. As the Supreme Court famously explained in Brunswick Corp. v. Pueblo Bowl-O-Mat, Inc., plaintiffs must prove “injury of the type the antitrust laws were intended to prevent and that flows from that which makes defendants’ acts unlawful.”134 In other words, plaintiffs must challenge a harm that affects the market as a whole. Limiting our scrutiny to monopolists and attempted monopolists helps effectuate Brunswick’s objectives. We suggest a presumption that false advertising by monopolists constitutes monopolization. Crucially, the most fundamental critique against applying antitrust to false advertising—that “false advertising” does not require marketwide effects—are addressed by the defendant’s control over the market. To satisfy the first of the two elements of a monopolization case, a plaintiff must show that the defendant has monopoly power. As discussed above,135 a plaintiff can do so indirectly by showing a market share of at least 75 percent (and more likely 90 percent) along with barriers to entry that could entrench that market position. A plaintiff also can prove market power directly, such as by showing the defendant’s power to impose price increases or output reductions. Second, the plaintiff must show that the defendant engaged in false advertising. As a matter of underlying substantive law, liability for false advertising already requires findings that the defendant’s conduct was literally false or misleading, was material, actually deceived or was likely to deceive consumers, and caused or was likely to cause harm to the plaintiff.136 These elements are logically and practically linked to each other; they constitute the wrong of false advertising, just as an agreement to set prices constitutes the wrong of price fixing. In particular, deception is generally presumed from literal falsity, or is demonstrated by showing misleadingness—if consumers receive a false message from a facially ambiguous or even literally true claim, they have been deceived. Likewise, once both deception and materiality have been shown, courts generally find a likelihood of harm, as consumers have been misled about facts that are likely to affect their decisions. The false advertising foundation provides a unique advantage for antitrust law, one not available in other settings. The reason is simple. False advertising’s underlying requirements focus on the bad conduct, show its relevance, and demonstrate the harm. These elements offer on a silver platter what antitrust needs to prove monopolization. In addition, materially false advertising by a monopolist threatens multiple concerns: It makes it more difficult to compete on the merits, can easily be repurposed to harm any competitor, and is hard to credibly rebut without souring consumers on factual claims more generally. Because of these harms and the satisfaction of false advertising’s elements, a monopolist’s materially false advertising should be presumed to affect the market as a whole. A presumption that a monopolist using false advertising has engaged in illegal monopolization also is appropriate given the near certainty of anticompetitive effects. Unlike other lawbreaking by a monopolist such as tax fraud, false advertising by definition harms at least one competitor, in what is a relatively small field. That is, by definition a monopolist controls most of the market, so there will be fewer competitors to harm. False advertising may even directly harm all the other competitors if the false claim is one of general superiority, or, as in the AT&T example, is directed at keeping existing customers from switching products. And by poisoning the informational environment, false advertising inherently threatens the key mechanism by which rivals can compete: by explaining to consumers what they can offer in a way that might persuade them. False advertising is also a technique that can easily be extended to the next competitor, further justifying a presumption that its use by a monopolist caused harm to competition. Another way to frame the presumption of harm to competition centers on how we know that harm to actual entities has crossed into the legal category of “harm to competition.” When an entity that meets the standards for monopoly power engages in materially false advertising that causes damage, we know that it is a monopolist and that it harmed identified victims (such as consumers or competitors) in a way likely to push the market as a whole toward an untrusting and untrustworthy market for lemons. When a monopolist introduces a valuable innovation to the market, in contrast, that can harm competitors, but it also produces social benefit, meaning that the harm should be tolerated. So too when a monopolist truthfully and nonmisleadingly advertises a superior product. But when the ready-made template of false advertising law makes clear that a monopolist harms consumers’ ability to trust information in the market and causes consumers to pay prices or buy products they otherwise wouldn’t have chosen, at the very least the burden should be on the monopolist to show that it did no structural damage to the market.

#### Alternative regulations fail and suppress competition.

Carrier and Tushnet 21, Michael A. Carrier Rutgers Law School Distinguished Professor, Rebecca Tushnet Harvard Law School Professor of Law (Iowa Law Review 2021 “An Antitrust Framework for False Advertising” https://papers.ssrn.com/sol3/papers.cfm?abstract\_id=3593914)//ellie

False advertising liability alone cannot address the marketwide harms caused by deceptive behavior. This Section first addresses antitrust’s comparative advantage for marketwide harms. It then offers examples of antitrust properly targeting conduct that violates other, non-antitrust laws, demonstrating that antitrust’s treatment of false advertising is an outlier. It concludes by showing that false advertising’s remedies cannot fully protect competition on their own. 1. Antitrust’s Comparative Advantage An antitrust-based framework for false advertising claims is necessary because of the unique role that the discipline can play. When companies engaging in false advertising have monopoly power, they possess the ability to harm not only an individual competitor but also the market as a whole. The consequences can be significant, especially for nascent competitors not able to enter the market, as the deception of consumers deprives them of the opportunity to obtain lower prices, more options, or enhanced quality. One way to understand the harms of false advertising to the market as a whole is revealed by George Akerlof’s classic explanation of the market for lemons.99 As Akerlof explains, in the absence of some way to guarantee the truth of claims about products, such as a used car’s quality, consumers reasonably respond by discounting all such claims. This distrust means that producers with actually superior products cannot charge the amount consumers would pay if they believed the superiority claim, which pushes superior (but more expensive to produce) products out of the market. If truthful advertisers are not able to guarantee their claims, producers unable to compete on their product characteristics suffer. And consumers are harmed by an unattractive (and perhaps even harmful, in the case of false health or safety claims) mix of products. Meanwhile, many false advertising techniques can be readily repurposed for new uses, meaning that a false advertiser can go from success to success in the absence of false advertising liability.100 Regulation that suppresses false claims—especially where such claims are most likely to have an effect—thus does more than protect individual consumers from fraud. It allows truthful producers to compete on a level playing field. In other words, addressing false advertising protects competition, not just competitors. The Supreme Court relied on Akerlof’s insights when it endorsed the pro-competitive effects of restrictions on false advertising. In California Dental Ass’n v. FTC, the Court addressed a dental association’s attempts to restrict “false or misleading” advertising that imposed significant limits on advertising “low prices” or other general price claims.101 The Court rejected the idea that such limits were inherently anticompetitive. Especially where information is hard to evaluate, even broad restrictions with the aim of preventing false advertising can be procompetitive.102 When false advertising threatens harms to the market as a whole, antitrust liability offers advantages over false advertising law. For starters, antitrust offers a more powerful toolkit deterring this conduct. Although false advertising law allows recovery of damages (albeit not as a penalty) and disgorgement of the profits from false advertising, courts impose high barriers to disgorgement, including requiring a showing of willfulness. In addition, courts have required plaintiffs to show a robust connection to the harm suffered to receive damages or disgorgement of profits. As a result, courts have denied awards in precisely the cases of concern: where there are a small number of potential competitors and where some of the monopolist’s gains from false advertising likely came at the expense of the overall market rather than a single plaintiff, making it difficult to allocate false advertising-based damage awards.103 There are two key ways in which antitrust offers more powerful protection against monopolists’ false advertising than federal false advertising law: remedies and eligible plaintiffs. First, antitrust offers the more powerful remedies of treble damages and automatic (as opposed to the Lanham Act’s exceptional104) attorneys’ fees that promise to provide robust deterrence against companies considering this behavior. Antitrust also offers injunctive relief preventing the continuation of the conduct. While a Lanham Act false advertising injunction generally is limited to the specific false claims that have been proven, an antitrust injunction could more generally target false advertising and marketwide harm to competition.105 Antitrust offers a more expansive territorial jurisdiction.106

