### OFF

Regulation CP

#### Text: The United States federal government should prohibit pay-for-delay and reverse payment settlements.

#### The counterplan PICs out of anti-trust legislation and the FTC and DOJ as enforcers---other agencies’ regulations solve.

Lawrence Fullerton et al. 08. Joel M Mitnick, William V Reiss, George C Karamanos and Owen H Smith. Sidley Austin LLP. Vertical Agreements The regulation of distribution practices in 34 jurisdictions worldwide. “United States.” https://www.sidley.com/-/media/files/publications/2008/03/getting-the-deal-through--vertical-agreements-2008/files/view-united-states-chapter/fileattachment/united-states-21.pdf

5 What entity or agency is responsible for enforcing prohibitions on anticompetitive vertical restraints? Do governments or ministers have a role?

The Federal Trade Commission (FTC) and the Antitrust Division of the Department of Justice (DoJ) are the two federal agencies responsible for the enforcement of federal antitrust laws. The FTC and the DoJ have jurisdiction to investigate many of the same types of conduct, and therefore have adopted a clearance procedure pursuant to which matters are handled by whichever agency has the most expertise in a particular area.

Additionally, other agencies, such as the Securities and Exchange Commission and Federal Communications Commission, maintain oversight authority over regulated industries pursuant to various federal statutes, and therefore may review vertical restraints for anti-competitive effects.

#### Prohibition solves the case.

Amy Klobuchar 13. Chair of the SUBCOMMITTEE ON ANTITRUST, COMPETITION POLICY AND CONSUMER RIGHTS OF THE COMMITTEE ON THE JUDICIARY, UNITED STATES SENATE, 7/23/13. “PAY-FOR-DELAY DEALS: LIMITING COMPETITION AND COSTING CONSUMERS.” https://www.judiciary.senate.gov/imo/media/doc/CHRG-113shrg87818.pdf

Now, this wasn’t always the case. From 2000 to 2004, after courts found these agreements to be illegal, there wasn’t a single pay-for-delay deal among the settlements entered into between brand and generic companies, not one, so pharmaceutical litigation can be settled without these cash sweeteners to delay generic com- petition.

### OFF

FTC DA

#### FTC’s increasing enforcement in privacy now---it’s focused on algorithmic bias.

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

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

#### Antitrust enforcement saps up FTC resources and personnel, which are finite.

Tara L. Reinhart, et al. 21. \*\*Head of Skadden, Arps, Slate, Meagher & Flom LLP’s Antitrust/Competition Group. \*\*Steven C. Sunshine, Co-head of Skadden, Arps, Slat, Meagher & Flom LLP’s Antitrust/Competition Group. \*\*David P. Whales, antitrust lawyer with over 25 years of experience in both private and public sectors. \*\*Julia Y. York, partner at Skadden, Arps, Slat, Meagher & Flom LLP. \*\*Bre Jordan, associate at Skadden, Arps, Slat, Meagher & Flom LLP focusing on antitrust law. “Lina Khan’s Appointment as FTC Chair Reflects Biden Administration’s Aggressive Stance on Antitrust Enforcement.” 6/18/21. https://www.skadden.com/insights/publications/2021/06/lina-khans-appointment-as-ftc-chair

Second, like all antitrust enforcers, Ms. Khan and the FTC will face resource constraints. Bringing antitrust litigation is an expensive and laborious process, often requiring millions of dollars for expert fees and a large army of FTC staff attorneys and taking many months or even years to accomplish. Typically, the FTC can only litigate a handful of antitrust matters at a time. It seems likely that Congress will provide more funding to the FTC in the current environment, but even with these extra resources, the FTC will still have to pick its cases carefully and cannot challenge every deal or every instance of alleged unlawful conduct.

#### That trades off with the necessary resources for privacy enforcement.

John O. McGinnis\* and Linda Sun\*\* 20. \*George C. Dix Professor, Northwestern University, and Associate-Designate, Wilmer Pickering Hale & Dorr LLP. “Unifying Antitrust Enforcement for the Digital Age.” Northwestern Public Law Research Paper No. 20-20. https://papers.ssrn.com/sol3/papers.cfm?abstract\_id=3669087

The FTC needs more resources to adequately address the nation’s growing privacy concerns. Currently, the FTC oversees both consumer protection—encompassing privacy—and antitrust,249 making the FTC the chief federal agency on privacy policy and enforcement250 and the nation’s de-facto privacy agency.251 The agency has long-standing experience in enforcing privacy statutes252 and also has special privacy assets, such as an internet lab capable of high-quality tech forensics to track invasions of privacy.253 The FTC, however, has failed to keep pace with the massive growth of privacy concerns—a phenomenon also driven by modern technology. Very few Americans feel conﬁdent in the privacy of their information in the digital age.254 According to a 2019 study, over 80% of Americans feel that they have little to no control over the data collected on them by companies and the government.255 To adequately address privacy concerns, the FTC needs more resources.256 The agency has been explicit that it needs more manpower to police tech companies. In requesting increased funding from Congress, FTC Director Joseph Simons said the money would allow the agency to hire additional staff and bring more privacy cases.257 A former director of the FTC’s Bureau of Consumer Protection, which houses the privacy unit, has called the FTC “woefully understaffed.”258 As of the spring of 2019, the FTC had only forty employees dedicated to privacy and data security, compared to 500 and 110 employees at comparable agencies in the UK. and Ireland, respectively.259 Without more lawyers, investigators, and technologists, the FTC will be forced to conduct privacy investigations less thoroughly, and in some cases, forgo them altogether.260 Currently, the FTC’s resources are spread thin across multiple missions, to the detriment of its privacy efforts. Removing the agency’s antitrust responsibilities would reallocate resources from the antitrust department to its privacy unit and other areas of consumer protection. Further, it would free up the scarce time of the commissioners to oversee this essential effort.261

#### Unchecked algorithmic bias risks massive inequality and extinction.

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

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

### \*OFF

States CP

#### The fifty states and all relevant territories should prohibit anticompetitive settlements related to pharmaceutical patents.

### OFF

Politics DA

#### Will pass now- Biden pressure and timing key

Shannon Pettypiece, 10-14-2021, "White House pushing Congress to reach deal on spending bill soon," NBC News, https://www.nbcnews.com/politics/white-house/white-house-pushing-congress-reach-spending-bill-deal-soon-n1281567

White House officials are signaling to Congress that the time is running short for negotiations over President Joe Biden's infrastructure and social spending packages and that they want a deal to get done quickly.

A person familiar with the White House's thinking said that while Biden believes good progress has been made in negotiations, he thinks it is crucial to pass the bills soon, and officials are pushing members to do so.

White House press secretary Jen Psaki said Thursday, "The time for negotiations is not unending, and we are eager to move forward, we are eager to deliver on what he promised to the American people." She said that the White House wasn't setting any deadlines but that "it is time to move forward with negotiations."

#### Antitrust reform requires PC and trades off with other legislative priorities.

Peter C. Carstensen 21, the Fred W. & Vi Miller Chair in Law Emeritus, University of Wisconsin Law School, February 2021, “THE “OUGHT” AND “IS LIKELY” OF BIDEN ANTITRUST,” https://www.concurrences.com/en/review/issues/no-1-2021/on-topic/the-new-us-antitrust-administration-en

14. Similarly, despite bipartisan murmurs about competitive issues, the potential in a closely divided Congress that any major initiatives will survive is limited at best. In part the challenge here is how the Biden administration will rank its commitments. If it were to make reform of competition law a major and primary commitment, it would have to trade off other goals, which might include health care reform or increases in the minimum wage. It is likely in this circumstance the new administration, like the Obama administration’s abandonment of the pro-competitive rules proposed under the PSA, would elect to give up stricter competition rules in order to achieve other legislative priorities.

15. Another key to a robust commitment to workable competition is the choice of cabinet and other key administrative positions. Here as well, the early signs are not entirely encouraging. In selecting Tom Vilsack to return as secretary of agriculture, the president has embraced a friend of the large corporate interests dominating agriculture who has spent the last four years in a highly lucrative position advancing their interests. Given the desperate need for pro-competitive rules to implement the PSA and control exploitation of dairy farmers through milk-market orders, the return of Vilsack is not good news. Who will head the FTC and who will be the attorney general and assistant attorney general for antitrust is still unknown, but if those picks are also centrists with strong links to corporate America the hope for robust enforcement of competition law will further attenuate!

16. In sum, this is a pessimistic prognostication for the likely Biden antitrust enforcement agenda. There is much that ought to be done. But this requires a willingness to take major enforcement risks, to invest significant political capital in the legislative process, and to select leaders who are committed to advancing the public interest in fair, efficient and dynamically competitive markets. The early signs are that the new administration will be no more committed to robust competition policy than the Obama administration. Events may force a more vigorous policy—I will cling to that hope as the Biden administration takes shape.

#### Infrastructure bill key to cyber security

Cat Zakrzewski, 8-14-2021, "The Senate’s $1 trillion infrastructure bill includes funding to secure Americans’ water systems and power grids from cyberattacks," https://www.washingtonpost.com/technology/2021/08/14/cybersecurity-infrastructure-senate-legislation/

A Senate bill intended to shore up the nation’s roads, pipes and electric grid includes billions to protect that aging infrastructure from cyberattacks.

With a series of high-profile ransomware attacks fresh in their minds, U.S. Senate negotiators wove cybersecurity investments throughout the bipartisan $1 trillion infrastructure proposal, which passed the Senate in a 69-to-30 vote on Tuesday and now moves to the House for a vote. The allocations are a reflection of the growing realization in Congress that a computer attack could leave Americans without water, power or other essentials.

“This is an incredibly serious threat to this country that’s only growing more serious,” said Sen. Angus King (I-Maine).

The Colonial Pipeline ransomware attack in May was a wake-up call that gave lawmakers and the public “a taste of what is potentially in store,” King said. The attack disrupted fuel supplies in the eastern United States, prompting gasoline shortages and panicked buying that affected millions for days.

The Colonial hack was just one in a series of attacks on lawmakers’ minds. King said he is particularly wary of attacks on the more than 100,000 public water systems in the United States, especially after a hacker in February took control of a water treatment facility in Oldsmar, Fla. The intruder raised the levels of sodium hydroxide to a hazardous point that could have sickened residents. An operator noticed the rising levels and was able to quickly intervene, but the incident highlighted the broader weaknesses at the facilities responsible for ensuring Americans have clean drinking water.

To King, one of the Senate negotiators, these incidents underlined that cybersecurity has to be a part of any work the government does on infrastructure, from broadband to power grids.

The bill directs the Federal Highway Administration to create a new tool to help transportation authorities better detect and respond to cyber attacks, which could range from ransomware attacks on transportation departments or hacks of traffic lights and road signs. It makes emergency funding available to respond to digital attacks on public water systems and makes grants available that can be used to help some water systems increase their ability to deal with cyberattacks as well as natural hazards and extreme weather.

It also calls on the Federal Energy Regulatory Commission to develop incentives to ensure that electric utilities are investing in cybersecurity and sharing data about potential threats.

The bill also authorizes nearly $2 billion in spending for specific cybersecurity initiatives, such as the creation of a $1 billion grant program to provide federal cybersecurity assistance to state and local governments, which experts say are among the most vulnerable institutions to ransomware attacks. The bill also would fund a new cyber director office, so that the federal government can better coordinate its response to major hacks, and would create a $100 million response and recovery fund, which the Department of Homeland Security could use to support both private companies and governments’ recoveries from cyberattacks.

The infusion of funding follows years of warnings from across the federal government of the vulnerability of U.S. critical infrastructure to cyberattacks. A year ago, the National Security Agency and the Cybersecurity and Infrastructure Security Agency warned that critical infrastructure systems, including energy, transportation and water systems, make “attractive targets for foreign powers attempting to do harm to U.S. interests or retaliate for perceived U.S. aggression.”

#### Cyberattacks go nuclear.

Michael T. Klare 19. Professor emeritus of peace and world security studies at Hampshire College and senior visiting fellow at the Arms Control Association. “Cyber Battles, Nuclear Outcomes? Dangerous New Pathways to Escalation.” https://www.armscontrol.org/act/2019-11/features/cyber-battles-nuclear-outcomes-dangerous-new-pathways-escalation

Another initiative incorporated in the strategy document also aroused concern: the claim that an enemy cyberattack on U.S. nuclear command, control, and communications (NC3) facilities would constitute a “non-nuclear strategic attack” of sufficient magnitude to justify the use of nuclear weapons in response.

Under the Obama administration’s NPR report, released in April 2010, the circumstances under which the United States would consider responding to non-nuclear attacks with nuclear weapons were said to be few. “The United States will continue to…reduce the role of nuclear weapons in deterring non-nuclear attacks,” the report stated. Although little was said about what sort of non-nuclear attacks might be deemed severe enough to justify a nuclear response, cyberstrikes were not identified as one of these. The 2018 NPR report, however, portrayed a very different environment, one in which nuclear combat is seen as increasingly possible and in which non-nuclear strategic threats, especially in cyberspace, were viewed as sufficiently menacing to justify a nuclear response. Speaking of Russian technological progress, for example, the draft version of the Trump administration’s NPR report stated, “To…correct any Russian misperceptions of advantage, the president will have an expanding range of limited and graduated [nuclear] options to credibly deter Russian nuclear or non-nuclear strategic attacks, which could now include attacks against U.S. NC3, in space and cyberspace.”1

The notion that a cyberattack on U.S. digital systems, even those used for nuclear weapons, would constitute sufficient grounds to launch a nuclear attack was seen by many observers as a dangerous shift in policy, greatly increasing the risk of accidental or inadvertent nuclear escalation in a crisis. “The entire broadening of the landscape for nuclear deterrence is a very fundamental step in the wrong direction,” said former Secretary of Energy Ernest Moniz. “I think the idea of nuclear deterrence of cyberattacks, broadly, certainly does not make any sense.”2

Despite such admonitions, the Pentagon reaffirmed its views on the links between cyberattacks and nuclear weapons use when it released the final version of the NPR report in February 2018. The official text now states that the president must possess a spectrum of nuclear weapons with which to respond to “attacks against U.S. NC3,” and it identifies cyberattacks as one form of non-nuclear strategic warfare that could trigger a nuclear response.

That cyberwarfare had risen to this level of threat, the 2018 NPR report indicated, was a product of the enhanced cybercapabilities of potential adversaries and of the creeping obsolescence of many existing U.S. NC3 systems. To overcome these vulnerabilities, it called for substantial investment in an upgraded NC3 infrastructure. Not mentioned, however, were extensive U.S. efforts to employ cybertools to infiltrate and potentially incapacitate the NC3 systems of likely adversaries, including Russia, China, and North Korea.

For the past several years, the U.S. Department of Defense has been exploring how it could employ its own very robust cyberattack capabilities to compromise or destroy enemy missiles from such states as North Korea before they can be fired, a strategy sometimes called “left of launch.”3 Russia and China can assume, on this basis, that their own launch facilities are being probed for such vulnerabilities, presumably leading them to adopt escalatory policies such as those espoused in the 2018 NPR report. Wherever one looks, therefore, the links between cyberwar and nuclear war are growing.

The Nuclear-Cyber Connection

These links exist because the NC3 systems of the United States and other nuclear-armed states are heavily dependent on computers and other digital processors for virtually every aspect of their operation and because those systems are highly vulnerable to cyberattack. Every nuclear force is composed, most basically, of weapons, early-warning radars, launch facilities, and the top officials, usually presidents or prime ministers, empowered to initiate a nuclear exchange. Connecting them all, however, is an extended network of communications and data-processing systems, all reliant on cyberspace. Warning systems, ground- and space-based, must constantly watch for and analyze possible enemy missile launches. Data on actual threats must rapidly be communicated to decision-makers, who must then weigh possible responses and communicate chosen outcomes to launch facilities, which in turn must provide attack vectors to delivery systems. All of this involves operations in cyberspace, and it is in this domain that great power rivals seek vulnerabilities to exploit in a constant struggle for advantage.

