# Navy Round 4 Wiki

## 1NC

### T FTCA

#### Interpretation: The core antitrust laws are only sections 1 and 2 of the Sherman Act and section 7 of the Clayton Act.

The Antitrust Division 07 – Law enforcement agency that enforces the U.S. antitrust laws

“Antitrust Division Statement Regarding the Release of the Antitrust Modernization Commission Report,” The Antitrust Division, Department of Justice, April 2007, https://www.justice.gov/archive/atr/public/press\_releases/2007/222344.htm

The AMC has made many specific recommendations in its report, and the Division is in the process of reviewing all of them. The Division commends the AMC for its three primary conclusions:

Free-market competition should remain the touchstone of United States' economic policy. The Commission's conclusion in this regard is a fundamental starting point for policy makers. Over a century of experience has shown that robust competition among businesses, each striving to be increasingly successful, leads to better quality products and services, lower prices, and higher levels of innovation.

The core antitrust laws—Sherman Act sections 1 and 2 and Clayton Act section 7—and their application by the courts and federal enforcement agencies are sound and appropriately safeguard the competitiveness of the U.S. economy.

New or different rules are not needed for industries in which innovation, intellectual property, and technological innovation are central features. Unlike some other areas of the law, the core antitrust laws are general in nature and have been applied to many different industries to protect free-market competition successfully over a long period of time despite changes in the economy and the increasing pace of technological advancement. One of the great benefits of the Sherman and Clayton Acts is their adaptability to new economic conditions without sacrificing their ability to protect competition.

#### Violation: Plan fiats expansion of the FTCA

#### That’s a voter – it explodes limits and destroys link uniqueness for DAs

### CP Per Se

#### The United States Federal Government should establish a presumption of illegality for anticompetitive settlements related to pharmaceutical patents

#### It’s competitive – the plan text says “prohibit” – that means “ban” and they were extra nice to include “all” in the plan text.

Kennard 93 – Judge, California Supreme Court

Joyce L. Kennard, THEODORE R. HOWARD et al., Plaintiffs and Appellants, v. GEORGE H. BABCOCK et al., Defendants and Respondents. No. S027061., Supreme Court of California, 1993, https://law.justia.com/cases/california/supreme-court/4th/6/409.html

As I pointed out earlier, the majority's conclusion is at odds with the great weight of authority. Also, in determining reasonableness based on the relationship between or among attorneys, the majority gives little regard to the relationship between the attorney and the client. Moreover, the majority fails to recognize that restrictive covenants are intended to and do restrict the practice of law. Rule 1-500 proscribes agreements that "restrict" the practice of law, not just those that prohibit "altogether" the practice of law. (Contra, Haight, Brown & Bonesteel v. Superior Court (1991) 234 Cal.App.3d 963, 969 [285 Cal.Rptr. 845] [rule 1-500 "simply provides that an attorney may not enter into an agreement to refrain altogether from the practice of law"].) To "restrict" means to restrain, to confine within bounds. (Webster's New Collegiate Dict. (9th ed. 1988) p. 1006.) To "prohibit" means to prevent, to [\*\*164] [\*\*\*94] forbid. (Id. at p. 940.) The terms are not synonymous.

#### CP solves – establishes a rebuttable presumption against reverse payment settlements, which solves bad deals but allows good deals

Feldman 8/27 – Distinguished Professor of Law Chair & Director of the Center for Innovation, UC Hastings Law

Robin Feldman, Arthur J. Goldberg Distinguished Professor of Law, Albert Abramson ’54 Distinguished Professor of Law Chair, and Director of the Center for Innovation, The Price Tag of 'Pay-for-Delay', UC Hastings Research Paper Forthcoming, 27 Aug 2021, https://papers.ssrn.com/sol3/papers.cfm?abstract\_id=3846484

There is an old saying in the field of psychology that insanity is doing the same thing over and over again while expecting to get a different result. After watching plaintiffs and competition authorities struggle to satisfy the rule of reason in order to establish a pay-for-delay case, it is clear that continuing down the same path is unlikely to be fruitful.