## 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 Section 5 enforcement by the Federal Trade Commission.

## FTC Advantage

#### **FTC failure to prohibit false advertising is an existential threat to the agency. Market-wide Section 5 enforcement restores FTC credibility, boosts fraud deterrence, and reduces litigation**

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.

### Scenario 1 is Terror

#### Section 5 is the only avenue for 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.

#### Fraud crackdowns stop major terror attacks

Michael Tierney 18, George & Mary Hylton Professor of International Relations; Director Global Research Institute (GRI), “#TerroristFinancing: An Examination of Terrorism Financing via the Internet,” International Journal of Cyber Warfare and Terrorism, vol. 8, no. 1, 01/2018, pp. 1–11

2. TERRORIST FINANCING AND THE INTERNET

As mentioned, terrorists’ use of the internet has become a major concern for security officials across the world in recent years. Like many other users, terrorists have found that the internet is an invaluable tool to share information quickly, in order to disseminate ideas and link up with likeminded individuals (Jacobson, 2010; Okolie-Osemene & Okoh, 2015). In this manner, terrorists use the internet for a variety of purposes, including recruitment, propaganda, and financing. As scholars have also noted, the internet is an attractive option for extremists due to the security and anonymity it provides (Jacobson, 2010). Yet while there have been a growing number of studies completed on the ways in which terrorist organizations use the internet to recruit and indoctrinate others, there has been relatively little focus on the methods by which terrorists finance themselves through online activities. Some researchers have attempted to fill gaps in this area by broadly studying internet aspects of terrorism financing. However, research on this particular aspect of terrorism financing still appears to be lacking, with little focus on new methods of terrorist financing via the internet or a marrying of strategies to combat online financing trends available to practitioners in the field.

For instance, Sean Paul Ashley (2012) assessed the mobile banking phenomenon, which is prevalent in regions such as the Middle East and Africa, and provides extremists with the ability to easily connect to the internet and remit funds around the world. The decentralization of this kind of banking, due to the fact that brick-and-mortar facilities are not needed to conduct transactions, has allowed terrorist financiersto more efficiently move funds while avoiding detection from authorities. Other researchers,such as MichaelJacobson (2010), have studied the waysin which terrorists engage in cyber-crime to raise and move funds. For example, Jacobson (2010) found that online credit card fraud was a fairly major source of terrorist financing. By stealing a victim’s private credit information, terrorists are able to co-opt needed funds and provide support to themselves or their counterparts. Yet as James Okolie-Osemene and Rosemary Ifeanyi Okoh (2015) note, the internet is mostly used to augment and assist activities which occur in the physical world. In this way, it would appear that the internet is far more useful as a means to move funds globally in support of terrorism, rather than simply as a method to raise funds.

#### High risk of nuclear terror.

CACNP 21 – (The Center for Arms Control and Non-Proliferation is a national nonpartisan nonprofit dedicated to enhancing peace and security through expert policy analysis and thought-provoking research. “Fact Sheet: Nuclear Terrorism: A Clear and Present Danger.” <https://armscontrolcenter.org/nuclear-terrorism-a-clear-and-present-danger/>, Last Updated March 2021 //ROBBIE)

Nuclear terrorism – the threat by a terrorist group to obtain and use a nuclear weapon, or to acquire enough nuclear material to create and use a crude weapon or dirty bomb – poses a serious threat to the United States and its allies. A Pentagon review of U.S. nuclear policy indicated that nuclear terrorism is the “most immediate and extreme danger” facing the United States. With just 25 kilograms worth of highly enriched uranium (HEU), small enough to fit in a suitcase, terrorists could make a nuclear weapon capable of inflicting the same devastation as the bombs used at Hiroshima and Nagasaki. Terrorists could also lace conventional explosives with radiological material to create a dirty bomb. A dirty bomb, while not as lethal as a nuclear weapon, is considered a weapon of mass disruption due to the widespread panic associated with the weapon’s radiological fallout. According to a 2011 Congressional Research report, a dirty bomb detonation would have six major consequences: immediate casualties from conventional detonation, panic, economic disruption, long-term evacuations, exorbitant decontamination costs, and long-term casualties from cancer. What Can Be Done? To address these threats, the United States and Russia, the two countries with the largest stockpiles of nuclear material, have worked together to secure nuclear weapons and facilities. These programs have also been extended to other countries with nuclear facilities and materials that could be at risk. There has been considerable progress over the last several decades to reduce the probability that terrorists might acquire nuclear material. These efforts include the complete removal of civilian highly enriched uranium from 30 countries and Taiwan and the conversion or closure of at least 94 research reactors that formerly used highly enriched materials. But there is still significant work to be done. There remains nearly 2,000 metric tons of weapons-usable nuclear material spread across the globe, some of it vulnerable to theft or sabotage. There are abundant examples of lax security standards, including the break-in at the U.S. maximum security facility for nuclear materials led by an unarmed 82-year old nun, an armed break-in at a South African nuclear facility in 2007, and at least 167 incidents in 2019 in which nuclear or radiological material was lost, stolen, or outside of authorized control. Programs tasked with securing these materials hovered around $2 billion under the Trump administration, which takes the funding and attention back to pre-2013 levels. Congressional appropriations for core nuclear security programs declined in the end of the Obama administration’s second term after the success of a series of Nuclear Security Summits. However, according to Sen. Dianne Feinstein (D- Calif.), the funding reduction led to a five-year delay for securing and converting nuclear reactors across the globe, pushing the completion of that project to 2035. [Chart Omitted] To prevent a nuclear terrorism incident, the United States and its international partners must secure radiological and fissile material with the goal of maintaining the highest security standards. Nuclear non-proliferation programs should receive full funding and support from both Congress and the White House.