The use of cyberspace to gain an advantage over adversaries takes many forms and is not always aimed at nuclear systems. China has been accused of engaging in widespread cyberespionage to steal technical secrets from U.S. firms for economic and military advantages. Russia has been accused, most extensively in the Robert Mueller report, of exploiting cyberspace to interfere in the 2016 U.S. presidential election. Nonstate actors, including terrorist groups such as al Qaeda and the Islamic State group, have used the internet for recruiting combatants and spreading fear. Criminal groups, including some thought to be allied with state actors, such as North Korea, have used cyberspace to extort money from banks, municipalities, and individuals.4 Attacks such as these occupy most of the time and attention of civilian and military cybersecurity organizations that attempt to thwart such attacks. Yet for those who worry about strategic stability and the risks of nuclear escalation, it is the threat of cyberattacks on NC3 systems that provokes the greatest concern.

This concern stems from the fact that, despite the immense effort devoted to protecting NC3 systems from cyberattack, no enterprise that relies so extensively on computers and cyberspace can be made 100 percent invulnerable to attack. This is so because such systems employ many devices and operating systems of various origins and vintages, most incorporating numerous software updates and “patches” over time, offering multiple vectors for attack. Electronic components can also be modified by hostile actors during production, transit, or insertion; and the whole system itself is dependent to a considerable degree on the electrical grid, which itself is vulnerable to cyberattack and is far less protected. Experienced “cyberwarriors” of every major power have been working for years to probe for weaknesses in these systems and in many cases have devised cyberweapons, typically, malicious software (malware) and computer viruses, to exploit those weaknesses for military advantage.5

Although activity in cyberspace is much more difficult to detect and track than conventional military operations, enough information has become public to indicate that the major nuclear powers, notably China, Russia, and the United States, along with such secondary powers as Iran and North Korea, have established extensive cyberwarfare capabilities and engage in offensive cyberoperations on a regular basis, often aimed at critical military infrastructure. “Cyberspace is a contested environment where we are in constant contact with adversaries,” General Paul M. Nakasone, commander of the U.S. Cyber Command (Cybercom), told the Senate Armed Services Committee in February 2019. “We see near-peer competitors [China and Russia] conducting sustained campaigns below the level of armed conflict to erode American strength and gain strategic advantage.”

Although eager to speak of adversary threats to U.S. interests, Nakasone was noticeably but not surprisingly reluctant to say much about U.S. offensive operations in cyberspace. He acknowledged, however, that Cybercom took such action to disrupt possible Russian interference in the 2018 midterm elections. “We created a persistent presence in cyberspace to monitor adversary actions and crafted tools and tactics to frustrate their efforts,” he testified in February. According to press accounts, this included a cyberattack aimed at paralyzing the Internet Research Agency, a “troll farm” in St. Petersburg said to have been deeply involved in generating disruptive propaganda during the 2016 presidential elections.6

Other press investigations have disclosed two other offensive operations undertaken by the United States. One called “Olympic Games” was intended to disrupt Iran’s drive to increase its uranium-enrichment capacity by sabotaging the centrifuges used in the process by infecting them with the so-called Stuxnet virus. Another left of launch effort was intended to cause malfunctions in North Korean missile tests.7 Although not aimed at either of the U.S. principal nuclear adversaries, those two attacks demonstrated a willingness and capacity to conduct cyberattacks on the nuclear infrastructure of other states.

Efforts by strategic rivals of the United States to infiltrate and eventually degrade U.S. nuclear infrastructure are far less documented but thought to be no less prevalent. Russia, for example, is believed to have planted malware in the U.S. electrical utility grid, possibly with the intent of cutting off the flow of electricity to critical NC3 facilities in the event of a major crisis.8 Indeed, every major power, including the United States, is believed to have crafted cyberweapons aimed at critical NC3 components and to have implanted malware in enemy systems for potential use in some future confrontation.

Pathways to Escalation

Knowing that the NC3 systems of the major powers are constantly being probed for weaknesses and probably infested with malware designed to be activated in a crisis, what does this say about the risks of escalation from a nonkinetic battle, that is, one fought without traditional weaponry, to a kinetic one, at first using conventional weapons and then, potentially, nuclear ones? None of this can be predicted in advance, but those analysts who have studied the subject worry about the emergence of dangerous new pathways for escalation. Indeed, several such scenarios have been identified.9

The first and possibly most dangerous path to escalation would arise from the early use of cyberweapons in a great power crisis to paralyze the vital command, control, and communications capabilities of an adversary, many of which serve nuclear and conventional forces. In the “fog of war” that would naturally ensue from such an encounter, the recipient of such an attack might fear more punishing follow-up kinetic attacks, possibly including the use of nuclear weapons, and, fearing the loss of its own arsenal, launch its weapons immediately. This might occur, for example, in a confrontation between NATO and Russian forces in east and central Europe or between U.S. and Chinese forces in the Asia-Pacific region.

Speaking of a possible confrontation in Europe, for example, James N. Miller Jr. and Richard Fontaine wrote that “both sides would have overwhelming incentives to go early with offensive cyber and counter-space capabilities to negate the other side’s military capabilities or advantages.” If these early attacks succeeded, “it could result in huge military and coercive advantage for the attacker.” This might induce the recipient of such attacks to back down, affording its rival a major victory at very low cost. Alternatively, however, the recipient might view the attacks on its critical command, control, and communications infrastructure as the prelude to a full-scale attack aimed at neutralizing its nuclear capabilities and choose to strike first. “It is worth considering,” Miller and Fontaine concluded, “how even a very limited attack or incident could set both sides on a slippery slope to rapid escalation.”10

What makes the insertion of latent malware in an adversary’s NC3 systems so dangerous is that it may not even need to be activated to increase the risk of nuclear escalation. If a nuclear-armed state comes to believe that its critical systems are infested with enemy malware, its leaders might not trust the information provided by its early-warning systems in a crisis and might misconstrue the nature of an enemy attack, leading them to overreact and possibly launch their nuclear weapons out of fear they are at risk of a preemptive strike.

“The uncertainty caused by the unique character of a cyber threat could jeopardize the credibility of the nuclear deterrent and undermine strategic stability in ways that advances in nuclear and conventional weapons do not,” Page O. Stoutland and Samantha Pitts-Kiefer wrote in 2018 paper for the Nuclear Threat Initiative. “[T]he introduction of a flaw or malicious code into nuclear weapons through the supply chain that compromises the effectiveness of those weapons could lead to a lack of confidence in the nuclear deterrent,” undermining strategic stability.11 Without confidence in the reliability of its nuclear weapons infrastructure, a nuclear-armed state may misinterpret confusing signals from its early-warning systems and, fearing the worst, launch its own nuclear weapons rather than lose them to an enemy’s first strike. This makes the scenario proffered in the 2018 NPR report, of a nuclear response to an enemy cyberattack, that much more alarming.

### OFF

Cap K

#### Anti-trust is a psy op to restore the prestige of capital and cover for union busting. Vote neg for socialist governance that refuses faith in smaller is better.

Henwood 21 [Doug, American journalist, economic analyst, author, and financial trader, contributor to the Nation. “Why Socialists Should Distrust Antitrust.” Jacobin. July 2021. <https://www.jacobinmag.com/2021/07/antitrust-law-monopolies-small-business-competition-large-corporations-bigness> //shree]

Last week, Joe Biden tweeted, “Let me be clear: capitalism without competition isn’t capitalism. It’s exploitation.”

It would be too much to expect this rather dim politician to understand, much less endorse, the classic Marxist analysis of profit originating in the exploitation of workers — they produce more in value for their employer than they’re paid in wages. But the remark, in all its naiveté, does capture a spreading belief in liberal policy circles that monopoly is at the heart of our economic troubles, from crappy jobs to crappy pay and benefits. I’m not convinced.

According to the introductory economics I learned in college — which was admittedly long ago — two essential features of monopolized markets were high prices and restricted supply. Those features weren’t at all visible in the US economy until the pandemic began messing with supply chains, resulting in short supplies in some sectors in the face of pent-up demand, demand that was supercharged with stimulus checks.

Even so, the shortages and price spikes are affecting just a few sectors, like new cars and lumber. They’ve yet to spread economy-wide, and there’s no sign they’re about to. They’re not the product of some long-term monopolization. For most of the last forty years, inflation has been quite low — in no small part because the working class was crushed as the 1970s turned into the 1980s and because shortages have been rare.

The giants that people point to as proof of our monopoly problem include Amazon, Google, and Facebook. Amazon, like Walmart before it, is known for low prices that crush competitors. (Workers too.) That’s not standard monopoly behavior. Google and Facebook dominate their fields, but most of their “products” are free. Yes, that means “you’re the product,” as the saying goes, but what kind of improvement would it be if broken-up Googles and Facebooks charged for their services or maintained the same monetizing-the-user’s-identity business model as the originals?

Nor is it clear how introducing competition would improve the quality of service. One of the lures of Facebook, for those subject to the lure, close to three billion users at the most recent count, is that so many people are on it. That facilitates communication. Breaking it up into competing services would be like making an AT&T phone customer incapable of contacting a Deutsche Telekom subscriber.

Behind antitrust is a faith in competition as a positive good. As socialists we should take exception to that. We already have too much competitive individualism in this society, and we don’t need any more. We need solidarity. Stimulating the war of each against all isn’t the way to get there.

A better way to handle bigness is to regulate the behemoths and encourage the growth of unions. That would do more to improve working conditions at Amazon than turning it into four or twenty little Amazons. As political economist Sam Gindin pointed out in an interview on my radio show, the deregulation movement of the 1970s and 1980s was a war on regulated oligopolies, and it was accompanied by union busting, wage cuts, and job losses. That could be a portent of life under monopoly busting.

Why is antitrust getting the attention of liberals these days? In his book on the history of American corporate governance, law professor Mark Roe notes that Franklin Roosevelt saw it as a war against “private” socialism that could stave off “government” socialism. We may be seeing something similar now. With socialism polling decently, socialists working their way into the Democratic Party, and the business class in disrepute with much of the population — Gallup reports that 73 percent of the public is either somewhat or very dissatisfied with major corporations, compared to 48 percent in 2001 — pursuing antitrust may be a campaign to restore the prestige of capitalism itself. Fronting small business as the emblem of commerce is a classic bourgeois self-defense strategy.

There’s nothing magic about smallness. Vincent Carosso ends his huge book on the Morgan banking family by quoting an unnamed socialist refusing to curse the peak Morgan, J. P., on his death: “We grieve that he could not live longer, to further organize the productive forces of the world, because he proved in practice what we hold in theory, that competition is not essential to trade and development.” It’s a sentiment worth recovering.

#### Capitalism drives extinction and structural violence

Allinson et al 21 [Jamie Allinson is Senior Lecturer in Politics and International Relations at Edinburgh University and author of The Age of Counter-revolution. China Miéville is the author of a number of highly acclaimed and prize-winning novels including October: The History of the Russian Revolution. Richard Seymour is the author of numerous works of non-fiction, His writing appears in the New York Times, London Review of Books, Guardian, Prospect, Jacobin. Rosie Warren is an Editor at Verso and the Editor-in-Chief of Salvage. All are writing for the Salvage Collective. “The Tragedy of the Worker: Toward the Proletarocene.” Introduction. July 2021. Verso EBook. ISBN: 9781839762963 //shree]

This is the question that vexed us as we set out to write The Tragedy of the Worker. From the vantage point of the present, the history of capitalist development is, as Marx expected, the history of the development of a global working class, the proletarianisation of the majority of the world’s population. But the very same process of that development has brought us to the precipice of climate disaster. Our position, to recall Trotsky’s rationalisation of War Communism in 1920, is in the highest degree tragic.

It is now clear that we will pass what scientists have long warned will be a tipping point of global warming, accelerating the already catastrophic consequences of capitalist emissions. How do we imagine emancipation on an at best partially habitable planet? Where once communists imagined seizing the means of production, taking the unprecedented capacities of capitalist infrastructures and using them to build a world of plenty, what must we imagine after the apocalypse has befallen us? What does it mean that as capitalism has become truly global, the gravediggers it has created dig not only capitalism’s grave, but also that of much organic life on earth?

Our answers to these questions remain rooted in the politics of revolutionary communism. Our stance is not based on the fantasy of a homeostatic nature that must be defended but on the critique of the capitalist metabolism – the Stoffwechsel- that must be overthrown. Earth scientists are accustomed to speak in terms of ‘cycles’ by which substances circulate in different forms: the water cycle, the rock cycle, the nitrogen cycle, the glacial-interglacial cycle, the carbon cycle, and others. One way of registering the catastrophe of climate change is to see these cycles – most of all, but not solely, the carbon cycle – as disordered, under- or over-accumulating. But this is to ignore the more fundamental circuit of which these now form epicycles, like Ptolemy’s sub-orbits of the heavenly bodies: the circuit of capital accumulation, M-C-M′.

This circuit accumulates profit and produces death. Neither is accidental. It is for this reason that the debates that capitalist ruling classes permit among themselves on ‘adaptation’ versus ‘mitigation’ take place on false premises. What is to be mitigated is the impact of climate change on accumulation, rendered through the ideology of ‘growth’ as something that benefits everyone. What we are to adapt to are the parameters of accumulation, sacrificing just enough islands, eco-systems, indigenous – and non-indigenous – cultures to maintain its imperatives for a period of time until new thresholds must be crossed, and new life sacrificed to the pagan idol of capital. Already, capitalist petro-modernity builds a certain quantum of acceptable death into its predicates: at the very least, the 8.7 million killed by fossil fuels each year according to Harvard University are considered a price worth paying for the stupendous advantages of fossil capital. And the sky can only keep going up, as deforestation, polar melt, ocean acidification, soil de-fertilisation and more intense wildfires and storms tear the web of life into patches. If the necropolitical calculus of the Covid-19 pandemic appears crass, just wait until its premises are applied to climate catastrophe.

### \*OFF

Rulemaking CP

#### Text: The United States federal government should delegate antitrust rulemaking authority to a new expert agency. The agency should begin notice-and-comment rulemaking to prohibit anticompetitive settlements related to pharmaceutical patents.

#### Solves the case, engages notice and comment.

Rebecca Haw 11. Climenko Fellow and Lecturer on Law, Harvard Law School. J.D., Harvard Law School, 2008; M. Phil, Cambridge University, 2005; B.A., Yale University, 2001."Amicus Briefs and the Sherman Act: Why Antitrust Needs a New Deal." Texas Law Review, vol. 89, no. 6, May 2011, p. 1247-1292. HeinOnline.

Without the informational benefits of expertise and notice-and-comment rulemaking, the Court may be a poor choice to define the broad proscriptions of the Sherman Act. Framed this way, the problem has an obvious solution: give the power to interpret the Act to an expert agency.240 This idea has academic support already, 241 and the case for it is strengthened by this Article's observation that the Court has tried to approximate administrative decision making by relying on amicus briefs. The obvious candidates for reallocation are the two existing antitrust agencies: the Department of Justice's Antitrust Division and the FTC.

A. The Agency Solution

Using agencies to give specific meaning to American antitrust's most important statute means avoiding the problems with the Court's current quasi-administrative process for rulemaking. As adjudicators, agency experts would know what kind of economic evidence is necessary for an efficient solution and would be better able to understand it when it is presented by the parties. Repeat exposure to antitrust cases would only reinforce this advantage, while also giving the administrative judges a broader perspective on what kinds of conflicts commonly arise in competition law, a perspective necessary for efficient policy making in the first instance. A Supreme Court Justice hears about one antitrust case a year, hardly the cross section of controversies necessary to make efficient economic policy writ large.