The rule of reason, untethered, is a meandering test that cannot even be described in a simple sentence. The formulation rises from the 1918 Board of Trade case:

“The true test of legality is whether the restraint imposed is such as merely regulates and perhaps thereby promotes competition or whether it is such as may suppress or even destroy competition. To determine that question the court must ordinarily consider the facts peculiar to the business to which the restraint is applied; its conditions before and after the restraint was imposed; the nature of the restraint and its effect, actual or probable. The history of the restraint, the evil believed to exist, the reason for adopting the particular remedy, the purpose or end sought to be attained, are all relevant facts. This is not because a good intention will save an otherwise objectionable regulation or the reverse; but because knowledge of intent may help the court to interpret facts and to predict consequences.”177

Application of the rule in practice is no less nebulous than its formulation, despite the fact that courts add numbers to each of the various steps. The Supreme Court itself has called the rule of reason complex and burdensome. The intricate requirements of the rule, not to mention the burden it places both on parties and the courts,178 make the rule of reason particularly ill-suited for examining the ever-increasing number of agreements between brand and generic competitors. Although some scholars have argued that the rule of reason should be shelved entirely, such a broad-scale change is unnecessary for these purposes.

Pinning pay-for-delay reform squarely on an outright ban may not prove tenable, and other commentators have proposed intriguing alternatives. By one policy, for instance, if companies are unable to prove that their patent infringement settlement value was less than the cost of litigation and other services, then all that the generic company can receive is what it would be entitled to by a court ruling that a brand patent is invalid or not infringed.179

In other words, all the brand company can promise is what the court would give the generic company if the parties proceeded with the patent infringement litigation, and the generic won. No-authorized-generic clauses, among other creative anticompetitive ploys, would be presumed illegal by this framework. At the same time, it would permit patent settlements to remain where they are potentially procompetitive, eliminating unnecessary litigation between drug companies. Other prospective solutions seek to improve upon the fines used currently to disincentivize pay-for-delay conduct. As our analysis demonstrates, even companies fined by the FTC for pay-for-delay may profit handsomely from the practice.180 Considering the failure of fines to sufficiently discourage pay-for-delay, some scholars have advanced alternative punishments for cited drug companies. For instance, a first-filing generic company that agreed to postpone production in exchange for a no-authorized-generic clause could be stripped of its 180-day exclusivity period.181 Additional legislation might stipulate that brand companies forfeit the chance to earn additional non-patent regulatory exclusivities for a drug whose monopoly period they paid off competitors to extend. This way, instead of simply reducing the profits of offending drug-makers, the repercussions of pay-for-delay redound as social benefit.

Despite potential remedy-related reforms, however, the most important change needed pertains to evaluating the anticompetitive nature of the agreement itself. The landmark decision in Actavis expressed optimism that courts would be able to manage the analysis in a more structured manner. That reality has not materialized. To resolve the problem, one should return to the basic notion that agreements between competitors are strongly disfavored under antitrust law.

Given that agreements between competitors are disfavored, the test for agreements between brands and generics in the context of Hatch-Waxman litigation should begin with a presumption that the agreement is anticompetitive. This approach respects the essential design of the Hatch-Waxman system to ensure rapid entry of generic drugs, in part, by providing an incentive for generic drug companies to challenge patents that are invalid or invalidly applied.182 Only when the public interest is clearly served should the presumption fall.

#### It’s net beneficial – per se ban wrecks generic entry – turns both advantages

Seth 8/6 – Interviewing Dan Leonard, CEO of the U.S. Association for Accessible Medicines

Akriti Seth, AAM CEO ‘Not Fully Aligned With Biden Administration On Pay-For-Delay Ban’, Generics Bulletin, *August 2021*, <https://generics.pharmaintelligence.informa.com/GB151157/AAM-CEO-Not-Fully-Aligned-With-Biden-Administration-On-Pay-For-Delay-Ban>

“We’ve been supportive of the Biden administration’s steps so far on a number of areas, but not all of them,” said Dan Leonard, CEO of the US Association for Accessible Medicines, as he talked about the recently signed executive order by US president Joe Biden asking the Federal Trade Commission to ban so-called “pay-for-delay” reverse-payment settlements.

In an exclusive interview with Generics Bulletin, Leonard acknowledged that “We’re not fully aligned with the administration on that particular topic.”

“We think there’s certainly an opportunity to work with the administration to make sure that a blanket change to patent settlements does not damage the marketplace for generics and that there has to be thoughtful patent legislation or an executive action on patent reform that we can partner on,” added Leonard.