#### That causes nuclear war---cash is key

Dr. Peter J. Hayes 18, Executive Director of the Nautilus Institute for Security and Sustainability, Ph.D. in Energy and Resources from the University of California-Berkeley, Professor of International Relations at RMIT University, “Non-State Terrorism and Inadvertent Nuclear War”, NAPSNet Special Reports, 1/18/2018, <https://nautilus.org/napsnet/napsnet-special-reports/non-state-terrorism-and-inadvertent-nuclear-war/>

The critical issue is how a nuclear terrorist attack may “catalyze” inter-state nuclear war, especially the NC3 systems that inform and partly determine how leaders respond to nuclear threat. Current conditions in Northeast Asia suggest that multiple precursory conditions for nuclear terrorism already exist or exist in nascent form. In Japan, for example, low-level, individual, terroristic violence with nuclear materials, against nuclear facilities, is real. In all countries of the region, the risk of diversion of nuclear material is real, although the risk is likely higher due to volume and laxity of security in some countries of the region than in others. In all countries, the risk of an insider “sleeper” threat is real in security and nuclear agencies, and such insiders already operated in actual terrorist organizations. Insider corruption is also observable in nuclear fuel cycle agencies in all countries of the region. The threat of extortion to induce insider cooperation is also real in all countries. The possibility of a cult attempting to build and buy nuclear weapons is real and has already occurred in the region.[15] Cyber-terrorism against nuclear reactors is real and such attacks have already taken place in South Korea (although it remains difficult to attribute the source of the attacks with certainty). The stand-off ballistic and drone threat to nuclear weapons and fuel cycle facilities is real in the region, including from non-state actors, some of whom have already adopted and used such technology almost instantly from when it becomes accessible (for example, drones).[16]

Two other broad risk factors are also present in the region. The social and political conditions for extreme ethnic and xenophobic nationalism are emerging in China, Korea, Japan, and Russia. Although there has been no risk of attack on or loss of control over nuclear weapons since their removal from Japan in 1972 and from South Korea in 1991, this risk continues to exist in North Korea, China, and Russia, and to the extent that they are deployed on aircraft and ships of these and other nuclear weapons states (including submarines) deployed in the region’s high seas, also outside their territorial borders.

The most conducive circumstance for catalysis to occur due to a nuclear terrorist attack might involve the following nexi of timing and conditions:

1. Low-level, tactical, or random individual terrorist attacks for whatever reasons, even assassination of national leaders, up to and including dirty radiological bomb attacks, that overlap with inter-state crisis dynamics in ways that affect state decisions to threaten with or to use nuclear weapons. This might be undertaken by an opportunist nuclear terrorist entity in search of rapid and high political impact.
2. Attacks on major national or international events in each country to maximize terror and to de-legitimate national leaders and whole governments. In Japan, for example, more than ten heads of state and senior ministerial international meetings are held each year. For the strategic nuclear terrorist, patiently acquiring higher level nuclear threat capabilities for such attacks and then staging them to maximum effect could accrue strategic gains.
3. Attacks or threatened attacks, including deception and disguised attacks, will have maximum leverage when nuclear-armed states are near or on the brink of war or during a national crisis (such as Fukushima), when intelligence agencies, national leaders, facility operators, surveillance and policing agencies, and first responders are already maximally committed and over-extended.

At this point, we note an important caveat to the original concept of catalytic nuclear war as it might pertain to nuclear terrorist threats or attacks. Although an attack might be disguised so that it is attributed to a nuclear-armed state, or a ruse might be undertaken to threaten such attacks by deception, in reality a catalytic strike by a nuclear weapons state in conditions of mutual vulnerability to nuclear retaliation for such a strike from other nuclear armed states would be highly irrational.

Accordingly, the effect of nuclear terrorism involving a nuclear detonation or major radiological release may not of itself be *catalytic* of *nuclear* war—at least not intentionally–because it will not lead directly to the destruction of a targeted nuclear-armed state. Rather, it may be catalytic of non-nuclear war between states, especially if the non-state actor turns out to be aligned with or sponsored by a state (in many Japanese minds, the natural candidate for the perpetrator of such an attack is the pro-North Korean General Association of Korean Residents, often called Chosen Soren, which represents many of the otherwise stateless Koreans who were born and live in Japan) and a further sequence of coincident events is necessary to drive escalation to the point of nuclear first use by a state. Also, the catalyst—the non-state actor–is almost assured of discovery and destruction either during the attack itself (if it takes the form of a nuclear suicide attack then self-immolation is assured) or as a result of a search-and-destroy campaign from the targeted state (unless the targeted government is annihilated by the initial terrorist nuclear attack).

It follows that the effects of a non-state nuclear attack may be characterized better as a *trigger* effect, bringing about a *cascade* of nuclear use decisions within NC3 systems that shift each state increasingly away from nuclear non-use and increasingly towards nuclear use by releasing negative controls and enhancing positive controls in multiple action-reaction escalation spirals (depending on how many nuclear armed states are party to an inter-state conflict that is already underway at the time of the non-state nuclear attack); and/or by inducing concatenating nuclear attacks across geographically proximate nuclear weapons forces of states already caught in the crossfire of nuclear threat or attacks of their own making before a nuclear terrorist attack.[17]