Agencies could take policy making a step further using notice-and-comment rulemaking. Unlike in adjudication, regulation by rulemaking can be initiated without the formal requirements of a case or controversy and a proper appeal to the Supreme Court. Informal letters of complaint could spark an investigation. A rule-making agency could announce its intention to regulate publicly and provide a convenient venue for, or even solicit, expert opinions on the economic impact of the proposed rule. Not only would it have the benefit of these numerous perspectives, but it would also have the obligation to respond to them in a reasoned manner. Its rule would be subject to judicial review, affording an opportunity to catch mistakes 242 or invalidate rules that do nothing but deliver rents to special interests.

Another advantage of rulemaking, an option for agencies but not for the Court, since it only operates through adjudication, is that rulemaking regulates behavior ex ante, while resolution of economic policy through cases is necessarily ex post. Antitrust courts worry obsessively about "chill"--deterring procompetitive behavior with overly broad rules for liability.2 43 In fact, the overruling of Dr. Miles in Leegin implies that the entire twentieth century was a period of inefficient business practices and stunted innovation in distribution because of an early misunderstanding of RPM. Only after a long and expensive period of litigation was Leegin redeemed for breaking the law by effecting a change in the law, and only after Leegin was issued were similar firms, perhaps walking the Colgate line better than Leegin, redeemed for wanting some control over their product's ultimate retail price.24 4 The problem of ex post rulemaking is made worse by the treble damages afforded successful plaintiffs suing under the Sherman Act.2 4 5 To create a new form of liability, the Court has to punish a firm threefold for complying with standing antitrust norms. Thus Supreme Court lawmaking in antitrust is a kind of one-way ratchet.246

The result of the current ex post scheme is that "antitrust law leaves considerable gaps between what is permissible and what is optimal." 2 47 With judges making the rules one case at a time, this gap is justifiable. As discussed above, when judges are not economically sophisticated enough to know where "optimal" lies, 24 8 laissez-faire is a very inexpensive regulatory regime for courts to follow, and raising the level of regulation would effect a kind of taking of property from firms operating under the status quo. So if the Court is making antitrust policy, laissez-faire may be the only sensible approach. But that is not to say that it is the most sensible approach. An agency could provide firms with the necessary clarity-ex ante-that they need when conducting business in a world where competitive behavior so closely resembles anticompetitive conduct. The current state of affairs is that much more is illegal on the books than antitrust lawyers think is actually likely to be struck down in a court.24 9 Lawyers thrive in such a legally uncertain world, but firm efficiency suffers.

#### Key to democracy and court acquiescence---notice and comment engages participants and creates deference.

Harry First and Spencer Weber Waller 13. Harry First, New York University School of Law. Spencer Weber Waller, Loyola University Chicago School of Law. “Antitrust’s Democracy Deficit”. Fordham Law Review, Volume 81 Issue 5 Article 13. https://ir.lawnet.fordham.edu/cgi/viewcontent.cgi?article=4890&context=flr

Redressing antitrust’s democracy deficit on the procedural side can be done with the tools of administrative law. Administrative law is the body of law that controls the procedures of governmental decision making.151 It allows interested persons to participate in decisions that affect their interests. Normally, it requires appropriate notice, the right to be heard, fair procedures, protection of fundamental rights, and judicial review of the resulting decision. These basic features are present in the administrative laws of most foreign legal systems and are part of a growing international consensus.152 The tradeoff is that the decisions of administrative agencies that properly follow these strictures normally are granted a degree of deference as to the interpretation of the laws they enforce.153 Frequently, but not inevitably, private parties also have the right to proceed with actions for damages against private parties who violate their regulatory obligations and even against the government itself when it acts unlawfully, either substantively or procedurally. These tools of administrative law are available to make antitrust enforcement decisions more transparent and more responsive to the interests that the antitrust laws were meant to serve, thereby promoting both better decision making and greater democratic legitimacy.

CONCLUSION

Free markets and free people cannot be assured by the efforts of technocrats. Ultimately, both come about through the workings of democratic institutions, respectful of the legislature’s goals and constrained from engaging in arbitrary action. Antitrust has moved too far from democratic institutions and toward technocratic control, in service to a laissez-faire approach to antitrust enforcement. We need to move the needle back. Doing so will strengthen the institutions of antitrust, the market economy, and the democratic branches of government themselves.

#### US democratic retreat causes terrorism, great power war, famine, and poverty.

Garry Kasparov 17. Chairman of the Human Rights Foundation, founded the Renew Democracy Initiative. “Democracy and Human Rights: The Case for U.S. Leadership”. Feb 16 2017. U.S. Senate. http://www.foreign.senate.gov/imo/media/doc/021617\_Kasparov\_%20Testimony.pdf

The Soviet Union was an existential threat, and this focused the attention of the world, and the American people. There existential threat today is not found on a map, but it is very real. The forces of the past are making steady progress against the modern world order. Terrorist movements in the Middle East, extremist parties across Europe, a paranoid tyrant in North Korea threatening nuclear blackmail, and, at the center of the web, an aggressive KGB dictator in Russia. They all want to turn the world back to a dark past because their survival is threatened by the values of the free world, epitomized by the United States. And they are thriving as the U.S. has retreated. The global freedom index has declined for ten consecutive years. No one like to talk about the United States as a global policeman, but this is what happens when there is no cop on the beat. American leadership begins at home, right here. America cannot lead the world on democracy and human rights if there is no unity on the meaning and importance of these things. Leadership is required to make that case clearly and powerfully. Right now, Americans are engaged in politics at a level not seen in decades. It is an opportunity for them to rediscover that making America great begins with believing America can be great. The Cold War was won on American values that were shared by both parties and nearly every American. Institutions that were created by a Democrat, Truman, were triumphant forty years later thanks to the courage of a Republican, Reagan. This bipartisan consistency created the decades of strategic stability that is the great strength of democracies. Strong institutions that outlast politicians allow for long-range planning. In contrast, dictators can operate only tactically, not strategically, because they are not constrained by the balance of powers, but cannot afford to think beyond their own survival. This is why a dictator like Putin has an advantage in chaos, the ability to move quickly. This can only be met by strategy, by long-term goals that are based on shared values, not on polls and cable news. The fear of making things worse has paralyzed the United States from trying to make things better. There will always be setbacks, but the United States cannot quit. The spread of democracy is the only proven remedy for nearly every crisis that plagues the world today. War, famine, poverty, terrorism–all are generated and exacerbated by authoritarian regimes. A policy of America First inevitably puts American security last. American leadership is required because there is no one else, and because it is good for America. There is no weapon or wall that is more powerful for security than America being envied, imitated, and admired around the world. Admired not for being perfect, but for having the exceptional courage to always try to be better. Thank you

## Innovation

#### 1] Pharma innovation is strong now.

Tanja Dowe 10/5/21.CEO of Debiopharm Innovation Fund, the strategic investment arm of the Swiss pharmaceutical company Debiopharm. “The ‘patient of the future’ is driving radical innovation in healthcare.” https://pharmaphorum.com/patients/future-patient-radical-innovation-healthcare-debiopharm/

Digital data collection, utilisation of real-word data and patient-centric thinking will all contribute to the rapid development of a new healthcare landscape, says Debiopharm Innovation Fund’s Tanja Dowe.

In recent years, we have seen thinking shift from focusing on a disease’s treatment to seriously considering the wider potential for its prevention, enabled by dramatic advances in data science and supported by a pressing need to reduce healthcare costs.

Leaps forward in both digital tools and widespread collection of medical and health data have provided many opportunities for the healthcare industry to adapt and change. The advent of COVID-19 has been a great testing environment for these technologies where, for example, the adoption of telemedicine was no longer an option but an urgent need to plug the gap in face-to-face medical care.

The healthcare industry is also changing as its ‘customers’ move from ‘boomer’ patients to digital natives. These individuals no longer accept the patient role of past generations. They want to be involved, proactive contributors to their own health, with access to their own health information.

This was also one of the key messages from the recent Healthcare Automation and Digitalization Congress (AUTOMA+) 2021, at which I led a round-table discussion on the ‘prevention versus treatment’.

The traditional patient role is rapidly changing

The world over, a dramatic shift is occurring in the characteristics of the typical patient. The time of individuals relying entirely on face-to-face interaction with their doctors is long past. In its place, a new persona has emerged. The ‘patient of the future’ demands control of their own healthcare – they are proactive individuals who follow their own health status with one of the almost 400 wearable devices on the market already today, and receive personalised health improvement advice through an app. They want personalised care all across the medical care pathway as well.

We can start to understand how we, in the healthcare industry, must respond to this seismic shift by looking initially at what is driving the transformation and, in particular, at three key factors.

Firstly, there is an ever-present need to reduce healthcare costs. This was a priority for healthcare services pre-COVID and is even more critical now in order to manage the huge burden of disease as we start to re-open the world. Prevention and treatment services for non-communicable diseases (NCDs) alone have been severely disrupted since the pandemic began, and the World Health Organization predicts a long-term upsurge in deaths from NCDs in the months and years that follow. Without finding a way to make healthcare more cost-efficient, the outcomes for patients are likely to fall sharply.

Secondly, there has been an unprecedented technological drive in the last decade, accelerated by increased medical data, advances in artificial intelligence (AI) and an abundance (and increased consumerisation) of digital tools, sparked by growing market appeal – as seen with the popularisation of health apps and digital monitoring systems, for example.

#### 2] Pay-for-delay is key to innovation.

Walid Chaiehloudj 21. Associate professor at Grenoble-Alpes University and Associate Researcher at the University Côte d’Azur. “PhD thesis summary: Pay-for-delay agreements”, Competition Forum – Resources,2021, n° 0007. https://competition-forum.com/phd-thesis-summary-pay-for-delay-agreements/

First of all, the current consumer welfare standard appeared to us to be misleading. By focusing the analysis on static competition, the European Commission has so far only focused on the price drop and the date of generic entry. Specifically, it has lost interest in the effects that pay- for-delay agreements could have on a medium- to long-term horizon. However, in the medium to long term, pay-for-delay agreements could lead to the emergence of new molecules and incremental innovations, which could prove valuable for patients who currently have no treatment at all. For this reason, it has been shown that the adoption of total consumer welfare would be a more balanced standard to take into account the specificities of the pharmaceutical sector and pay-for- delay agreements.

Secondly, it was explained that pay-for-delay agreements can in certain circumstances provide an incentive to innovate and encourage pharmaceutical companies to pursue heavy and costly investments in research and development. Not only can pay-for-delay agreements be seen as a powerful incentive for innovation, but also as a tool for the early diffusion of innovation, which is beneficial to the consumer. Thus, pay-for-delay agreements could in certain circumstances contribute to the general interest and serve the purposes of patent law.

#### 3] Plan nukes regulatory certainty AND creates vagueness that monopolists exploit to dodge enforcement

D. Daniel Sokol 9, Assistant Professor at the University of Florida Levin College of Law, Senior Advisor at White & Case LLP, LLM from the University of Wisconsin Law School, JD from the University of Chicago Law School, MSt in History from Oxford University, AB from Amherst College, “Limiting Anticompetitive Government Interventions That Benefit Special Interests”, George Mason Law Review, 17 Geo. Mason L. Rev. 119, Fall 2009, Lexis

Antitrust litigation produces regulatory uncertainty because different courts may rule inconsistently with the same set of facts. Anecdotal evidence indicates that when courts do not understand complex antitrust issues, they rule based on a highly procedural formalism. 140 These problems of procedural formalism in antitrust decisions create particular concerns in conduct cases or with regard to penalties for conduct, regardless of the origin of the legal system. 141 For example, in New Zealand, telecommunications regulation focused on a general antitrust solution in conjunction with courts rather than with sector regulation. 142 In a case involving interconnection rates within telecommunications between the incumbent provider and a new entrant for access to the local loop, the case took five years to decide, with significant procedural delay. 143 The lack of the New Zealand judicial system's understanding of the complex pricing issues and methodologies for interconnection underlying the case meant that the conflicting court decisions left little certainty-none of the courts came up with a specific interconnection price. This enabled the incumbent Telecom Corporation to maintain its monopoly position, and it left the victims of its anticompetitive behavior without any effective means of redress. 144 A similar problem occurred in Chile, where the Chilean Supreme Court recently overruled the Chilean Competition Tribunal in cases regarding tacit collusion based on procedural rather than substantive grounds, and where it seemed apparent that the Supreme Court did not understand the antitrust issues. 145 [\*148]

#### 4] ABR won’t get close to extinction, intervening actors solve it, their internal link can’t

Ed Cara 17, science writer for The Atlantic, Newsweek, and Vocativ, 1/27/17, “The Attack Of The Superbugs,” http://www.vocativ.com/394419/attack-of-the-superbugs/

Antibiotic-resistant infections kill at least 700,000 people worldwide a year right now, according to an exhaustive report commissioned by the UK in 2014, and without any substantial medical breakthroughs or policy changes that slow down resistance, they may claim some 10 million deaths annually by 2050 — eclipsing cancer in general as a leading cause. These deaths largely won’t come from pan-resistant infections, just tougher ones. A preventable death there, a preventable death here. Leaving that aside, antibiotics, along with proper sanitation and nutrition, gird our entire way of living. Most every invasive surgery, pregnancy, organ transplant and chemotherapy session we go through will become riskier. Other diseases like HIV, malaria or influenza will become deadlier, since bacteria often exploit the opening in our immune system they leave behind. And already precarious populations like those living with cystic fibrosis, prisoners, and the poor will lose years off their lives. For all the warranted gloom, though, Farewell does think there are reasons to be hopeful. “I don’t think we are doing enough, but the scientific community along with many governmental and private foundations are very actively involved in finding not only new antibiotics, but new solutions to this problem,” she said. There’s been a noticeable change in attitude and increased urgency surrounding antibiotic resistance, she said, one that she hadn’t seen even five years ago, let alone twenty. Until recently, that attitude change could be seen from places as high up as the U.S. federal government. In 2014, former President Obama issued an executive order aimed at addressing antibiotic resistance, the first real acknowledgement of the problem from an administration, devoting funding and outlining a national action for combatting resistance. Through its federal agencies, the administration pushed to reduce antibiotic use on farms and encouraged doctors to stop using them in excess. “There has been a lot of work done the last couple of years, much of it spurned by [Obama’s] National Action Plan,” said Dr. David Hyun, a senior officer for Pew Charitable Trusts’ Antibiotic Resistance Project. The CDC, in particular, has used its funding to open up regional labs that allow them to better detect and respond to antibiotic-resistant outbreaks like the Nevada case, he said. They ultimately hope to create an expansive surveillance system that can easily keep track of resistance rates on a national, state and regional level. A parallel system also exists for monitoring resistance in the food chain, shepherded by the CDC and the U.S. Department of Agriculture. In fact, it was this sort of cooperation between national and local health agencies that enabled Nevada doctors to stop the worst from happening, said Dr. Lei Chen. The swift identification of a possible CRE strain by the hospital, coupled with the woman’s medical history, led to a precautionary quarantine, while also prompting Chen’s public health department and eventually the CDC into action. And it may help prevent future cases from spilling into the public. According to Chen, the CDC has allocated funding this year to all of Nevada’s state public health departments so they can better detect CRE and other dangerous resistant strains. Under the Trump administration, there’s no telling how these small victories will hold up or whether they will advance. All references to antibiotics once found on the Whitehouse.gov site have been removed, including a link to the Obama administration’s national action plan, and the fact that they’re already tried to bar USDA scientists from discussing their work with the public while stripping funding from other public health agencies isn’t encouraging. Even with the best public policy, however, there’s no clear light at the end of the tunnel. Antibiotic resistance has gradually been worsening, even within the last 15 to 20 years, when superbugs like methicillin-resistant Staphylococcus aureus (MRSA) first became widely known, said Hyun. The effort needed to develop new drugs has been in short supply, hamstrung by pharmaceutical companies’ inability to recoup the costs of bringing new antibiotics to market. That’s because, unlike the latest heart medication, any new antibiotics will have to be treated like the last drops of water during a drought, used as little as possible — the exact opposite way to make money off a new product. Yet, much like climate change, the financial toll of not doing anything will total in the trillions years down the road. And it already numbers in the billions now, according to the CDC. Of course, we need bacteria to survive. And most need or pay no mind to us in return. Even pan-resistant bacteria don’t really mean harm. Some have been found in perfectly healthy people, a fact that’ll either comfort you or keep you awake at night, only causing problems when our immune system wavers. There’s no army of sentient E. coli that will rise up and someday overthrow the human race. But barring the calvary showing up, a new fear of ours will learn to settle in, almost unnoticed. It’ll creep in when we pick our heads up from a nasty fall that scrapes our skin open or breaks our bones; when we wave goodbye to our loved ones before they enter an operating room, or when we cradle our newborns into a world teeming with the living infinitesimal, wishing there was still a way to shield them from it as our parents once could for us. A fear of naked vulnerability. The antibiotic apocalypse will be gentle, if it fully arrives, but it won’t be any less devastating to the human spirit.