Furthermore, Leonard pointed out that “there are many instances where patent settlements are pro-patient and because of patent settlements between the originator and generic company, affordable medications come online even sooner for patients.”

Talking about successful pro-consumer patent settlements, Leonard said, “There are many examples that we could cite. That’s the kind of thing we need to make sure that the administration and policymakers understand [so] that there isn’t just a sledgehammer that comes down.” Leonard expressed concern over the ban that could “ultimately make it harder for patients to have access to critical medications.”

“We have to educate policymakers to make sure that a blanket or broad-brush approach doesn’t damages patient access at the end of the day,” Leonard said, insisting that “there should be pro-consumer patent settlements like we have seen in the past.”

In a recent interview with Generics Bulletin, Jeff Francer, senior vice president and general counsel of the AAM, had expressed concern over Biden’s executive order, suggesting that “we could have a slowdown in the availability of generics and biosimilars, because [a ban on pay-for-delay] would force generics and biosimilars to always have to litigate to finality on dozens and dozens of patents, which is enormously expensive and time consuming.” (see sidebar)

### CP Prizes

#### The United States federal government should implement a binding agreement to provide a value-based pricing prize mechanism for pharmaceutical innovation which would be reviewed by an independent adjudication committee

#### Adaptable, binding prize agreements create efficient R&D incentives that create new breakthrough innovation

Ganjour and Chernyak 11 – Afschin Gandjour is a medical doctor, health economist, and Gandjour received an M.D. from Hannover Medical School in Germany, an M.B.A. from Duke University, a Ph.D. in health economics from the University of Cologne in Germany, and an M.A. in philosophy from the University of Düsseldorf in Germany. He held faculty positions at the University of Cologne Medical School, Baylor College of Medicine, and Louisiana State University Pennington. Nadja Chernyak, Department of Public Health, Center of Health and Society, Heinrich-Heine University Düsseldorf, Düsseldorf, Germany.

Afschin Gandjour and Nadja Chernyak, October 2011, “A new prize system for drug innovation,” Health Policy, [https://www.sciencedirect.com/science/article/pii/S0168851011001114?via%3Dihub#](https://www.sciencedirect.com/science/article/pii/S0168851011001114?via%3Dihub)!

VBP = Value based pricing

In this paper we propose a new prize system for drug innovation, where public authority (e.g., a third party payer) is committed to pay a price based on the value of health benefits accrued over time. We define a minimum WTP for health benefits based on the cost-effectiveness of palliative or nursing care and provide a formal method to adjust the price upward based on the severity of disease. The proposed methodology allows us to overcome the lack of a formal method to determine reward size which is inherent in some other proposals linking prize payment to the value of health benefits.[9](https://www.sciencedirect.com/science/article/pii/S0168851011001114?via%3Dihub" \l "fn0045) Furthermore, we suggest a formal method to adjust prizes downward for imperfect information on health benefits, including information on potential drug overuse. Therefore, our approach does not presuppose perfect information on health benefits. The proposed reward mechanism enables refinement of a reward size by periodic reassessment of health benefits of a drug on the basis of newly available information, e.g., from post-marketing drug trials, pragmatic trials and [observational studies](https://www.sciencedirect.com/topics/medicine-and-dentistry/observational-study). The proposal is envisaged as a non-voluntary alternative to the current patent system. In this system approval of bioequivalent drugs including generics is abolished.

The proposed prize scheme can improve allocative efficiency of drug spending compared to the current patent system because no unrealized social benefits (deadweight loss) are created, as long as the threshold value reflects the real WTP for health gains. This prize system also provides strong incentives for innovation because the innovator reaps the full social surplus. Furthermore, the system prevents welfare loss from excessive marketing of the innovator and firms producing copycat drugs (me-too drugs with no proven additional benefit and generics). While [generic drug](https://www.sciencedirect.com/topics/medicine-and-dentistry/generic-drug) producers may still market their production capability to the innovator, the corresponding marketing effort seems small compared to that for the general population under the current system.