### Scenario 2 is Greenwashing

#### FTC authority is key to solve greenwashing.

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The Green Guides, by their own terms, are not binding regulations. 48 Rather, they “help marketers avoid making environmental marketing claims that are unfair or deceptive under § 5 of the FTC Act”49 by providing “a ‘safe harbor’ for marketers who want certainty about how to make environmental claims.”50 To put this in context, the FTC’s rulemaking power under § 18 of the FTC Act provides that the Commission may promulgate two different kinds of rules—interpretive rules and legislative rules. 51 The FTC categorizes the Green Guides as interpretive rules, meaning that they are “general statements of policy with respect to unfair or deceptive acts or practices in or affecting commerce.”52 Legislative rules, by contrast, “define with specificity acts or practices which are unfair or deceptive . . . in or affecting commerce.”53 A full analysis of the differences between interpretative and legislative rules, and the scholarship surrounding this topic, is beyond the scope of this paper; however, it is appropriate to briefly consider the significance of interpretative and legislative rules in the FTC context. Legislative rules are subject to the requirements of the Administrative Procedure Act,54 as well as additional procedural requirements prescribed in § 18(b)(1) of the FTC Act and in the Magnuson-Moss Warranty-Federal Trade Commission Improvement Act (FTC Improvement Act), which was passed in 1975. 55 Congress passed the FTC Improvement Act in the wake of several controversial FTC rulemakings. These additional procedural hurdles are intended to, and generally do, slow the FTC rulemaking process. 56 Since the passage of the FTC Improvement Act, the FTC has issued fewer binding rules, 57 and instead has increasingly relied on interpretive rules or industry guides, such as the Green Guides, to avoid the cumbersome FTC Improvement Act requirements. 58 These industry guidelines occupy a middle ground between being truly voluntary and legally binding. The FTC’s decision to tackle deceptive and fraudulent “green” marketing using an industry guide, rather than a binding regulation, enabled the FTC to more quickly address the problem at a time when it was under pressure by various stakeholders to do so. While the expedited action was a significant advantage, this approach caused other challenges. First, voluntary federal guidelines do not preempt disparate state regulations. The Green Guides expressly state that they “do not preempt federal, state, or local laws.”59 Although some state laws now adopt by reference the Green Guides in some manner,60 the issue of disparate state regulations still is not entirely resolved. 61 Second, despite that the Green Guides expressly state that they are not binding regulations, they read like binding regulations and the FTC has sometimes treated them like binding regulations. The Green Guides classify certain practices as “deceptive” and describe what marketers “should” and “should not” do when making environmental claims in order to comply with § 5 of the FTC Act. These specific directions are arguably inconsistent with a “general statement[] of policy,”62 as an interpretive rule is supposed to be, and instead “define with specificity [unfair] acts or practices,”63 as legislative rules do. To this end, former FTC Commissioner Mary L. Azcuenaga issued a statement of dissent upon the release of the Green Guides in 1992, questioning whether the Green Guides were legislative rules masquerading as interpretative guidance. 64 A third problem with the interpretive guidance approach is the difficulty with enforcement. The FTC Act is the sole piece of legislation that grants the Commission statutory powers of enforcement over deceptive advertising and other forms of marketing. Because the Green Guides are nonbinding, they “are not independently enforceable.”65 Therefore, a violation of the Green Guides is not a violation of a legally binding rule pursuant to the FTC Act, and the FTC is burdened with proving that each Green Guides violation also violates § 5 of the FTC Act. A related issue is that voluntary guidelines typically are not viewed as final agency actions, which both complicates judicial review and reduces judicial deference to the FTC’s determination that a marketer has violated § 5. 66 In sum, the Green Guides were intended to curb the growing problem of deceptive and fraudulent “green” marketing in the United States, and they have succeeded in doing so in many respects. Companies marketing products or services have a clearer roadmap for compliance with § 5 of the FTC Act, and American consumers can be more confident that they are not being “greenwashed.” This confidence, in turn, leads to higher demand for sustainable products and can reduce the negative impacts of consumption on environmental quality. The form of the Green Guides as an interpretive guidance document, rather than a binding regulation, leads to several challenges in compliance and enforcement. The substantive purview of the Green Guides is also a factor. While the Green Guides respond to some of the most significant environmental marketing deceptions of the past—such as claims of being “ozone-layer friendly”—they are silent on one of the issues that matters most to today’s consumers: “organic” claims. The next section of this Essay discusses the rise of fraud in organic claims, particularly for nonagricultural products.

#### Greenwashing spills over and wreck all green products---it makes consumers distrustful.

Rotman et al 20 – (Robin M. Rotman is an Assistant Professor of Environmental Law and Policy at the University of Missouri. She is also an Adjunct Professor at Georgetown University. Robin received her J.D. from Yale Law School in 2009. Chloe J. Gossett received her B.S. from the University of Missouri in 2019, with a major in Environmental Science and minor in Mathematics. Hope D. Goldman received her B.S. from Georgetown University in 2019, with a major in Science, Technology, and International Affairs. “Greenwashing No More: The Case for Stronger Regulation of Environmental Marketing.” University of Missouri School of Law Scholarship Repository, online PDF, pg. 439, published Summer 2020 //ROBBIE)

As shown by the history of FTC enforcement actions involving environmental marketing, there has never been a lack of unscrupulous marketers that are willing to deceive consumers to gain an unfair advantage over competitors. While Moonlight Slumber and Truly Organic may be extreme examples of deceptive “organic” claims in marketing made at the expense of vulnerable populations, such as babies and pregnant women, it is unrealistic to assume that they are isolated cases. More likely, they are emblematic of the latest trend in greenwashing—the misuse of buzzwords like “organic” and “vegan”—which the FTC must take further action to address. III. RECOMMENDATIONS Greenwashing hurts business competitors, consumers, and the environment. It is well documented that even isolated instances of greenwashing can make consumers skeptical of all products marketed as “green,” and can lead consumers to question not only the supposed ecoattributes of those products, but all claims about those products made in marketing materials. 122 Purchasers of “green” products are not the only ones who are affected; exposure to fraudulent “green” marketing materials can leave broad swathes of consumers confused, dissatisfied, and disloyal. 123 If allowed to continue, greenwashing can ultimately lead consumers to avoid products that are marketed as “green.”124 Frankly, this is a shame given the magnitude of environmental challenges and the importance and urgency of reducing the environmental impact of consumptive activities. Because greenwashing can have far-reaching impacts on consumer purchasing, the problem of fraudulent or deceptive “organic” claims regarding nonagricultural products affects more than the businesses and consumers operating in that sector. Many businesses and numerous consumers are impacted due to the effect on consumer decisionmaking that can then artificially affect competition and opportunity. This section of the Essay offers three recommendations for reducing unfounded and deceptive “organic” claims in the marketing of nonagricultural products. First, the FTC should take immediate steps to tighten its investigation and enforcement oversight regarding “organic” claims and to improve coordination with the USDA NOP. Second, the FTC should add provisions regarding “organic” claims to its next revision of the Green Guides, which is slated for revision in 2022. Finally, in the longer term, the FTC should consider making the Green Guides into legislative rules, similar to the NOP regulations.

#### **Green products are try or die for a global shift to sustainability but only legal checks on greenwashing make it possible**

Osman, 20 – Jheni, Science journalist, author, presenter. “Greenwashing: the tipping point,” Client Earth, November, <https://www.clientearth.org/latest/latest-updates/stories/greenwashing-the-tipping-point/> -- Iowa

The global eco-awakening means former ‘green sheen’ business practices no longer work. Embracing sustainability is the key to future profit. Global temperatures are nudging ever closer to the feared 1.5C rise. Experts worry that this potential ‘tipping point’ could push Earth systems into irreversible climate change. But society is also at a tipping point where a relatively small change might trigger an outsized impact.

“A single loud noise can set off an avalanche,” says Dr Aoife Brophy Haney, Research Lecturer at the Smith School of Enterprise and the Environment at the University of Oxford. “‘Sensitive intervention points’ exist in social, political and economic situations. A lone Swedish schoolgirl can inspire climate action around the world.”