#### 5] Burnout and geographic dispersion check disease.

Sebastian Farquhar 17. \*\*Project Manager at FHI responsible for external relations, M.A in Physics and Philosophy, Oxford. \*\*John Halstead, Global Priorities Project. \*\*Owen Cotton-Barratt, Research Associate in the FHI at Oxford, Lecturer in Mathematics at St. Hugh’s College. \*\*Stefan Schubert, PhD in philosophy, Researcher at the Centre for Effective Altruism. \*\*Haydn Belfield, Academic Project Manager, Centre for the Study of Existential Risk, Cambridge. \*\*Andrew Snyder-Beattie, Director of Research at FHI. “Existential Risk: Diplomacy and Governance.” *Future of Humanity Institute*. Oxford, Global Priorities Project. <https://www.fhi.ox.ac.uk/wp-content/uploads/Existential-Risks-2017-01-23.pdf>.

For most of human history, natural pandemics have posed the greatest risk of mass global fatalities.37 However, there are some reasons to believe that natural pandemics are very unlikely to cause human extinction. Analysis of the International Union for Conservation of Nature (IUCN) red list database has shown that of the 833 recorded plant and animal species extinctions known to have occurred since 1500, less than 4% (31 species) were ascribed to infectious disease.38 None of the mammals and amphibians on this list were globally dispersed, and other factors aside from infectious disease also contributed to their extinction. It therefore seems that our own species, which is very numerous, globally dispersed, and capable of a rational response to problems, is very unlikely to be killed off by a natural pandemic.

One underlying explanation for this is that highly lethal pathogens can kill their hosts before they have a chance to spread, so there is a selective pressure for pathogens not to be highly lethal. Therefore, pathogens are likely to co-evolve with their hosts rather than kill all possible hosts.39

## Access

#### 1] Expanded antitrust enforcement of anticompetitive practices causes backlash---turns the case.

Alison Jones 20. Professor of Law at King's College London, with William E. Kovacic, March, “Antitrust’s Implementation Blind Side: Challenges to Major Expansion of U.S. Competition Policy.” The Antitrust Bulletin. https://journals.sagepub.com/doi/full/10.1177/0003603X20912884

One possible solution to rigidities that have developed in Sherman Act jurisprudence is for the FTC to rely more heavily on the prosecution, through its own administrative process, of cases based on Section 5 of the FTC Act and its prohibition of “unfair methods of competition.”93 This section allows the FTC94 to tackle not only anticompetitive practices prohibited by the other antitrust statutes but also conduct constituting incipient violations of those statutes or behavior that exceeds their reach. The latter is possible where the conduct does not infringe the letter of the antitrust laws but contradicts their basic spirit or public policy.95

There is no doubt therefore that Section 5 was designed as an expansion joint in the U.S. antitrust system. It seems unlikely to us, nonetheless, that a majority of FTC’s current members will be minded to use it in this way. Further, even if they were to be, the reality is that such an application may encounter difficulties. Since its creation in 1914, the FTC has never prevailed before the Supreme Court in any case challenging dominant firm misconduct, whether premised on Section 2 of the Sherman Act or purely on Section 5 of the FTC Act.96 The last FTC success in federal court in a case predicated solely on Section 5 occurred in the late 1960s.97

The FTC’s record of limited success with Section 5 has not been for want of trying. In the 1970s, the FTC undertook an ambitious program to make the enforcement of claims predicated on the distinctive reach of Section 5, a foundation to develop “competition policy in its broadest sense.”98 The agency’s Section 5 agenda yielded some successes,99 but also a large number of litigation failures involving cases to address subtle forms of coordination in oligopolies, to impose new obligations on dominant firms, and to dissolve shared monopolies.100 The agency’s program elicited powerful legislative backlash from a Congress that once supported FTC’s trailblazing initiatives but turned against it as the Commission’s efforts to obtain dramatic structural remedies unfolded.101

#### 2] Cartels are diversifying---drugs aren’t key.

Peter O’Dowd 20. Senior editor for Here & Now, with Allison Hagan, 2/7/20. “Why Avocados Attract Interest Of Mexican Drug Cartels.” https://www.wbur.org/hereandnow/2020/02/07/avocados-mexican-drug-cartels

Reports on the murders say clandestine avocado farms had something to do with the two deaths. Mexican drug cartels have broken into the lucrative avocado business in the state of Michoacán, where most of the avocados imported to the U.S. come from.

For several years, the cartels have been diversifying their portfolios to include a range of legal economies in addition to drugs, says Eduardo Moncada, an assistant political science professor at Barnard College.

“Avocados represent a major source of income in the state of Michoacán in Mexico,” says Moncada, who is writing a book in part about extortion in Michoacán. “And as such, they've been mobilizing to try and capture money from that sector.”

The cartel engages in extortion of avocado producers, transporters and packers to gain control over the sector. By taking over lands used to produce avocados, they become “informal owners” of the fields and profit from sales, he says.

The cartels are broadening their portfolios beyond avocados, too. Taking control of land — like the butterfly reserve — allows them to produce more agricultural goods, and the wood and timber there is also valuable, he says.

Mexico’s war on drugs began in 2006 under the reign of former President Felipe Calderón. On top of the violence that the conflict unleashed, it also fragmented the country’s handful of large cartels to many smaller ones, he says.

“In order to survive and thrive in that kind of context, the cartels began to diversify their portfolios in a way to try and gain resources,” he says.

#### 3] Cartels are dead

Stewart 17 (Scott, Stratfor analyst of terrorism and security issues “Mexico's Cartels Will Continue to Splinter in 2017”, https://worldview.stratfor.com/article/mexicos-cartels-will-continue-splinter-2017)

Stratfor has tracked Mexico's drug cartels for over a decade. For most of that time, our annual forecasts focused on the fortunes and prospects of each trafficking organization. But as Mexican organized crime groups have gradually fractured and fallen apart — a process we refer to as balkanization — we have had to refine the way we think about them. The cartels are no longer a handful of large groups carving out territory across Mexico, but a collection of many different smaller, regionally based networks. So, rather than exploring the outlook of every individual faction, we now take them as loose gatherings centered on certain core areas of operation: Tamaulipas, Tierra Caliente and Sinaloa.

#### 4] There is no correlation between readiness and conflict and past declines disprove the impact

Mark F. Cancian & Seamus Daniels 18. \*\*Mark F is a senior adviser with the International Security Program at the Center for Strategic and International Studies (CSIS) in Washington, D.C. \*\*Seamus Daniels is a research assistant for defense budget analysis at CSIS. “The State of Military Readiness: Is There a Crisis?” Center for Strategic & International Studies. 04-18-18. https://www.csis.org/analysis/state-military-readiness-there-crisis

Q4: Has readiness declined? A4: **In 2013**, readiness took a hit as a result of sequestration. Because cuts had to be made late in the fiscal year, the services were forced to cut **facility maintenance**, **international exercises**, and most significantly, **training activities**. The services have been digging out of that hole ever since. Some commentators have raised concerns about a “readiness crisis” while others, like retired Gen. David Petraeus and Michael O’Hanlon, have argued that readiness is essentially sound. Part of the difficulty in assessing the state of the military’s readiness is the lack of publicly available data as measured by the DRRS. That problem is exacerbated by directives from the secretary of defense to limit public discussion of readiness shortfalls. Readiness discussions are further distorted by the opposing incentives to exaggerate shortfalls to defend budgets and to exaggerate capabilities to deter adversaries. The Trump administration emphasized readiness in its FY 2017 and FY 2018 budgets. Nevertheless, readiness data are conflicting. Some metrics, like Army rotations to Combat Training Centers, service flying hours, and Navy ship steaming days, have recovered from post-2013 lows, but others, like Navy and Marine Corps aircraft availability, remain depressed. With overall DOD budgets rising, targeted readiness increases, such as aviation spare parts, may be better investments than across-the-board increases. The services have worked hard to deploy forces at a high level of readiness because these forces are either going into conflicts (such as Afghanistan, Iraq, or Syria) or will be the first sent to a crisis or a new conflict (carrier battle groups and Marines afloat). Low readiness levels, therefore, typically affect nondeployed forces at their home bases. These forces would deploy if an emergency erupts that the forward-deployed forces cannot handle. The risk is that they would need to deploy before they can be brought up to a high level of readiness. Q5: Have low readiness levels caused an increase in accidents? A5: There would seem to be a connection here: lower readiness, less training, fewer skills, more accidents. However, it is **difficult to determine the direct connection** between readiness and recent incidents. Accidents have **continued to occur even as readiness funding has recovered**. What is clear is that the high tempo of current operations (optempo) has taken a toll on the readiness of forces.

## Econ

#### 1] The aff doesn’t solve healthcare costs---they’re rising for many reasons that the aff doesn’t affect

Gabrielle Smith 21. Cites CMS, NCBI, CDC, KFF, BBC, 3/19/21. “Seven reasons for rising healthcare costs.” https://www.peoplekeep.com/blog/seven-reasons-for-rising-health-care-costs

However, despite this historic drop, economists at CMS expect the pandemic’s effects to be short term, with health spending projected to grow at an average annual rate of 5.4% and reach $6.2 trillion by 2028.

With no end in sight to rising healthcare costs, it’s important to understand what exactly causes these spikes in the first place. Let’s take a look at seven reasons for rising healthcare costs in the U.S.

Seven reasons for rising healthcare costs

1. Medical providers are paid for quantity, not quality

Most insurers—including Medicare—pay doctors, hospitals, and other medical providers under a fee-for-service system that reimburses for each test, procedure, or visit. That means the more services provided, the more fees are paid.

This encourages a high volume of redundant testing and overtreatment, including on patients that have questionable potential to improve their health.

On top of this, our medical system is not integrated. The World Health Association defines integrated health services as “the organization and management of health services so that people get the care they need, when they need it, in ways that are user friendly, achieve the desired results and provide value for money.”

So what does that have to do with cost? Integrated health means providers, management, and support teams are all in communication with one another on a patient’s care. On the other hand, in an unintegrated system, the lack of coordination can result in patients receiving duplicate tests and paying for more procedures than they truly need.

2. The U.S. population is growing more unhealthy

According to the National Center for Biotechnology Information, half of the U.S. population has at least one chronic condition, such as asthma, heart disease, or diabetes, which all drive up costs. A staggering 85% of healthcare costs in the U.S. are for the care of a chronic condition.

What’s more, recent data from the Center for Disease Control and Prevention finds that over 40% of adults in the U.S. are either overweight or obese, which also leads to chronic illness and inflated medical spending.

As the U.S. population gets sicker and more overweight, the risk involved in insuring the average American goes up. And in turn, the higher the risk, the higher the cost of insurance premiums. Data from the Kaiser Family Foundation (KFF) shows between 2015 and 2020 the average annual premiums for family coverage rose from $15,545 to $21,342—that’s a whopping 37%.

3. The newer the tech, the more expensive

Medical advances can improve our health and extend our life, but they also add to the cost of healthcare and the overutilization of expensive technology.

According to a study by the Journal of the American Medical Association, (JAMA) Americans tend to associate more advanced technology and newer procedures with better care, even if there’s little to no evidence to prove that they’re more effective.

This assumption leads to both patients and doctors often demanding the newest (read: most expensive) treatments and technology available.

4. Many Americans don’t choose their own healthcare plan

Data from the KFF finds that roughly 49% of the U.S. population gets their insurance through their employer. That means nearly half of Americans don’t actually make any true consumer decisions about the cost of their care or coverage, because it was already made for them by their employer.

Organizations have an incentive to purchase more expensive healthcare plans because the amount employers pay toward coverage is tax deductible for the organization and tax exempt to the employee. In addition, low deductibles or small office co-payments can encourage overuse of care, driving both demand and cost.

5. There’s a lack of information about medical care and its costs

Despite a wealth of information at our fingertips online, there’s no uniform or quick way to understand treatment options and the costs associated with them. We would never buy a car without comparing models, features, gas mileage, cost, and payment options—but yet, this is how we buy healthcare.

Kaiser Health News (KHN) reports that even when evidence shows a treatment isn’t effective or is potentially harmful, it takes too long for that information to become readily known, accepted, and actually change how doctors practice or what patients demand.

And in too many cases, even when hospitals make their service prices available, they are difficult to navigate and understand. Many of the chargemasters that have been legally required to be made public are written using codes that only medical care professionals can understand.

See our infographic to learn more about estimating your medical expenses

6. Hospitals and providers are well-positioned to demand higher prices

According to the Center for Studying Health System Change, mergers and partnerships between medical providers and insurers is one of the more prominent trends in America’s current healthcare system.

Increased provider consolidation has decreased the market competition, which normally allows for lower prices, improved productivity, and innovation. Without this competition, these near-monopolies created in some markets have both providers and insurers in a position to drive up their prices unopposed.

For example, a study done by the American Journal of Managed Care found that hospitals in concentrated markets were able to charge considerably higher prices for the same procedures offered by hospitals in competitive markets. The cost for a coronary angioplasty was found to be 25% higher, while a total knee replacement was 19% higher.

7. Fear of malpractice lawsuits

Oftentimes called “defensive medicine,” some doctors will prescribe unnecessary tests or treatment out of fear of facing a lawsuit. The cost for these treatments add up over time—a study done by JAMA estimates that an annual $46 billion are wasted in defensive medicine practices.

This is no surprise given that our current regulatory system is structured to support the fee-for-service model of healthcare delivery and payment. The Commonwealth Fund reports that the fear that healthcare providers will withhold important services in order to stay under budget is a bigger concern to Americans than the overutilization of services.

Sources: CMS, NCBI, CDC, KFF, BBC

#### 2] Their ev is hype---pay-for-delay is sufficiently policed now and facilitates lower-cost medicine.

AJMC 21. The Center for Biosimilars @ the American Journal of Managed Care, 6/23/21. https://www.centerforbiosimilars.com/view/industry-panelists-say-pay-for-delay-settlements-have-a-good-side

“Pay-for-delay” settlements between originator companies and biosimilar developers have a bad reputation that may not be wholly deserved, said an intellectual property attorney at the American Conference Institute’s 12th summit on Biosimilars & Innovator Biologics.