The Greta Thunberg-inspired eco-awakening has filtered its way to the dinner table. We’re now being quizzed by the kids at home about what we’re doing at work to look after the planet. E-marketing. Tick. Clean energy provider. Tick. E-scooters and electric pool cars. Tick. Tick.

Diversionary tactics

A classic greenwashing tactic involves PR spin or deflection. Either a company will advertise a product with environmental achievements that are already mandated by existing laws, or a company doesn’t change their behavior, but just markets themselves as being green.

Take the case of oil giant ExxonMobil. An internal document from 1980, obtained by DeSmog, shows Imperial Oil Limited (Exxon’s Canadian subsidiary) was well aware that burning of fossil fuels increased carbon dioxide in the atmosphere. Initially, Imperial Oil and Exxon engaged in climate science programmes. But, by the late 1990s, Exxon and Imperial Oil were spreading doubt about climate change. (Exxon became a founding member of the Global Climate Coalition - an international lobby group that opposed action to reduce greenhouse gas emissions and challenged the science behind global warming, but was disbanded in 2002).

A 2017 analysis by Harvard Research Associate Geoffrey Supran of ExxonMobil’s climate change communications between 1977 and 2014 gave an insight into the company’s greenwashing actions. The communications analysed ranged from internal company documents to paid for editorial-style newspaper or magazine advertisements (known as ‘advertorials’). What Supran found was that as documents became more publicly accessible, they increasingly communicated doubt about climate change. For example, 83% of peer-reviewed papers and 80% of internal documents acknowledged that climate change is real and caused by humans, but only 12% of advertorials did, with 81% instead suggesting doubt about the issue.

"Within hours of publishing our study, ExxonMobil responded with ad hominem attacks," says Supran. "I was invited by the European Parliament to testify about ExxonMobil's history of climate denial. The day before, they sent a private memo (which has now been leaked) to Members of Parliament to try to discredit me. If these experiences tell us anything, it's that the Exxon tiger hasn't changed its stripes."

ExxonMobil is not alone. Internal documents uncovered by DeSmog in 2018 reveal that Shell was also aware of the impact of fossil fuels on climate change back in the 1980s. But the company’s marketing strategy changed following an internal document in 1999, which recommended that it should focus on promoting its eco-actions, such as its commitment to the Kyoto Protocol.

More recently, Shell has been vocal about calling for environmental action. In 2018, CEO Ben van Beurden said mass reforestation was needed to limit temperature rise to 1.5oC and hit UN targets. The same year, Shell said it would support calls to bring forward the UK’s 2040 ban on new petrol and diesel car sales. And, the previous year, Shell had bought NewMotion, the owner of one of Europe’s largest electric car charging networks. All steps in the right direction. But critics claim the core of the business hasn’t changed. In 2018, Shell approved a $12bn liquefied natural gas project in Canada, and a report in 2020 by the Institute for Energy Economics and Financial Analysis (IEEFA) revealed that fossil fuels still make up around 90% of Shell’s capital expenditure (the money spent on acquiring or maintaining fixed assets).

“Fossil fuel companies have done little to nothing to reduce emissions or modify their business models without significant pressure from regulation, litigation, shareholder activism, or environmental groups exerting pressure,” says Davies, “the free market approach to saving the planet simply does not work.”

Chasing green points

In other industries, clever use of language has been used to layer a ‘green sheen’ on companies, products or services. Critics called it a PR stunt when Amazon purchased the KeyArena in Seattle and renamed it Climate Pledge Arena. Zara met with some opposition when it announced that by 2025 all of its clothes would be made from 100% 'sustainable fabrics’, as the definition of this term is still up for debate. And Coca Cola has been ridiculed for their ‘World without waste’ campaign: ‘a bold, ambitious goal: to help collect and recycle a bottle or can for every one we sell by 2030’… ‘To do that, we aim to invest our marketing dollars and skills to help people understand what to recycle, how to recycle, and where to recycle’ - which essentially boils down to encouraging consumers to recycle more.

And it’s not just industry. Public service has come under the cosh too for chasing disproportionate green points. Take the case of South Tyneside council. Back in 2019, they got a bit of flack for their claim that local taxis were going green. An all-electric fleet? No. Fully biodegradable licence plates. Who knew licence plates could be made from biodegradable materials?

Even with the best intentions, when a company or institution can’t live up to its promises, it’s easy to slip into greenwashing in practice. And the problem is that greenwashing works because we want it to. Many environmental issues, such as climate change, are huge complicated beasts. It's easier to let others fix these big issues - we just want the problem to go away. So when a company appears to offer ‘sustainable’ solutions, we are sucked in by products and services that seem to be green. (A global survey in 2015 found that two thirds of consumers are happy to pay more for environmentally-friendly products. This rises to 72% for under 20s.) We’re busy people. We don’t want to read the small print.

As Dave Powell, co-presenter of Sustainababble podcast and the former Head of Environment at the New Economics Foundation, points out – "we're going to continue to be greenwashed, and to greenwash ourselves, because we want to do the right thing."

What is greenwashing?

Gone are the days of profit eclipsing all else. Social responsibility is now high up the agenda. The pressure is on to ‘be green’ from customers, employees, shareholders. It’s no wonder that some companies exaggerate their green practices - and others run the risk of ‘greenwashing’.

"Greenwashing involves companies either misleading consumers about the green credentials of a product or service, or misleading consumers about the environmental performance of the company as a whole,” says Brophy Haney. "Historically, big business has been able to get away with greenwashing because there has been limited understanding of what ‘green’ means, and a plethora of different definitions and certifications with little standardisation."

Joining the good guys

It’s wanting to do the right thing that makes us fall prey to another clever greenwashing trick - companies signing up to eco-initiatives which can mask the reality of their practices.

Forest in Poland

The Forest Stewardship Council (FSC) was set-up to provide a global tool for certifying sustainable wood. To qualify, a logging company needs to ensure harvesting maintains the forest's biodiversity, productivity and ecological processes, and they don’t generate financial profit at the expense of the forest resources, the ecosystem or affected communities. The FSC is an invaluable initiative - there are now over 200 million FSC certified hectares in 89 countries around the world. But, in the past, the FSC system has been abused. For example, in 2016, more than 90% of timber on two shipments from Peru to Mexico and the US was illegal in origin. The main exporter Inversiones La Oroza still has the FSC logo on its website, despite the FSC suspending its certification in 2017. There are other examples of illegal logging abuses.