These agreements are now reviewed by the Federal Trade Commission (FTC), and there is evidence that they are better structured in recent years and play a constructive role in allowing competitor drugs to come to market sooner, said Karin A. Hessler, assistant general counsel for the Association for Accessible Medicines.

The FTC gets a copy of every single settlement agreement that occurs…and they put out a yearly report analyzing settlement agreements, and what has come out of the last 2 yearly reports that the FDC has issued is that Activis has been highly effective in policing these agreements.

Panelists also discussed recent changes to the Purple Book manual of patent information on biologics and various legislative developments that are intended to improve the competitiveness of the US biologics market.

Much alarm has been raised about settlements between originator and biosimilar developers that involve an exchange of royalties or agreements not to enter certain markets before a certain time. In exchange for these agreements, biosimilar companies may avoid costly litigation battles and bring their products to market sooner.

Hessler said an important 2013 Supreme Court decision, FTC v Activis, clarified when reverse payment patent settlements (pay for delay) are in fact acceptable and this, she said, has led to a gradual improvement in the quality of such agreements, such that pay-for-delay deals are in many cases playing a constructive role in facilitating patient access to lower-cost medicine.

“The FTC gets a copy of every single settlement agreement that occurs…and they put out a yearly report analyzing settlement agreements, and what has come out of the last 2 yearly reports that the FDC has issued is that Activis has been highly effective in policing these agreements,” Hessler said.

Quoting from the December 2020 FTC report, Hessler stated that despite a high number of such settlements, “those that include the types of reverse payments that are likely to be anticompetitive remain very low.”

## Regulation

#### 2. “Do both” is antitrust duplication---the disputes collapse resources, effectiveness, and signaling.

Carl W. Hittinger and Tyson Y. Herrold 19. Carl W. Hittinger (LAW ’79) is a senior partner and serves as BakerHostetler’s Antitrust and Competition Practice National Team Leader and the litigation group coordinator for the firm’s Philadelphia office. He concentrates his practice on complex commercial and civil rights trial and appellate litigation, with a particular emphasis on antitrust and unfair competition matters, including class actions. Tyson Y. Herrold is an associate in the firm’s Philadelphia office in its litigation group. His practice focuses on complex commercial litigation, particularly antitrust and unfair competition matters, as well as civil rights litigation. "Antitrust Agency Turf War Over Big Tech Investigations". Temple 10-Q. https://www2.law.temple.edu/10q/antitrust-agency-turf-war-over-big-tech-investigations/

Disputes over clearance can have tangible adverse effects on enforcement. First, some have commented that delays caused by clearance disputes can narrow the efficacy of remedial options, particularly with mergers. As Sen. Richard Blumenthal has commented, “The Big Tech companies are not waiting for the agencies to finish their cases. They are structuring their companies so that you can’t unscramble the egg.” Structural remedies are favored by Delrahim, who has commented that alternative, behavioral remedies should be used sparingly: “The division has a strong preference for structural remedies over behavioral ones. … The Antitrust Division is a law enforcer and, even where regulation is appropriate, it is not equipped to be the ongoing regulator.”

Second, disputes over clearance and, more so, duplicative investigations waste agency resources, threaten to blunt their effectiveness, and can lead to inconsistent and confusing governmental positions. In the Sept. 17 oversight hearing, Simons and Delrahim were both criticized for requesting an increase in funding: “As you both acknowledged, both of you could use, and desperately need, more resources. That being the case, it makes no sense to me that we should have duplication of effort, when that has a tendency inevitably to undermine the effectiveness of what you’re doing.” Duplicative investigations dilute the specialization that is a principal goal of the agencies’ clearance agreement and raise the risk that one agency will take legal positions that undercut the other. No doubt the DOJ’s amicus brief in the Qualcomm case influenced the U.S. Court of Appeals for the Ninth Circuit’s decision to issue a stay pending appeal.

So how will the FTC and DOJ resolve their latest turf war? Perhaps they will revisit their clearance agreement and decide to split their authority by company or the business practice being investigated, based on prior agency experience, rather than by industry as Appendix A currently does. Or maybe Congress will decide to consolidate civil antitrust enforcement jurisdiction under one agency. That seems like a long shot considering the political implications. However, during the Senate’s antitrust oversight hearing, Sen. Josh Hawley proposed “cleaning up the overlap in jurisdiction by removing it from one agency” and “clearly designating enforcement authority to one agency.” One thing is sure—the agencies should not be duplicating civil antitrust investigations. Stay tuned.

#### “Expanding the scope” of “anti-trust laws” must be the DOJ and FTC.

Jarod Bona 21. Bona Law PC. "Five U.S. Antitrust Law Tips for Foreign Companies". Antitrust Attorney Blog. 1-16-2021. https://www.theantitrustattorney.com/five-u-s-antitrust-tips-foreign-companies/

1. Two federal and many state agencies enforce antitrust laws in the United States

The United States government has two separate antitrust agencies—the Federal Trade Commission (FTC) and the Antitrust Division of the Department of Justice (DOJ). The FTC is an independent federal agency controlled by several Commissioners, while the Antitrust Division of the DOJ is part of the Executive Branch, under the President.

Both of them enforce federal antitrust laws (among other laws). Their jurisdictions technically overlaps, but they tend to have informal agreements between each other for one or the other to handle certain industries or subjects. If you are part of a major industry, your antitrust lawyer may be able to tell you whether the DOJ or FTC is likely to oversee competition issues in your field.

#### 2. Jurisdiction: the plan expands the DOJ and FTC role.

Babette E. Boliek 11. Associate Professor of Law at Pepperdine University School of Law. J.D., Columbia University School of Law; Ph.D., Economics University of California, Davis. FCC Regulation Versus Antitrust: How Net Neutrality is Defining the Boundaries, 52 B.C.L. Rev. 1627 (2011). <http://lawdigitalcommons.bc.edu/bclr/vol52/iss5/2>

There is a crucial battle playing out in the world of Internet access provision. While the Internet is the natural home of competing business giants and warring digital avatars, the contest that will have the most sweeping ramifications for the future of the Internet is the turf war being waged between the Federal Communications Commission (FCC), on the one hand, and the Federal Trade Commission (FTC) and the Department of Justice (DOJ), on the other.1 Nothing less than jurisdiction over the development of the Internet is at stake.

Jurisdiction over Internet access provision is not the first confrontation between these particular government agencies; in fact, they have clashed many times.2 But it is the current iteration of the FCC’s “net neutrality” regulations that has generated the latest contest. Roughly defined, net neutrality encompasses principles of commercial Internet access that include equal treatment and delivery of all Internet applications and content.3 For some, net neutrality stands further for the proposition that Internet access operators should not be permitted to provide different qualities of service for certain application providers (e.g., guaranteed speeds of transmission), even if those application providers can freely choose their desired quality of service.4 Net neutrality has reinvigorated what may be described as an underlying interagency tug of war that reaches deep within, and far beyond, the communications industry.

Although the two regimes share a commonality of purpose—to protect consumers and to promote allocative efficiencies in production—the two have quite distinct, predominately opposing, means of securing social benefits. As Justice Stephen Breyer stated when serving as a judge on the U.S. Court of Appeals for the First Circuit, although regulation and the antitrust laws “typically aim at similar goals—i.e., low and economically efficient prices, innovation, and efficient production methods” —regulation looks to achieve these goals directly “through rules and regulations; [but] antitrust seeks to achieve them indirectly by promoting and preserving a process that tends to bring them about.”5 The battle between these two regimes may be broadly summarized in a single issue thusly: in the face of the industry-specific regulator, what is (or what should be) the role of antitrust law?6

Antitrust law preserves the process of competition across all industries by condemning anticompetitive conduct when it occurs. In contrast, industrial regulation by its nature is a public declaration that, in a given industry, market forces are too weak or underdeveloped to produce the consumer benefits that are realized in competitive markets— regulated industries are carved out from the rest of the economy and are subject to proactive, regulatory intervention that goes above and beyond antitrust enforcement measures.7 Not surprisingly, regulatory agencies were historically created as substitutes for market forces in the few markets that, by the nature of the product or technology, were natural monopolies or severely prone to monopoly.8 In the vast major- ity of markets, however, the antitrust law is the default government control, designed to supplement market forces to inhibit or prevent the growth of monopoly.

Again, although the goals of the two regimes may be similar, the means by which each can achieve those goals are in opposition. Therefore, the threshold determination of which industries are to be singled out for industry-specific regulation, and to what degree, is of vital importance as it simultaneously determines the predominance of the regulator versus the antitrust authority in securing the social good.

This Article sets forth a framework to identify the boundaries between FCC regulatory power and antitrust authority. The goal is to pinpoint for Congress the problematic use of regulatory discretion in defining, or redefining, those boundaries and to propose the standard by which Congress may address inappropriate use of existing FCC jurisdiction. Specifically, this Article creates a new categorization of “procedural opportunism” and “substantive opportunism” to identify problematic, regulatory assertions of jurisdiction. The central issue examined in this Article is to posit what is (or should be) the boundaries of antitrust law in relation to the FCC’s regulatory authority. This important issue has reached a point of public crises in the current net neutrality debate.9 Rather than act reflexively, this is an opportunity for Congress to act clearly to redefine the boundaries between the two regimes that have otherwise been blurred by regulatory overreach.

#### 3. Legal code---antitrust requires Title 15 of US Code.

Sanjukta M. Paul 16. David J. Epstein Fellow, UCLA School of Law. The Enduring Ambiguities of Antitrust Liability for Worker Collective Action. Loyola University Chicago Law Journal. https://www.congress.gov/116/meeting/house/110152/witnesses/HHRG-116-JU05-Wstate-PaulS-20191029-SD002.pdf

Unlike the Clayton Act, which was the first legislative attempt at a labor exemption from antitrust,202 the Norris-La Guardia Act did not grapple directly with trade regulation in subject matter—even with how trade regulation applies to labor—although it had the effect of modifying its reach. Norris-La Guardia is not an antitrust statute. Instead, it is incorporated into Title 29 (“Labor”) of the United States Code. By contrast, the Clayton Act was conceived and written as an antitrust statute, was incorporated into Title 15, the antitrust and trade regulation section of the Code, and portions of it dealt with matters other than labor.

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#### 1] empirically more effective than antitrust at achieving economic outcomes

Sumit K. Majumdar 21. Sumit K. Majumdar Ph. D. is Professor in the Jindal School of Management at the University of Texas at Dallas. “Stick Versus Carrot: Comparing Structural Antitrust and Behavioral Regulation Outcomes.” The Antitrust Bulletin. June 2021. DOI:[10.1177/0003603X211023463](https://doi.org/10.1177/0003603X211023463)

A. Evaluation of Structural Versus Behavioral Remedy Outcomes

The issue is which method works better, the antitrust (structural) or the regulatory (behavioral)? Using a standard test of differences in magnitude between two variables, as natural experiment 3 I evaluate if the antitrust (structural) approach or the regulatory (behavioral) remedy has had a greater impact in enhancing efficiency. Results are in Table 4. Column (A) relates to the performance outcome variable comparatively evaluated. Column (B) reports if the antitrust (structural) impact is less than that of the regulatory (behavioral) measures, on performance, and column (C) reports if the difference has been statistically significant.

**For the productive efficiency score, the regulatory (behavioral) remedy has statistically had a greater impact than the antitrust (structural) method in enhancing efficiency.** (Recollect that Tables 2 and 3 reported results on how the structural vs. behavioral remedies impacted efficiency scores. The impacts were 2.23% for the structural remedy (column [A] in panel [B] of Table 2) and 4.33% (column [A] in panel [B] of Table 3) for the behavioral remedy.)

B. Robustness Check

An evaluation of why price caps, as endogenous phenomena,64 were implemented would depend on firm-level factors, such as past performance; these would have influenced the implementation of price cap regulatory schemes for specific firms. As a robustness check, controlling for inclusion of endogenous factors, past performance variables have been included as price caps determinants for each observation, in a selection equation with the price cap variable then determining performance in an outcome equation. The results show the price cap estimates to be of relatively the same magnitude (in fact, they are larger), sign, and significance as the estimate values already reported in this article.65

C. Summary

**Overall, significantly larger positive outcomes have emerged from sector-specific regulatory (behavioral) remedy applications** vis-`a-vis the concurrent antitrust (structural) remedy application. The use of further performance variables to comparatively test the ideas has yielded very similar results. Such additional results are available on request.

#### 2] Regs solve pay for delay.

Michael L. Fialkoff 14. J.D., University of Michigan Law School (expected 2015). “Pay-For-Delay Settlements in the Wake of Actavis.” Michigan Telecommunications and Technology Law Review, Vol. 20:523. https://repository.law.umich.edu/cgi/viewcontent.cgi?article=1196&context=mttlr

A possible, though unlikely, solution to the issues raised in Part HI would be Supreme Court action to clarify and expand the holding of Actavis to encompass pernicious non-monetary settlement arrangements. Although the Supreme Court might eventually clarify its position on this issue, such a decision seems unlikely to occur in the immediate future. A second solution would be for Congress to pass antitrust-based legislation codifying and ex-panding the Actavis holding. This solution also seems unlikely. There have been several attempts made in Congress to legislate broadly against pay-for-delay settlements under antitrust law, but thus far these attempts have been unsuccessful.133

A more effective, and possibly more feasible, approach would be to alter the regulatory framework of the pharmaceutical industry to reduce the eco- nomic incentives for pay-for-delay arrangements involving both overt mone- tary reverse payments and non-monetary de facto reverse payments. This Note now proposes a solution in this vein: the FDA should make the 180- day Hatch-Waxman generic exclusivity period available to a subsequent ANDA filer if the first-filer settles its patent challenge.

This proposal modiﬁes two elements of the existing regime. First, if the ﬁrst ANDA-ﬁler settles its patent challenge by agreeing to delay entry into the market, then that manufacturer should forfeit the 180-day period of ge-neric exclusivity provided by the Hatch-Waxman Act. As noted in Part LA, the forfeiture provision is difﬁcult to trigger in the event of settlement—forfeiture requires a ﬁnal appellate judgment that the proposed settlement violates antitrust law.134 Hemphill and Lemley have argued, and this Note agrees, that the forfeiture provision of the Hatch-Waxman Act should be augmented to reach those instances where the first-to-file generic manufac-turer settles without obtaining a judgment of non-infringement or patent invalidity.135

Second, in the event that the ﬁrst-ﬁler forfeits the ISO-day period of exclusivity, the exclusivity window should be made available to the next-in- line ANDA-ﬁler. This is the crux of the current proposal. Recall that under the current regulatory regime, the period of generic exclusivity attaches only to the ﬁrst-ﬁler.I36 In the event that the ﬁrst ANDA-filer forfeits the 180-day window, the period of exclusivity does not cede to any subsequent ﬁler.I37 Allowing subsequent ANDA-filers the beneﬁt of this period of ex-clusivity in the event that the ﬁrst-ﬁler settles would make anticompetitive arrangements like those in Actavis and Lamictal less feasible for the both the brand-name manufacturer and the generic manufacturer.

The proposed modification to the regulatory regime addresses the issue of pay-for-delay settlements at a different level than a judicial decision or new antitrust law. Rather than simply declaring a particular genus of settle- ment illegal or subject to heightened antitrust scrutiny, this modification works to reduce the incentives for anticompetitive pay-for-delay settlements. Additionally, as discussed below, the proposed modification to the regula- tory regime is more adaptable in dealing with different forms of anticompeti- tive arrangements between brand-name and generic manufacturers. The following subsections describe how this proposed rule would operate under the facts of Actavis and Lamictal to reduce incentives for anticompetitive settlement.