There will always be some businesses willing to take advantage of sustainable initiatives. This is also the case with Sustainable Development Goals (SDGs). Four of the 17 SDGs laid out by the UN in 2015 focus directly on environmental issues: affordable and clean energy, climate action, life below water, and life on land. According to a 2018 report by the World Business Council for Sustainable Development, while 89% of companies analysed recognised the importance of SDGs, only 15% had done anything concrete about them, such as making sure their strategy tallies with specific SDG criteria and measuring their contributions to key SDGs. A 2018 KPMG report found similarly - while 40% recognised SDGs in their corporate reporting, only 8% reported a business case for action and only 10% had set specific and measurable business performance targets.

This all smells of greenwashing - or, more specifically, SDG-washing.

“SDGs and ‘net zero’ have kind of created an opportunity for a lot more greenwashing, because it allows you to describe yourself as a green company when you’re doing a thing that’s fundamentally not green,” says Powell. “You effectively buy your way out of trouble, for example, by promising to plant large numbers of trees.”

‘Net zero’ means not adding more greenhouse gases to the atmosphere than can be taken out. The UK government has committed to a legally-binding ‘net zero’ emissions target by 2050. Many countries have signed up, as have many companies.

Greenwashing is a way for companies to appear socially responsible while continuing to operate as they wish.

The environmental responsibility of companies

In 2020, AT&T committed to be carbon neutral across its entire global operations by 2035, signing up to net zero Scope 1 and 2 emissions. Microsoft went a step further, pledging to be carbon negative by 2030 and, by 2050, to remove from the environment all the carbon the company has put into the system since 1975 when it was founded. Shell laid out ambitious plans to hit net zero emissions by 2050, pledging zero Scope 1 and 2 emissions by 2050 or sooner, and slash the emissions intensity (emissions per unit of energy) of its Scope 3 energy products by 30% by 2035 and by 65% by 2050. In the UK supermarket sector, Sainsbury’s is aiming for net zero across its own operations by 2040, Tesco and Waitrose are aiming for 2050. Steps in the right direction. But these targets don’t extend to supermarket supply networks, which account for a large portion of emissions.

"There is still much work to be done in thinking about how far the environmental responsibility of companies extends into supply chains in different industries. Greenwashing still works on certain topics where data is more difficult to come by. But there is increasing clarity on how to measure the environmental impacts of companies, and of products and services,” says Brophy Haney.

"As part of their climate strategies, many companies are relying on voluntary carbon offsetting. However, if not done well, offsetting can result in greenwashing. To mitigate this risk, government and society at large should support the use of best practice guidelines, such as the recently released ‘Oxford Principles for Net Zero Aligned Carbon Offsetting’, to help ensure offsetting is done in a rigorous and credible way that ultimately contributes to net zero goals."

The next steps

Where once this issue seemed black and white, now many forms of greenwashing are more shades of grey.

“We think of greenwashing as an act of deliberate deceit. Make no mistake it can be, but things have moved on a bit from 20 years ago,” says Powell. “One man’s greenwashing is often another’s ‘pragmatic response’. And sometimes there might be legitimate disagreement.”

Some companies are attempting to tackle this by being open about the challenges of ensuring profitability in this new green era. For example, outdoor clothing retailer Patagonia is trying to be transparent with customers. It admits to using chemicals to create its products and acknowledges its struggle to remain a responsible company. (Patagonia’s revenue has quadrupled in the last decade).

“While a degree of scepticism is sensible in relation to green claims made by business, it is also important to give credit where it is due for companies that are sincerely trying to transition to low energy and low emission business models,” says Ed Simpkins, a partner at strategic communications agency Finsbury. “Reputation is important for most businesses and can be a driver of real change, so recognition for genuine efforts is as important as calling out greenwashing.”

Planet over Profit sign

Simpkins points out that, in the past, there was no cost attached to being wasteful with resources. Today, legislation means that it can be more cost effective to invest in green practises than to not do so.

“I work with one business that specialises in buying companies that have a comparative advantage compared with others in their sector, because they produce fewer emissions. These days, ‘being green’ is compatible with running a business in a sensible and cost-effective way.”

Indeed, there are all sorts of economic benefits for businesses ranging from cost savings from reducing carbon emissions in a company’s direct operations, to managing supply chain risks in response to extreme weather events. Long-term the main economic benefits are associated with identifying new market opportunities and shaping the way new markets operate.

“The critical challenge we face now across many industries is connecting individual technologies in ways that fundamentally shift patterns of production and consumption,” says Brophy Haney. “This is where rethinking business models can help, not by focusing on the solution per se, but by stepping back and focusing on what customers actually need now and in the future. Big business can help best by mobilising resources, talent and creativity to develop visions of a better future. Across many industries and systems, there is a lack of a collective vision for how things could change. Mobilising collaboration within and across industries is critical to ensure that any changes we make now are radical rather than incremental. Initiatives like the Climate Emergency Playbook by B Lab UK encourage companies to develop their own plans, and to reach out by sharing best practices and influencing stakeholders.”

Companies that can show over time that they make a positive impact in the world are companies that are going to be around for longer. We need business as unusual to solve these issues.

That’s exactly what Unilever has been up to for the last few years. When Paul Polman became CEO of the company back in 2009, he brought in with him a (what was at that time) quite radical idea for the business world. The vision: ‘to double the size of the company while reducing our overall impact on the environment’. Unilever committed to do this across their entire value chain. Recognising that this ambition was only achievable over the long-term, the company abolished quarterly reporting. The share price did initially go down by 8%, but then eventually it went back up. And, in the last decade, shareholder return was up 300%. In the process, Unilever has helped to influence industries and governments around the world, such as creating coalitions for net zero and the Tropical Forest Alliance for sustainable palm oil.

"Companies that can show over time that they make a positive impact in the world are companies that are going to be around [for longer]. We need business as unusual to solve these issues," said Polman, when he spoke to Peter Drobac, Director of the Skoll Centre for Social Entrepreneurship, at the University of Oxford on the Reimagine podcast. Polman left Unilever in 2019 to co-found IMAGINE - a collective made up of chief execs committed to rapidly scaling up corporate social responsibility efforts. “The current projection is that we will achieve the sustainable development goals only by 2071. So we're now not trying to convince people of what needs to be done, but to move forward faster at speed and scale. IMAGINE’s premise is to get 20-25% of an industry sector together to create a tipping point. Once you create a tipping point, you accelerate the implementation of sustainable development goals.”

Sweeping change

In 2020, for the first time ever, a clean energy group overtook a major oil company. The world’s largest solar and wind power generator NextEra exceeded ExxonMobil in stock market value. Meanwhile, Cambridge University recently agreed to step away from all direct and indirect investments in fossil fuels by 2030.

Pressure is building from all angles from competitors to consumers, environmentalists to employees. Legislators are scrambling to keep up. The EU is currently looking at how to integrate sustainability considerations into its financial policy framework so that it can free-up cash for sustainable growth. One of the main aims is to clamp down on greenwashing by forcing asset managers to provide transparent information about the sustainability of their investments. The new legislative framework is due to come into force in March 2021 (although asset managers are now being given more time to comply with new disclosure requirements).