#### 3] Regs CP solves drug prices

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The high prices Americans pay for drugs has emerged as a major health policy concern. A majority of voters in both the Democratic and Republican parties want the government to take action to lower prices, and lawmakers in both houses of Congress have introduced bills aimed at doing so. Drug companies, meanwhile, argue (as they long have) that negotiating or regulating prices would cripple research budgets, stifle innovation, and lead to fewer treatments in the future. In a new article in the New England Journal of Medicine, we describe the three-stage journey that every successful drug makes during its life cycle and how adjusting the incentives during each period and tying them to price concessions could achieve the best of both worlds: stimulate innovation and lower prices. First comes the “innovation period,” during which new products are developed, tested, and prepared to be submitted to the Food and Drug Administration for its approval. If they win FDA approval (most don’t), drugs enter a “monopoly period” and are protected from competition through patents and by the FDA. When these protections end, the “competitive period” starts: Other companies can now make and sell copies of the brand-name drug. Policies — laws passed by Congress and regulations enforced by presidential administrations — strongly influence how long these periods last and how much profit or loss companies experience in each. The ability to charge high prices is only one part of the risk-reward calculus for drug manufacturers. Conceptualizing the market as a whole opens up other avenues for reform. To help patients, lawmakers should take three actions. Link innovation-friendly policies to price concessions. The process of drug development is uncertain and expensive, but there are many ways to reduce both the risk of failure and the cost of innovation that don’t require allowing drug companies to charge exorbitant prices. In 1981, for example, Congress created tax credits to offset research costs, and in 2000, Medicare began covering medical expenses for patients in clinical trials. More recently, regulations have been introduced to speed drugs through the FDA’s review process, which can save companies hundreds of millions of dollars. These innovation-friendly policies have never been linked to explicit price concessions from drug companies, but in the future, they should be. Revamp how long and how thoroughly new drugs enjoy monopoly protection. New drugs enjoy two types of monopoly protection: one through patents, the other through market exclusivity granted by the FDA. The FDA generally gives companies five to 12 years of exclusive rights to sell a new drug after approval, but patent protections can last decades because manufacturers often patent not just the original molecule but also minor changes to the drug like its coating or how it can be given. Enbrel, which is used to treat inflammatory conditions like rheumatoid arthritis, was developed in the 1990s, but it’s thicket of patents runs more than 100 deep and doesn’t run out until 2029. Meanwhile, the drug costs nearly $70,000 a year. Reducing the number and types of patents available to drug manufacturers would limit how long patients and taxpayers are exposed to those price tags. Absent action that limits the duration of drug monopolies, money that should be encouraging the development of new drugs will continue to flow to companies that are best at blocking competitors to older drugs. In addition to guaranteed monopolies, policymakers often hamstring insurers from using their market muscle to obtain price concessions. For example, not only is Medicare prohibited from negotiating drug prices, it is also required to cover every FDA-approved drug across six “protected” classes — regardless of how effective a drug is. Allowing Medicare and other payers to exclude some drugs from their formularies would improve their bargaining leverage and could lower prices. Both the Obama and Trump administrations considered this approach, but their efforts eventually stalled. Remove obstacles to competition from generics. Competition is a sacred American ideal — and a central mechanism through which drug prices ultimately fall — but policymakers have been slow to remove the barriers generic drugs face when trying to enter the market. Most people are familiar with “pay-for-delay” tactics through which companies pay would-be competitors not to bring generics to market, but they also use other tricks to smother competition before it begins. By citing safety concerns, for example, some companies refuse to provide the samples that generic manufacturers need to prove that their products are equivalent to branded drugs. The CREATES Act, which was signed into law in December, could put an end to some of these shenanigans, but other competitive challenges remain.

#### 4] Regs solves and complements market competition and innovation.

Geradin et. al. 8. DAMIEN GERADIN, ANNE LAYNE-FARRAR, AND A. JORGE PADILLA. Damien Geradin, Ph.D. Cambridge (1995) is a Professor of Competition Law at Tilburg Law and Economics Center (TILEC) and a Partner at Howrey LLP; Anne LayneFarrar, Ph.D. University of Chicago (1999) and Jorge Padilla, D.Phil. Oxford (1992) are economists at LECG Consulting. THE COMPLEMENTS PROBLEM WITHIN STANDARD SETTING: ASSESSING THE EVIDENCE ON ROYALTY STACKING. 4-25-2008. Pg. 168-170

1. Patent Reform As a solution to holdup and other licensing problems, Shapiro (2006) calls for policy changes to improve patent quality, reducing the odds that weak patents are granted by the patent office. He argues that poor quality patents are the worst offenders in terms of holdout, holdup, and other IPR licensing inefficiencies. Thus, weeding out such patents at the U.S. patent office would go a long way to solving IPR licensing issues later on within (as well as outside of) standard setting. This is the least controversial of the proposals. It is widely recognized, and not just among the academics pushing for radical change in the patent system, that IPR reform is long overdue. To name just a few of the more recent examples, see the article by Nancy Gallini, the working paper by Mark Lemley, Doug Lichtman, and Bhaven Sampat, and the book by Adam Jaffe and Josh Lerner––all of which review, assess, and expound on the need for intelligent patent reform.99 We agree that patent reform would be helpful, on a number of fronts. As this article was being written, Congress appeared to agree as well. While some of the specific elements remain controversial, the Patent Reform Act of 2007 had been passed by the House of Representatives and was being considered by the Senate.100 The Act calls for a number of reforms, including, among other things: Damages calculations: The latest version would allow judges discretion in the method for calculating reasonable royalties. Judges could follow an apportionment analysis (based on the incremental value contributed by the patented technology), entire market analysis (where the full end product is used as the basis for royalties), or other criteria, such as the Georgia Pacific 15 factors. This provision would address concerns over patents on minor components obtaining large royalties by virtue of the calculations being based on the overall product sales.101 Of course, from a purely mathematical standpoint, an ad valorem royalty rate can be adjusted up or down as the base decreases or increases, rendering such concerns mute. For instance, a 2.5% rate on 100% of the product sales would be equivalent to a 5% rate on a 50% increment of the overall product sales. Willful infringement: The standard for establishing treble damages would be raised from its current negligence standard.102 Patent owners would have to present clear and convincing evidence that the infringer unreasonably disregarded prior notices, copied the patented technology outright, or behaved in some other blatant fashion. Accused infringers would be allowed to present a “good faith belief” defense. The theory behind this proposal is that with a reduced threat of treble damages, holdup should be less likely. Post grant review: Patents could be challenged more easily by third parties. During the so-called “first window of review,” up to 12 months after issuance, the patent would not be presumed valid, as it is today. Increased scrutiny should lead to higher quality issued patents. This proposal thus targets perceived low patent quality, the problem at the root of many other patent concerns. Lawsuit venue: The proper venue for patent infringement cases would be restricted so that the venue matched more closely the circumstances of the case. This would reduce “venue shopping,” where patent holders file suit in jurisdictions more likely to be favorable to their case.103 On a purely pragmatic note, we point out that regardless of whether this particular Act is ultimately passed (and in what form), well thought out patent reform would be complementary to existing voluntary market mechanisms, including property preempting investments, reputation effects, cross licensing, and patent pools. Solid patent reforms are probably among the best ways to alleviate the risk of royalty stacking and other licensing issues, as stemming the patent flood and eliminating weak patents would reduce overall patent counts and limit those remaining to valuable contributions. As with all reforms, patent reform should be done with care to avoid unintended consequences.104

#### 1. CP encourages efficiency in any industry.

Kristelia A. García 14, Associate Professor, University of Colorado Law School, “Penalty Default Licenses: A Case for Uncertainty,” NYU Law Review, Vol. 89, No. 4, October 2014, https://scholar.law.colorado.edu/cgi/viewcontent.cgi?article=1071&context=articles

Companies, like individuals, are risk averse. The existence of a fallback option, even a poor one, allows them to take a chance on private negotiation. This is the case because the parties know they have an alternative should the deal not work out. Moreover, the fallback allows them the freedom of dabbling in individual deals with only one partner or a handful of them, affording valuable feedback on which terms work and which ones do not without committing the time and effort required to negotiate individually with all comers. If the private terms prove functional and an industry norm begins to take shape-as in the case of the Clear Channel-Big Machine deal-it can then be extended to the larger, more comprehensive partners and eventually reflected in the underlying legal regime.

CONCLUSION

When coupled with a penalty default, uncertainty can bring greater efficiency to the marketplace by encouraging private ordering, which allows for tailored terms and responsiveness to rapid technological change. This is great news in the music sampling context, where for years scholars, legislators, and industry players have been debating a statutory license. 271 This Article suggests that a penalty default license for samples, coupled with existing uncertainty about the future state of protections for derivative works, might alleviate efficiency concerns by encouraging more and better private negotiation. 272

This prescription is particularly timely given the imminent rewrite of "the next great copyright act," 273 and may find application outside the United States as well. In the European Union, for example, there has been a recent push for single-market licensing of intellectual property rights. 274 Copyright territoriality has largely thwarted this initiative, 275 whereas private ordering has resolved it. In November 2012, for example, Google accomplished something the European Union has thus far been unable to: The company struck a private, multiterritory agreement with thirty-five European countries. 276

Acknowledgment of the role uncertainty and penalty defaults play in increasing effectiveness in the market for statutory licensing and in copyright enforcement is only the beginning. A better understanding of uncertainty as a tool for efficiency has application in any industry facing change as a result of rapid technological growth, evolving consumer preferences, or ambiguity about the future state of the law.

## Innovation

#### Innovation is high now---new ways of analyzing data and shift to digital health---that’s Dowe

#### Pharma innovation is staggering.

Samuel Thangiah 21. Co-Founder and Executive Director of Life Science Integrates, 8/9/21. “People, partnerships, pharma: exploring the science of innovation.” https://www.chemistryworld.com/eureka-moments/people-partnerships-pharma-exploring-the-science-of-innovation/4014059.article

Pharmaceutical innovation is moving at a staggering pace. And behind every great research group driving the industry, there is also a team of collaborators, patients and experts from various backgrounds playing a key part in enabling discoveries and bringing novel therapeutics to market.

As the world has been focused on tackling the Covid-19 pandemic over the last 18 months, it’s no surprise to see the pharmaceutical sector increasingly develop and strengthen partnerships to accelerate innovations.

From the growing range of patient entities through to new possibilities stemming from technology and patient-generated data, the pharmaceutical industry has continued to identify more and more ways to improve the sector. This includes more collaboration with patients, advocacy groups and its workforce. Opening a dialogue within the industry, and extending that to include patients, is creating a new culture that fosters those all-important lightbulb moments more rapidly than ever before.

As the pharmaceutical industry continues to emerge from the setbacks of Covid-19, it has been noted that the companies that have come back stronger than before are the same ones that have spent time training and upskilling their workers. However, the need for this attitude shift has not just come from the pandemic: the digitalised industrial revolution has also forced a need to retrain staff in certain positions.

#### Innovation is up---R&D and new drugs growing.

CBO 21. Congressional Budget Office, April 2021. “Research and Development in the Pharmaceutical Industry.” https://www.cbo.gov/publication/57126

In this report, the Congressional Budget Office assesses trends in spending for drug research and development (R&D) and the introduction of new drugs. CBO also examines factors that determine how much drug companies spend on R&D: expected global revenues from a new drug; cost to develop a new drug; and federal policies that affect the demand for drug therapies, the supply of new drugs, or both.

What Are Recent Trends in Pharmaceutical R&D and New Drug Approvals?

The pharmaceutical industry devoted $83 billion to R&D expenditures in 2019. Those expenditures covered a variety of activities, including discovering and testing new drugs, developing incremental innovations such as product extensions, and clinical testing for safety-monitoring or marketing purposes. That amount is about 10 times what the industry spent per year in the 1980s, after adjusting for the effects of inflation. The share of revenues that drug companies devote to R&D has also grown: On average, pharmaceutical companies spent about one-quarter of their revenues (net of expenses and buyer rebates) on R&D expenses in 2019, which is almost twice as large a share of revenues as they spent in 2000. That revenue share is larger than that for other knowledge-based industries, such as semiconductors, technology hardware, and software.

The number of new drugs approved each year has also grown over the past decade. On average, the Food and Drug Administration (FDA) approved 38 new drugs per year from 2010 through 2019 (with a peak of 59 in 2018), which is 60 percent more than the yearly average over the previous decade.

Many of the drugs that have been approved in recent years are “specialty drugs.” Specialty drugs generally treat chronic, complex, or rare conditions, and they may also require special handling or monitoring of patients. Many specialty drugs are biologics (large-molecule drugs based on living cell lines), which are costly to develop, hard to imitate, and frequently have high prices. Previously, most drugs were small-molecule drugs based on chemical compounds. Even while they were under patent, those drugs had lower prices than recent specialty drugs have. Information about the kinds of drugs in current clinical trials indicates that much of the industry’s innovative activity is focused on specialty drugs that would provide new cancer therapies and treatments for nervous-system disorders, such as Alzheimer’s disease and Parkinson’s disease.

#### Plan kills innovation---disincentivizes R&D

Natalie Stoltz 14. J.D., 2013, Saint Louis University School of Law. "Reverse Payment Agreements: Why a Quick Look Properly Protects Patents and Patients," Saint Louis University Law Journal 58, no. 4 (Summer 2014): 1189-1214. HeinOnline.

A. Inadequacy of Per Se, Scope of the Patent, and Rule of Reason Tests

Analysis under the per se test is too favorable to generic challengers, providing no deference to the lawful patent held by a brand name pharmaceutical company.167 Although per se analysis provides for cost- effective litigation, it is too one-sided in the case of "reverse payments."'68 Additionally, it would likely stem innovation as pharmaceutical companies may be less inclined to spend enormous sums on research and development if they cannot sustain monopoly-level profits for a reasonable period of time.169 The per se test does not take the need to foster innovation into consideration. As such, it gives no deference to the purpose of patent laws and patent protections. Finally, courts are wary of relying on per se rules of illegality if there is "no justification other than the enhancement of predictability and the reduction of judicial investigation" for it may be viewed as abdicating their responsibility to tackle difficult economic problems. 170 In this instance, any per se rule would unduly burden the pharmaceutical industry and possibly reduce innovation and competition in the industry; thus, it is an inadequate response to reverse payment agreements. As such, the Supreme Court properly disregarded this approach for "reverse payment" agreements.

#### The aff increases litigation---that stifles innovation and turns their costs advantage

Sheila Kadura ‘8. Ph.D. in Molecular and Cellular Biology, Baylor College of Medicine, and J.D. candidate, University of Texas School of Law, 2008. "Is an Absolute Ban on Reverse Payments the Appropriate Way to Prevent Anticompetitive Agreements between Branded- and Generic- Pharmaceutical Companies," Texas Law Review 86, no. 3 (February 2008): 647-666. HeinOnline.

The FTC is concerned that a reverse payment will delay market entry of the generic product because the generic firm would most likely negotiate for 1 30 an earlier market-entry date in the absence of the reverse payment. However, as noted above, an absolute prohibition on reverse payments likely hinders settlement, and preventing settlement increases the likelihood that a court will find a particular patent both valid and infringed.13' At least one empirical study has indicated that the patent owner's likelihood of success at trial has increased in recent years, 132 and the Cipro 133 and Tamoxifen 134 examples provide illustrations of the principle that increased litigation can be detrimental to the goal of expanding the number of generic products avail- able to consumers.