In the last few years, the world has woken up to the fact that a society with diverging wealth equality and dwindling planetary resources is not sustainable. Many employees are now not willing to work for companies who do not employ sound sustainable practices. This global green awakening is causing a seismic shift in how companies do business.

“Awareness of the crisis has now fully taken hold of a generation of people – that was not the case 10 or 20 years ago,” says Davies. “Climate change is a top tier issue 'politically' for the first time ever. It gives me hope that no-one will get elected without being asked what their plan is on climate change. It also means that the fossil fuel companies will double down in terms of greenwashing to try to gain access to the policy arena.”

#### Greenwashing obstructs sustainable development – that kills our last chance to solve climate change

ClientEarth 21 – (ClientEarth is an environmental law charity, a company limited by guarantee, registered in England and Wales; research assistance from DeSmog. “The Greenwashing Files.” https://www.clientearth.org/projects/the-greenwashing-files/, last updated 25 March 2021 //ROBBIE)

It’s never been more urgent for companies everywhere to be more sustainable. Yet the ‘green’ advertising of those companies most responsible for climate change and environmental damage is misleading the public about their sustainability. To have an even chance of keeping global warming below catastrophic levels, we need to reduce carbon dioxide emissions to zero by mid-century. And by 2030, global emissions need to be half what they were in 2010. Too few fossil fuel companies are facing up to this reality. Many companies are responding to the climate crisis with ‘green’ marketing, while their core business remains fossil fuels. Their adverts are using greenwashing to distract the public from the harm their products cause to people and planet. Following our world-first complaint against BP’s advertising, we've investigated some of the world's biggest fossil fuel companies and uncovered the truth. Our Greenwashing Files highlight how advertising doesn’t always match up to reality. ClientEarth worked with environmental investigators DeSmog to conduct the following analysis: [interactive pages omitted] The problem with greenwashing Science tells us that if we burn the fossil fuel reserves that have already been found, odds are we are unlikely to keep warming below 1.5°C – the world’s aim under the Paris climate agreement. Studies show there are plans to produce 120% more fossil fuels by 2030 than is consistent with staying under this threshold. We simply cannot burn all the world’s stock of coal, oil and gas and hope to avoid climate disaster. Companies that are still pushing new fossil fuel exploration and projects cannot justify calling themselves 'sustainable' and cannot claim to be changing in line with society’s aims under the Paris Agreement goals. Yet companies’ marketing campaigns create the impression they are at the forefront of a rapid transitioning to low-carbon energy. And they are increasingly using social media to target younger audiences, including paying social media ‘influencers’. Some companies are doing more to grow low-carbon energy than others. But company marketing rarely reflects the full picture of their business strategy and investments. There may seem to be nothing wrong with companies highlighting ‘green’ projects. But these ads are a problem where they create a misleading impression of their overall business and its environmental harms. And the danger is that this obstructs the world’s efforts to move away from fossil fuels – thus endangering human rights across the world. Marketing campaigns can mislead the public on the true environmental cost of continuing to pump and use fossil fuels in the climate emergency. Unfortunately, if fossil fuel companies protect their business models in this way, then the science is clear: our planet and our societies face catastrophic consequences.

#### Warming outweighs other risks by a trillion times.

Ng ’19 [Yew-Kwang; May 2019; Professor of Economics at Nanyang Technology University, Fellow of the Academy of Social Sciences in Australia and Member of the Advisory Board at the Global Priorities Institute at Oxford University, Ph.D. in Economics from Sydney University; Global Policy, “Keynote: Global Extinction and Animal Welfare: Two Priorities for Effective Altruism,” vol. 10, no. 2, p. 258-266]

Catastrophic climate change

Though by no means certain, CCC causing global extinction is possible due to interrelated factors of non‐linearity, cascading effects, positive feedbacks, multiplicative factors, critical thresholds and tipping points (e.g. Barnosky and Hadly, [2016](https://onlinelibrary-wiley-com.proxy.lib.umich.edu/doi/full/10.1111/1758-5899.12647#gpol12647-bib-0005); Belaia et al., [2017](https://onlinelibrary-wiley-com.proxy.lib.umich.edu/doi/full/10.1111/1758-5899.12647#gpol12647-bib-0008); Buldyrev et al., [2010](https://onlinelibrary-wiley-com.proxy.lib.umich.edu/doi/full/10.1111/1758-5899.12647#gpol12647-bib-0016); Grainger, [2017](https://onlinelibrary-wiley-com.proxy.lib.umich.edu/doi/full/10.1111/1758-5899.12647#gpol12647-bib-0027); Hansen and Sato, [2012](https://onlinelibrary-wiley-com.proxy.lib.umich.edu/doi/full/10.1111/1758-5899.12647#gpol12647-bib-0029); IPCC [2014](https://onlinelibrary-wiley-com.proxy.lib.umich.edu/doi/full/10.1111/1758-5899.12647#gpol12647-bib-0031); Kareiva and Carranza, [2018](https://onlinelibrary-wiley-com.proxy.lib.umich.edu/doi/full/10.1111/1758-5899.12647#gpol12647-bib-0033); Osmond and Klausmeier, [2017](https://onlinelibrary-wiley-com.proxy.lib.umich.edu/doi/full/10.1111/1758-5899.12647#gpol12647-bib-0056); Rothman, [2017](https://onlinelibrary-wiley-com.proxy.lib.umich.edu/doi/full/10.1111/1758-5899.12647#gpol12647-bib-0066); Schuur et al., [2015](https://onlinelibrary-wiley-com.proxy.lib.umich.edu/doi/full/10.1111/1758-5899.12647#gpol12647-bib-0069); Sims and Finnoff, [2016](https://onlinelibrary-wiley-com.proxy.lib.umich.edu/doi/full/10.1111/1758-5899.12647#gpol12647-bib-0072); Van Aalst, [2006](https://onlinelibrary-wiley-com.proxy.lib.umich.edu/doi/full/10.1111/1758-5899.12647#gpol12647-bib-0079)).[7](https://onlinelibrary-wiley-com.proxy.lib.umich.edu/doi/full/10.1111/1758-5899.12647#gpol12647-note-1009_67)

A possibly imminent tipping point could be in the form of ‘an abrupt ice sheet collapse [that] could cause a rapid sea level rise’ (Baum et al., [2011](https://onlinelibrary-wiley-com.proxy.lib.umich.edu/doi/full/10.1111/1758-5899.12647#gpol12647-bib-0006), p. 399). There are many avenues for positive feedback in global warming, including:

* the replacement of an ice sea by a liquid ocean surface from melting reduces the reflection and increases the absorption of sunlight, leading to faster warming;
* the drying of forests from warming increases forest fires and the release of more carbon; and
* higher ocean temperatures may lead to the release of methane trapped under the ocean floor, producing runaway global warming.