Another concern is that the increased litigation that occurs in the absence of preferred settlement options may stifle innovation. Clearly, generic products save consumers money, but it is important to remember that such products cannot exist unless a branded-pharmaceutical product is first developed and shown to be safe and effective, which is an expensive endeavor.135 The decreased certainty that accompanies increased litigation may be particularly troublesome in the context of pharmaceutical innovation because the pharmaceutical industry relies heavily on a strong patent system to attract investors due to the high cost and risk associated with drug development.136 In addition to concerns regarding the uncertainty surrounding litigation, the act of litigating is itself quite costly. For example, one study found that pharmaceutical companies spend twenty-seven cents on litigation for every dollar they spend on researching and developing new pharmaceuticals. 137 Th

e financial uncertainties associated with litigation may prevent branded and generic firms from bringing products to market.'38 For example, both parties may freeze assets that would be used for research and development so that these assets are available to pay litigation expenses or to cover potential damages or lost profits.139 Based on these observations, one must be concerned that increased litigation will actually raise branded- and generic-drug prices because the expenses associated with litigation-and the uncertainty it brings-must be absorbed by either the branded- or generic-40 drug manufacturers or by consumers. 140

#### Litigation is too slow and enforced inherently reactionary.

Tom Wheeler et. al. 20. Wheeler is a Senior Fellow at the Shorenstein Center at Harvard Kennedy School and a Visiting Fellow at the Brookings Institution; Phil Verveer is a former Senior Counsellor to the Chairman of the FCC and presently a Senior Fellow at the Shorenstein Center at Harvard Kennedy School; Gene Kimmelman is a Senior Fellow at the Shorenstein Center at Harvard Kennedy School. "New Digital Realities; New Oversight Solutions." Shorenstein Center. 8-20-2020. https://shorensteincenter.org/new-digital-realities-tom-wheeler-phil-verveer-gene-kimmelman/

ANTITRUST: AT BEST A PARTIAL SOLUTION Our first national competition law, the Sherman Act, was written in 1890 in the era of “trusts,” financial constructions that gave control over multiple state-chartered companies to a common entity. Twenty-four years later it was updated with the Clayton Act to establish a national policy to protect against a broader definition of restricted competition. The antitrust laws were created to protect competition in an industrial environment. The application of these statutes to the digital environment has been impeded not only by the challenge of applying industrial concepts to a digital reality but also by the evolution in jurisprudence over the last forty years. Today’s implementation of competition policy began in the 1970s with the broad adoption by courts and prosecutors of the so-called Chicago School’s assertion that most competition-related government interventions in the economy were counterproductive.[9] The only true measure of a company’s market power, according to the strong version of the theory, is the effect on consumers as measured principally by prices. In the intervening decades this version of the “consumer welfare test” has become a conservative litmus test for judicial appointments and a guiding light of antitrust policy. It appears to have a majority of the United States Supreme Court as adherents. The 2018 decision in Ohio v. American Express Co. is both the first time the Supreme Court has addressed an antitrust claim involving a two-sided platform and an instance of the Court majority’s non-interventionist priors. The decision has, at least, increased the complexity of antitrust enforcement involving digital platforms. But without regard to its intrinsic merits, it illustrates one thing beyond any serious dispute: A process that began with a government complaint in October 2010 and not ultimately resolved until June 2018 is insufficient to deal with today’s digital platforms. Something more will be required. Such a “something” begins with the recognition of certain digital platforms (or certain components of them) as essential facilities. As common experience and multiple studies have illustrated, however, these essential services do not confront effective competition and are unlikely to do so in the future. The consequences are significant.[10] The introduction of competition in the case of targeted advertising, for instance, would have as predictable consequences that advertisers would pay less, publishers would receive more, and consumers would see an improvement in the quality and quantity of services available online. While an important tool in the toolbox, it must be realized that antitrust remedies are blunt instruments. They are, for instance, an ex post response to a problem rather than an ex ante policy that would discourage such difficulties in the first place. Furthermore, antitrust enforcement is inherently uncertain and reliably lengthy, a period in which the targets continue their anticompetitive behavior. By the time of even successful conclusions, rapid tech changes often have redefined the relevance of the initial complaint (See US v. Microsoft). There is also a substantial question of whether courts rather than specialized regulatory agencies are best equipped to deal with the issues raised by the digital platforms. Professor Weiser cites Judge Easterbrook for the proposition that “courts are inherently ill-suited for such a role both because they lack the ability to gather, and the expertise to process, the necessary information.”[11] Conclusion: Antitrust is an important tool but cannot be relied upon as the only tool. There must be realistic expectations as to what the tool can accomplish. There also must be a regulatory partner to the judicial remedy of antitrust.

## Access

#### Backlash kills all FTC enforcement.

Adam Speegle 12. J.D. Candidate, May 2012. “Antitrust Rulemaking as a Solution to Abuse of the Standard-Setting Process”. Michigan Law Review. March 2012, Vol. 110, No. 5 (March 2012), pp. 847-873. https://www.jstor.org/stable/23216802

Another major concern with bringing cases under an independent Section 5 is that, as the application of the provision expands and the bounds of its flexibility are tested, the FTC risks eventual backlash from the courts or Congress similar to the backlash it experienced in the 1980s.129 The FTC relies on Section 5 in both antitrust and consumer protection actions. A negative holding on Section 5's use in the standard-setting context may not only bear on future patent holdup enforcement efforts but may also severely impede the FTC's efforts in other areas. If the FTC fails to limit the application of Section 5, it risks subjecting Section 5 to the same or more severe judicial and congressional treatment than it experienced in the past.130 Additionally, many states have their own statutes that are modeled after the FTCA. These state statutes are interdependent with the federal FTCA, and state courts interpret them using federal FTCA precedent.131 Because holdings related to the FTCA at the federal level can, for better or for worse, impact these state statutes, unfavorable Section 5 precedent could also undermine actions

## FTC DA

#### 3. Economy---algorithmic bias turns the economy---drains business profitability.

Kalinda Ukanwa 21. Assistant professor of marketing at the University of Southern California’s Marshall School of Business, 5/23/21. “Algorithmic bias isn’t just unfair — it’s bad for business.” https://www.bostonglobe.com/2021/05/23/opinion/algorithmic-bias-isnt-just-unfair-its-bad-business/

These moves respond to growing concerns that algorithms have been reproducing discrimination in situations such as home lending, the allocation of health care, and decisions about who deserves parole. While many people hoped machines could help us make fairer decisions, as the use of AI has exploded it’s become clear that all too often they simply replicate and even amplify our existing prejudices.

An important part of the story has been missing, however. It’s one that might make businesses more amenable to regulation or even preclude the need for it by motivating them to act on their own. Algorithmic bias is not only a pressing ethical and societal concern — it’s also bad for business.

My research shows that over time, word of mouth about algorithmic bias among customers will hurt demand and sales and cut into profits. This damage won’t just hit a few unlucky companies that find themselves embroiled in public controversy around algorithmic discrimination. It can occur even if the inner workings and biases of an algorithm remain invisible to the public.

To understand how this can happen, consider one tech giant’s failed attempts at algorithmic design. In 2014, Amazon launched an internal tool to evaluate resumes. Although the algorithm was not programmed to look at the gender of the job applicants, it was trained using data from the company’s previous decade of hiring decisions, and the applications in that period mainly came from men. Based on past patterns, the algorithm learned to downgrade resumes that mentioned certain women-only colleges or women’s sports or clubs.

Amazon dropped that tool once these biases were discovered, but companies still widely use algorithms for recruiting and hiring. Not only are employers potentially missing out on valuable candidates, but over time these losses will compound through word of mouth. People learn about opportunities from members of their social circles, who often have race, age, gender, and other demographic characteristics in common. When women hear that their female friends and colleagues have been passed over for jobs at a particular company, they are less likely to apply, even if they know nothing about why these other candidates were rejected.

Using group characteristics to make decisions about whether and how to provide services to individual consumers may seem logical in some cases and may even be profitable in the short term. For example, a property manager might believe there are legitimate business reasons to choose tenants based on their age or education level. But my research, which uses computational methods to simulate consumer behavior, shows that these types of “group-aware” algorithms will tend to become less profitable over time.

In a study I conducted with Roland Rust, we simulated how customers would respond to two banks. One bank is “group-aware” and has various loan-approval thresholds for members of different groups. For example, women might have to meet a higher standard than men to get a loan. The other bank in the model is “group-blind”: It has the same approval threshold for every applicant.

Our model indicates that most members of the favored group meet the loan threshold at both banks, so they are likely to apply to either. But members of the group being discriminated against learn from one another to avoid the group-aware bank in favor of the group-blind one. Furthermore, members of the group experiencing discrimination also influence some members of the favored group to avoid the group-aware bank. As time passes, there is a net movement of customers toward the group-blind bank, hurting the profitability of the group-aware bank.

In short, when consumers learn from one another that a company is less likely to serve them, even if the discrimination is unintentional, they’ll avoid that company and it’ll lose revenue.

Algorithms often become group-aware when they aren’t intended to be. AI teases out correlations in the data that serve as stand-ins for group membership. For example, in our geographically segregated society, ZIP codes and other location data are a common proxy for race. Ride-sharing companies discovered the problem when a study revealed that their location-based pricing algorithms charge customers more for rides to or from neighborhoods primarily occupied by people of color. In other words, programming an AI system to ignore people’s gender or race or leaving this information out of the data set entirely isn’t enough to ensure an algorithm is group-blind.

What can companies do to make algorithms treat people fairly? Here are three key steps they can take:

1. Rather than removing group identifiers, businesses should include demographic characteristics in their data so they can continually audit their algorithms to determine whether they inadvertently discriminate against certain groups. There are a number of tools to evaluate whether bias is creeping in. IBM’s AI Fairness 360 is an open-source tool kit that helps detect bias in machine learning models. Microsoft’s FATE research group produces reports and tools aimed at reducing bias and increasing transparency and accountability in AI.

2. Companies can model how their systems’ decisions will affect demand over the long run among consumers who learn that some groups are treated differently. For example, if a bank used a model similar to the one in my study, it could easily see the long-term impact of a group-aware algorithm for making loans.

3. Whenever possible, algorithms should be designed to make decisions using context-specific data about individuals — looking at someone’s bill payment frequency in loan decisions, for example, or a patient’s cholesterol levels in health care, or a student’s grades in education — rather than trying to infer such information from other data points like their education level or where they live. The data used to train the algorithm is important too. Increasing the variation among and representation of different kinds of consumers allows algorithms to better evaluate individuals on their own merits.

Algorithms can lead to fairer outcomes, but only if they are designed and managed carefully. As computers increasingly make influential decisions about our lives, from the health care and financial services we receive to our educational and career prospects, we must remain alert to the potential for bias. There are strong ethical and moral reasons to do so, but there is also a business case to be made. We need to make sure companies understand how algorithmic bias can hurt their bottom lines.

#### 1. FTC focusing its resources on privacy now.

Jessica Rich et al. 10/3/21. Former director of the Federal Trade Commission’s (FTC) Bureau of Consumer Protection (BCP), with Laura Riposo VanDruff, Alysa Z. Hutnik & William C. MacLeod. “FTC Chair Khan’s Vision for Privacy – and Some Dissents.” https://www.adlawaccess.com/2021/10/articles/ftc-chair-khans-vision-for-privacy-competition-and-big-tech-and-some-dissents/

First, Khan’s statement reiterates her commitment to address privacy through a “cross-disciplinary” approach that uses the tools of competition law, not just consumer protection law, to address privacy harms. She states that “concentrated control over data has enabled dominant firms to capture markets and erect entry barriers while commercial surveillance has allowed firms to identify and thwart emerging competitive threats,” resulting in reduced privacy.

To address these concerns, as outlined further in the report, the agency intends to focus “most” of its limited resources against the “data practices of dominant digital platforms,” including through additional compliance reviews and order modifications and enforcement, “as necessary,” against, for example, Facebook, Google, Microsoft, Twitter, and Uber.

The Report adds that (with more resources from Congress), the FTC also will prioritize:

Adtech and “Walled Garden” Advertising Practices, including:

“[B]usiness models that depend on expansive and potentially illegal data collection to fuel targeted advertising and user engagement,” and

“Exclusionary or predatory conduct by dominant digital platforms to defend their data troves, resulting in lower levels of privacy and data protections and more intrusive ads.”

Children’s Tech: “Platforms and other online services that are potentially violating COPPA, an area of particular importance given that many children may be increasingly relying on online services for both educational, entertainment, and social purposes during the pandemic.”

Other Privacy Considerations, such as data uses involving health, biometric, or other sensitive data, discriminatory algorithmic practices, or other deceptive or unfair data practices.

#### 2. FTC currently implementing Biden’s XO to focus on privacy.

Crowell & Moring 9/1/21. Law firm. “FTC Rulemaking Pursuant to Biden’s Executive Order and Beyond: What is Settled, Not Settled, and What to Expect Going Forward.” https://www.crowell.com/NewsEvents/Events/FTC-Rulemaking-Pursuant-to-Bidens-Executive-Order-and-Beyond-What-is-Settled-Not-Settled-and-What-to-Expect-Going-Forward

On July 13, President Biden signed the sweeping Executive Order on Promoting Competition in the American Economy, which contained 72 directives to multiple federal agencies aimed at establishing a “whole-of-government” effort to promote competition across broad swaths of the American economy. Many recommendations within that Executive Order called upon the FTC to issue new rules relating to consumer protection, privacy, and competition issues. Even before the Executive Order, several Commissioners and other commentators were calling upon the FTC to exercise its rarely-used independent rulemaking authority to issue new rules to address a broad range of issues.

This webinar will focus on how the FTC and other federal agencies may seek to implement these recommendations and directives to engage in new rulemaking. It will focus on the scope of FTC’s rulemaking authority and the rulemaking process, opportunities companies may have to participate in the rulemaking process, and how to prepare for the challenges new FTC rules may create.

#### 2. The FTC’s changing their approach to allow them to focus on enforcement cases

Lauren Feiner 21. News Associate at CNBC, 8/3/21. “FTC struggles to keep up with merger filings, tells some businesses to merge at own risk.” https://www.cnbc.com/2021/08/03/ftc-tells-some-businesses-to-merge-at-own-risk.html

By law, regulators have a set amount of time to review pre-merger filings before parties consummate their deals. Regulators can issue a so-called second request to halt the process and ask for more information, but after receiving those documents, they have a set period of time to review and choose whether to block the deal before parties can again move forward.

While declining to block a merger doesn’t count as a rubber stamp or preclude the regulator from seeking to unwind it in the future, it often provides businesses some reassurance to move forward in the process.

But due to constrained resources, Vedova said there are some deals the FTC simply cannot investigate fully within the timeframe set by law. As a result, the FTC has begun sending letters to parties in such deals that basically say the agency hasn’t completed its review but can’t hold up their merger any longer, so the parties should proceed at their own risk.

“Accordingly, even if the parties consummate the above-referenced transaction, the Commission may still take further action as the public interest may require, which may include any and all available legal actions and seeking any and all appropriate remedies,” a sample letter to such businesses says.

The FTC’s new approach will likely create more uncertainty for businesses whose deals remain under review outside of the standard timeline.

The FTC splits oversight of HSR merger review with the Department of Justice Antitrust Division. Still, both agencies have pleaded with lawmakers for years for more resources to deal with greater demands on their agencies. Both, for example, have filed within the last year major antitrust lawsuits against two of the largest businesses in the world: Facebook and Google.

Merger reviews can often take precedence over misconduct cases within the agencies due to the tight timeline regulators are bound to by law for M&A. The FTC’s new approach could give staff more room to work on non-merger cases even as the agency is faced with a surge in HSR filings.

#### 4. Other enforcement is all talk

JED GRAHAM 9/16/21. Writes about economic policy for Investor's Business Daily.

Khan is clearly using her bully pulpit to the utmost, trying to dissuade merger talks from reaching fruition.

But right now it's all talk. She has turned a few heads, but the S&P 500 and Big Tech leaders have kept cruising. Facebook stock is up 11% since Khan took the FTC's helm on June 15, while Apple has climbed 15% and Google stock 18%. That's despite reports that the Justice Department is preparing to file a second Google antitrust suit over its ad dominance.