Though there are also avenues for negative feedback, the scientific consensus is for an overall net positive feedback (Roe and Baker, [2007](https://onlinelibrary-wiley-com.proxy.lib.umich.edu/doi/full/10.1111/1758-5899.12647#gpol12647-bib-0065)). Thus, the Global Challenges Foundation ([2017](https://onlinelibrary-wiley-com.proxy.lib.umich.edu/doi/full/10.1111/1758-5899.12647#gpol12647-bib-0026), p. 25) concludes, ‘The world is currently completely unprepared to envisage, and even less deal with, the consequences of CCC’.

The threat of sea‐level rising from global warming is well known, but there are also other likely and more imminent threats to the survivability of mankind and other living things. For example, Sherwood and Huber ([2010](https://onlinelibrary-wiley-com.proxy.lib.umich.edu/doi/full/10.1111/1758-5899.12647#gpol12647-bib-0071)) emphasize the adaptability limit to climate change due to heat stress from high environmental wet‐bulb temperature. They show that ‘even modest global warming could … expose large fractions of the [world] population to unprecedented heat stress’ p. 9552 and that with substantial global warming, ‘the area of land rendered uninhabitable by heat stress would dwarf that affected by rising sea level’ p. 9555, making extinction much more likely and the relatively moderate damages estimated by most integrated assessment models unreliably low.

While imminent extinction is very unlikely and may not come for a long time even under business as usual, the main point is that we cannot rule it out. Annan and Hargreaves ([2011](https://onlinelibrary-wiley-com.proxy.lib.umich.edu/doi/full/10.1111/1758-5899.12647#gpol12647-bib-0004), pp. 434–435) may be right that there is ‘an upper 95 per cent probability limit for S [temperature increase] … to lie close to 4°C, and certainly well below 6°C’. However, probabilities of 5 per cent, 0.5 per cent, 0.05 per cent or even 0.005 per cent of excessive warming and the resulting extinction probabilities cannot be ruled out and are unacceptable. Even if there is only a 1 per cent probability that there is a time bomb in the airplane, you probably want to change your flight. Extinction of the whole world is more important to avoid by literally a trillion times.

## Solvency

#### Any approach but antitrust is incoherent – 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.

#### **Regs can’t address market-wide harms from false ads, only antitrust can**

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

[\*1844] False advertising law allows consumers to receive some redress for the money they paid for "unlimited" data that wasn't, 5 but there's no obvious remedy for the damage AT&T caused to the market as a whole. Antitrust law has been kneecapped by the courts and thus is powerless to act. In short, the law's neglect of the injuries caused by false advertising threatens structural harm to competitive markets.

In this Essay, we address these problems. We do so by focusing on the actors most likely to harm the market: monopolists and attempted monopolists. These actors are a numerically small percentage of businesses (and of false advertising defendants), but they can do great harm. Our emphasis on monopolists and attempted monopolists addresses courts' concerns of overbroad enforcement, preventing false advertising from morphing automatically into an antitrust violation. And it carves out a critical role for antitrust while embracing - rather than neglecting - antitrust's partner in fighting unfair competition, false advertising law.

We begin by introducing the laws of antitrust and false advertising, explaining the regimes' objectives and methods. We then survey the antitrust caselaw, critiquing three approaches courts considering false advertising claims have taken. Finally, we introduce our antitrust framework for false advertising claims. At the heart of the framework is a presumption that monopolists engaging in false advertising violate antitrust law, with that presumption rebuttable if the defendant can show that the false advertising was ineffective. The framework also applies to cases of attempted monopolization by incorporating factors (falsity, materiality, and harm) inherent in false advertising law, along with competition-centered issues on targeting new market entrants and entrenching barriers to entry. To illustrate how our framework should work, we apply it to an important area: advertising for biosimilars, which are pharmaceutical products with a substantial and growing role in treating numerous diseases.

False advertising that exacerbates monopoly power has been dismissed by antitrust law for too long. This Essay seeks to resolve the contradiction in the law by showing how false advertising threatens the proper functioning of markets.

#### Only robust penalty enforcement solves false ads – litigation and regulation fail

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The pharmaceutical industry has provided the setting for other examples of antitrust scrutiny of conduct that violates non-antitrust rules, particularly those relating to fraud. The Walker Process 121 line of cases holds that the fraudulent procurement of a patent or enforcement of a patent obtained by fraud can violate antitrust law. 122 Other cases involve the allegedly fraudulent [\*1869] listing of patents in the "Orange Book," 123 an annual compilation of drugs and their associated patents. 124 And courts have recognized antitrust liability when a brand company makes "repeated and allegedly false patent descriptions" to the FDA. 125

Despite these cases, one could conceivably argue that antitrust should not apply to actions that are also governed by a separate regulatory regime. In Verizon Communications v. Law Offices of Curtis V. Trinko, the Supreme Court indicated that where another regulatory regime is guaranteeing competition, there may not be a need for antitrust enforcement. 126 That case can only be fully understood, however, in relation to the industry in which it arose. The Court in the case was evaluating the Telecommunications Act, which provides the Federal Communications Commission ("FCC") with general - and effective - regulatory authority over the industry, including its competitive structure (e.g., restrictions on concentrated ownership and must-carry requirements). 127

Other settings require more robust antitrust enforcement. For example, the FDA has very specific authority over drugs and medical devices, but it does not pervasively regulate industry structure in the way that the FCC does. Instead, the FDA has concluded "that issues related to ensuring that marketplace actions are fair and do not block competition would be best addressed by the FTC, which is the Federal entity most expert in investigating and addressing anticompetitive business practices." 128 Much more similar to [\*1870] the FDA than FCC, false advertising regulation lacks the pervasive control and monitoring, including reporting requirements, of telecommunications law. 129

False advertising litigation cannot effectively stand in for the antitrust function. False advertising, unlike the FCC's jurisdiction, is broad rather than deep: it covers a wide variety of competitive situations, from mouthwash to specialized airline components, but only by barring falsity and deception rather than by pervasively dictating market structure. Of critical significance, moreover, false advertising law is itself underenforced. The FTC has substantial resource constraints. And consumers themselves are rarely able to sue for the harms they suffer. Consumer contracts typically contain mandatory arbitration provisions, making schemes like AT&T's market-shaping deception harder to fight. As a result, there is no "false advertising regime" that effectively fosters competition and negates the need for antitrust enforcement. 130