The new antitrust enforcement regime may not change all that much "until they show that they can sue and win," Kovacic said.

#### 2. Budget increase---it’s neg uniqueness---it means the FTC can handle what it’s currently doing, not an expansion. Proves the staffing link.

Kiran Stacey 8/10/21 – Washington Correspondent for the Financial Times, 8/10/21. “Washington vs Big Tech: Lina Khan’s battle to transform US antitrust.” https://www.ft.com/content/eba8d3d7-dba7-4389-858c-5406c31b413d

Even if Khan does win some of the landmark cases she is likely to bring, some worry the FTC will not have the capacity to write new competition rules and rewrite merger guidelines at the same time. “The FTC can put together legal teams that can match the best in the bar, punch for punch, in a major case,” says Kovacic. “But the number of those teams is a couple, it is not 10.” For years the commission’s budget and staffing levels have been chipped away. It now has roughly 50 per cent of the staff it had in 1980 and is currently trying to review a record number of mergers. In the first nine months of this fiscal year, the FTC received 2,573 notifications ahead of a large merger — already 50 per cent more than were received in the whole of last year. Last week, the commission published a statement warning that it would not be able to review all mergers within 30 days of a notification being made, as required by law. Instead, the FTC said, if it had not had time to review a merger before it took place, it would reserve the right to take action even after it had been completed. “This year, the FTC has been hit by a tidal wave of merger filings that is straining the agency’s capacity to rigorously investigate deals ahead of the statutory deadlines,” the commission said in a statement. The commission is also facing an uphill battle to retain staff. Some people say they feel demoralised by the pace of change and irritated they have not yet met their new chair — something Khan’s allies say is an unfortunate result of the pandemic. “There are only so many times you can hear that your institution has failed for years before you start to doubt your place in it,” says one staff member. But a bigger problem is that companies and private law firms are gearing up for a more aggressive FTC by trying to poach its talent. “I usually have to place a couple of FTC people in any given year,” says Lauren Drake, a partner at the Washington-based recruiting firm Macrae. “So far this year I have had 10.”

#### 1. FTC is cash-strapped---the plan destroys other enforcement priorities.

Nicolás Rivero 21. Technology reporter at Quartz. “Biden’s antitrust crusaders can’t crusade without Congress.” 3/11/21. https://qz.com/1982437/lina-khan-and-tim-wu-need-congress-to-push-their-antitrust-agenda/

But there are clear limits to their power. The most the FTC can do is bring more antitrust cases that ask courts for more aggressive remedies, like breakups. That would allow the agency to make a point about what it considers acceptable business behavior. But many of those lawsuits would be bound to lose in front of judges who have grown far more skeptical of antitrust cases over the past four decades and far more conservative over the past four years.

A larger caseload would also require Congress to approve more funding for the cash-strapped agency, which is already struggling to pay for its current docket. “The agencies have been asked on many occasions to do a lot with relatively little…but it’s not for free,” says former FTC chair and George Washington University law professor Bill Kovacic. If the FTC wants to pursue more large cases without a bigger budget, “they’ll have to make choices, and those choices will involve backing off of other areas of enforcement.”

#### 2. Limited resources force tradeoffs in enforcement decisions.

Bernard (Barry) A. Nigro Jr. et al., 21 – Chair of Fried Frank's Global Antitrust and Competition Department, former Principal Deputy Assistant Attorney General at the DOJ, with Nathaniel L. Asker and Aleksandr B. Livshits, 1/5/21. “Managing Antitrust Risk in the Biden Administration.” Fried Frank Antitrust & Competition Law Alert. https://www.friedfrank.com/siteFiles/Publications/FFAntitrustAggressiveAntitrustEnforcement01052021.pdf

Further, despite a record number of litigated cases, the budget at the antitrust agencies is insufficient to match the rhetoric of more enforcement. The DOJ had 25% fewer full-time employees in 2019 than it had 10 years earlier9 and the FTC recently imposed a hiring freeze. With limited resources, the agencies are forced to make important tradeoffs in deciding what matters to challenge, settle, or walk away from. Indeed, Commissioner Wilson reportedly voted against bringing a lawsuit to block CoStar’s acquisition of RentPath, in part, because of limited FTC resources.10 Although the agencies will receive a modest budget increase for the current fiscal year,11 it is far short of what some think is needed.12 As antitrust enforcement has become a bipartisan issue, a significant increase in the antitrust agencies’ budgets in the future is likely.

#### 3. It directly undermines privacy enforcement.

David Hyman 19 – Professor at Georgetown University Law Center, with William E. Kovacic, “Implementing Privacy Policy: Who Should Do What?” 29 Fordham Intell. Prop. Media & Ent. L.J. 1117 (2019). https://ir.lawnet.fordham.edu/iplj/vol29/iss4/3

The case for making an enhanced FTC the national privacy regulator is straightforward. Of all U.S. privacy implementation institutions, the FTC has unequaled capacity in the form of expert case handling and policy teams and physical resources (including the development, over the past decade, of an internet laboratory to do high-quality forensic work, and the hiring of technology experts to assist in that effort). The agency’s capacity also is the product of extensive experience in applying its UDAP authority and enforcing statutes such as the FCRA and COPPA. The FTC has a broad portfolio of policy instruments (litigation, rulemaking, consumer and business education, data collection, the preparation of reports, the convening of conferences), and it has demonstrated its ability to use all of them to good effect in the privacy domain. The FTC’s stature as an independent agency gives it additional credibility in the eyes of foreign officials, who generally distrust the vesting of privacy powers in an executive department.

Within an enhanced FTC, privacy policy implementation also would be informed by the Commission’s larger experience with consumer protection. The FTC’s privacy unit is one part of its Bureau of Consumer Protection, rather than being a self-contained bureau. This reflected the institution’s reasonable view that the effort to safeguard consumer interests in “privacy” was one dimension of “consumer protection,” rather than a wholly distinct policy realm. Our impression is that many matters that involve privacy issues also raise problems that fit within other areas of the FTC’s consumer protection program. The analysis of the “privacy” issue often benefits from perspectives developed in the course of applying the agency’s deception and unfairness authority in other cases. The intertwining of privacy issues with other consumer protection concerns in many scenarios has important implications for how the mandate of a privacy agency should be defined. In whatever setting one ultimately might place a “privacy” mandate, we would expect that the host agency would have a mandate that incorporates powers that traditionally have been associated with the FTC’s broader consumer protection program.83

The FTC’s expertise in antitrust should also help it develop and enforce privacy policy. Enforcing antitrust law has given the FTC ongoing involvement in multiple high-tech markets—as well as an understanding of how competition can motivate companies to offer better privacy protections. The FTC’s work in both consumer protection and antitrust draws upon a Bureau of Economics with over 80 PhDs in economics.84 The Bureau of Economics has developed considerable skill in sub-disciplines (including behavioral economics) with special application to privacy issues.

Of course, inputs are not the same thing as outputs. The FTC has not always achieved the full integration of perspectives that the combination of these institutional capacities would permit. And, although there are policy complementarities across the domains of antitrust, consumer protection, and privacy, this combination of functions is not an unmixed blessing. An agency with all three functions might seek to use its position as a gatekeeper with respect to one policy domain to leverage concessions from firms over which it exercises oversight in another domain.85 Such temptations have been present when the FTC has applied its antitrust powers to review mergers involving companies in the information services sector.86

Finally, there is the possibility that any one of these functions might be diminished if all three are contained in the same agency. An agency focused solely on privacy will make privacy policy its single concern. An agency responsible for antitrust, consumer protection, and privacy is likely to find itself making tradeoffs as it sets priorities for how to use its resources.

#### Treading on new turf magnifies the link---the agency will take time AND money to develop new proficiencies

Seth B. Sacher & John M. Yun 19, Sacher is an Economist, Washington, DC; Yun is from the Antonin Scalia Law School, George Mason University, “TWELVE FALLACIES OF THE "NEO-ANTITRUST" MOVEMENT,” 26 Geo. Mason L. Rev. 1491, 1493, Summer 2019, Lexis

VII. Fallacy Seven: Not Recognizing That Their Proposals Will Strain Competition Agency Resources, Increase Uncertainty, and Make These Agencies More Political and Subject to Capture

Most of those that have worked within, or before, the antitrust agencies, despite their inevitable disagreement with certain actions or policies, are generally very impressed with the high degree of skill, professionalism, and dedication exhibited by the career staff. As will be discussed more fully in the [\*1515] context of Fallacy XI below, many proponents of neo-antitrust do not accept the proposition that the antitrust agencies and their staffs function relatively well, in spite of the views of many (on all sides of the political spectrum) who have had experience working within or before the antitrust agencies. Regardless of how neo-antitrust proponents view the agencies, many of their proposals run a serious risk of adversely affecting competition agency performance.

There are a number of objective reasons to expect antitrust agencies to function relatively well. First, antitrust agencies tend to be small relative to many other regulatory agencies and bureaucracies in general. Second, their staffs tend to be highly trained professionals, consisting primarily of lawyers and Ph.D. economists. Third, they have a well-defined objective (i.e., the consumer welfare standard or some similar standard based on economic reasoning, such as the total welfare standard). Finally, although antitrust is considered a form of regulation, it is distinct from other forms of regulation in that it does not involve a continuing relationship between the regulated firms and the regulator. As a goal, antitrust seeks to enable markets to more nearly achieve certain social objectives on their own.

First, advocates of neo-antitrust would like to see the responsibilities of the antitrust agencies expanded in a number of ways. This includes more aggressively enforcing existing antitrust laws, as well as the consideration of issues beyond those currently within that purview. Further, many of their proposals, such as requiring data sharing, monitoring markets to prevent tipping, or approving platforms' algorithm changes, will require significantly more active market supervision than is currently the case. While many [\*1516] proponents of modern antitrust would agree that the antitrust agencies are underfunded, there is certainly a point at which expanding the antitrust agencies will have "bureaucratic" diseconomies of scale. Fully following the recommendations of neo-antitrust advocates could very well require many antitrust agencies to expand beyond some critical point, which will inevitably lead to significantly larger bureaucracies and associated inefficiencies.

#### Healthcare review is particularly resource intensive.

Alden Abbott 21. Senior Research Fellow, Mercatus Center, 4/29/21. “Lack of Resources and Lack of Authority Over Nonprofit Organizations Are the Biggest Hindrances to Antitrust Enforcement in Healthcare.” https://www.mercatus.org/publications/antitrust-and-competition/lack-resources-and-lack-authority-over-nonprofit

The problem of resource constraints is particularly acute in the case of healthcare merger reviews, given the increasing consolidation of healthcare institutions. As one noted healthcare scholar stated in 2019, “The Affordable Care Act did not start the consolidation rapidly occurring with hospitals/health systems and medical groups, but it most definitely accelerated the movement to combine. In the last five years, the number and size of consolidations have been at an all-time high.” Moreover, according to health policy analyst Brian Miller and coauthors, “experts have expressed concern regarding a new merger wave due to pandemic-induced financial distress driven by the temporary cessation of profitable elective care and decreased hospital use.” Antitrust enforcers will need additional resources to ensure that this trend does not yield mergers that undermine the competitive process and harm consumers.

#### FTC enforces the plan.

Jacqueline LaPointe 19. Editor at Xtelligent Healthcare Media, 5/16/19. “FTC Official Calls for More Aggressive Healthcare Merger Approach.” https://revcycleintelligence.com/news/ftc-official-calls-for-more-aggressive-healthcare-merger-approach

The FTC is responsible for enforcing antitrust laws in healthcare markets to prevent anticompetitive conduct that would increase costs, decrease care quality, and/or stifle innovation for consumers. To live up to its mission, the agency has been busy challenging several recent healthcare merger proposals such as the Penn State Hershey Medical Center-PinnacleHealth System deal in Pennsylvania and the DaVita-Renal Ventures Management LLC deal.

#### More ev.

Enrico Böhme et al. 21. School of Business and Economics, Research Group Institutional Economics, Philipps-University Marburg, with Jonas Severin Frank & Wolfgang Kerber. “Optimal Incentives for Patent Challenges in the Pharmaceutical Industry.” Review of Industrial Organization (2021). https://link.springer.com/article/10.1007/s11151-021-09815-0

Since the prices of pharmaceutical products sharply decrease after the entry of generics, any unjustified delay in generic firms’ entry can lead to high additional health costs for consumers and society. For that reason, the U.S. Federal Trade Commission (FTC) has challenged patent settlements with reverse payments in the pharmaceutical industry since 1999 (FTC 2002). In particular, patent settlements in which the (patent-holding) originator firms pay large sums to generic firms—‘reverse payments’—and agree on future entry dates of generics have been the object of competition and antitrust law proceedings.

#### The FTC adjusted its process to handle the merger wave.

NYT 8/17/21. The New York Times. “Biden antitrust stance raises concern.” https://finance-commerce.com/2021/08/biden-antitrust-stance-raises-concern/

Antitrust activity is heating up this summer. New bipartisan legislation aimed at Big Tech was just introduced in the Senate, and federal agencies have adopted a skeptical stance on deal-making.

“I believe the antitrust agencies should more frequently consider opposing problematic deals outright,” Lina Khan, the chair of the Federal Trade Commission, wrote in a letter to Sen. Elizabeth Warren, D-Mass., released last week.

The tough talk advances the Biden administration’s position, expressed in a sweeping executive order last month, that cracking down on consolidation protects consumers, markets and workers. But some antitrust lawyers, including former regulators, told the DealBook newsletter that they feared this stance could chill legitimate deals and give enforcers the impression that approving any merger is politically fraught.

Mergers are surging in “astounding” numbers, the FTC said recently. A “tidal wave” of filings has strained resources, and the agency is adjusting its premerger review process, telling companies that they close at their own risk after the usual 30-day review deadline, as deals may later be deemed illegal. The agency already can challenge done deals, but the initial review framework is meant to minimize this insecurity, Christine Wilson, one of two Republican FTC commissioners, wrote in a statement. She said the FTC’s altered process might be driven as much by politics as by the rise in merger activity.

#### Not actually a tidal wave of mergers.

Kirk Arner 8/10/21. Legal fellow at the Hudson Institute, with Harold Furchtgott-Roth. “The Harmful Death of Modern Merger Review.” https://www.realclearmarkets.com/articles/2021/08/10/the\_harmful\_death\_of\_modern\_merger\_review\_789287.html

But is the FTC’s assertion actually true? Has the FTC been hit by an unprecedented “tidal wave” of merger filings?

No, it hasn’t.

According to the FTC’s own 2019 report, the number of HSR transactions requiring filings roughly doubled between 2010 and 2017, growing from a little over 1,100 transactions in 2010 to just north of 2,000 in 2017. Between 2017 and 2020, transactions stabilized at roughly 2,000 to 2,100 per year.

The available data through 2021 do suggest an uptick in filings. Between January and July of this year, there were 2,067 total transactions filed. Over 7 months, that’s an average of 295 per month. Projecting this average out over 12 months would result in 3,540 total transactions filed for the entirety of 2021.

This increase may seem stark. But when viewed in the proper historical context, it’s hardly a “tidal wave.”

We need only look to historical data for proof—in particular, data from 1995 through 2000. During these years, there was only one month with fewer than 300 transactions filed. The vast majority of months during this period had 400, 500, or more transactions filed per month. This stands in stark relief to the 295 transactions per month in 2021 to date.

The year 1998 is particularly instructive. That year, the month with the fewest transactions was January, with 614 filed. Transactions peaked in June, with 862 filed that month. In only 2 months of that year were there fewer than 700 transactions filed. The end result? An astonishing 9,264 transactions were filed that year—more than triple the projected rate for 2021.