### DA Hospitals

**Healthcare consolidation is booming now and has momentum for the future**

**Diamond et al. 21** – Brandee Diamond is an M&A partner at Foley & Lardner LLP; Louis Lehot is an emerging growth company, venture capital, and M&A lawyer at Foley & Lardner; Eric Chow is an M&A lawyer with Foley & Lardner LLP

Brandee Diamond, Louis Lehot, and Eric Chow, "Healthcare Shines in M&A’s Major Comeback So Far In 2021," Healthcare Innovation, 4-12-2021, https://www.hcinnovationgroup.com/finance-revenue-cycle/mergers-acquisitions/article/21218175/healthcare-shines-in-mas-major-comeback-so-far-in-2021

In 2020, everything changed. Jobs were cut, businesses were shuttered, and too many people lost their lives. But the global pandemic also triggered a response that is creating new jobs, stimulating innovation, and **forging new business models**. The market for mergers and acquisitions has **weathered the storm** of COVID-19 and is **surging** into the second quarter of 2021 with **all pistons firing**, particularly in **healthcare**.

Today, there is so much more besides COVID testing and vaccinations happening behind the doors of healthcare providers worldwide. Think about it. Your town's family doctor's office down the street might now be part of a giant healthcare system. Or, your local urgent care center may be considering a merger with a leading healthcare corporation. These are unprecedented times in virtually every facet of the word in every nook and cranny on the planet, and **healthcare is at the forefront** when it comes to M&A.

In 2020, the healthcare industry was **beaten down** from the **overflowing** of COVID patients causing the **ripple effect** of non-emergency procedures' **postponements**. Looking forward, however, healthcare M&A activity is **set to increase** with the return of non-urgent **medical interventions** and healthcare companies **betting on growth** to get stronger and healthier.

The 2021 rebound

Early in 2020, there was a massive drop-off in M&A deals compared to the prior-year period, particularly for more significant transactions. However, the M&A market still had plenty of **potential for momentum**. Tragically, as the coronavirus's **full impact hit** by late March, most deal-making came to a screeching halt. Since companies put their resources into transitioning staff to working from home, reviewing finances, and maximizing dollars, many **paused** any pre-planned M&A deals and stopped filling the top of the funnel for a new pipeline.

As companies, investors and bankers adapted to virtual deal-making over the last year, M&A in sectors unaffected or boosted by the lockdown slowed. By summer 2020, transactions grew each month with key announcements in technology and **healthcare** corporate **consolidations**. Despite a slowdown for deals in the second quarter of 2020, activity increased in the second half, triggering an annual volume above $3 trillion for the seventh year in a row. And by winter, the pace of M&A deals **exceeded the historical average** with a fourth-quarter record of 1,250 global M&A transactions, equal to over $1 trillion.

This year, there is already **significant growth** on the horizon. In fact, 53 percent of U.S. executives said their companies plan to **increase M&A investment** in 2021. And, according to Morgan Stanley, “**All the elements** **are there** for an active M&A market in 2021, from corporations looking for **scale and growth** to private equity firms and SPACs looking to **invest capital**.” For some, growth will come from market leaders finding strength in a recovering economy. In contrast, others that have seen business models destroyed by the pandemic will explore how smaller deals in complimentary sectors can help innovate their businesses. Overall, targets will come from sellers, including businesses that have **struggled during the recession**, private investors, and companies that are reassessing assets.

M&A activity in healthcare to watch

As 2021 unfolds, there will an increase in **urgent care M&A activity**. We will likely see urgent care systems **buying smaller urgent care systems**, healthcare companies that don't have much to do with urgent care making **mergers and acquisitions**, and urgent care buying companies that complement their services. For example, retail chains like Walmart and CVS are opening more healthcare clinics. These days, urgent care clinics are not just used for emergency or immediate problems but are now also giving out vaccines and even doing annual physicals.

In healthcare, a merger's primary goal is to improve the quality of care while concurrently driving efficiencies that should lower costs. The reality is that today, it’s becoming more challenging to **stay in business** when your company is only known for one thing. Oftentimes, larger companies **offer more services**, which helps the patient and the provider’s pocket. Most of the time, consolidation happens because **customers prefer to combine trips**. The **fear of exposure** to the virus and **aiming to limit outings** will likely **push healthcare** companies to **make moves in M&A** as it relates to consolidation.

As of late, youth sports activities have become more sophisticated, with more businesses catering to them. As popularity grows, unfortunately, sports-related injuries grow too - creating **more opportunities** for healthcare companies. Ultimately, the pandemic is another reason for healthcare companies to offer **all-in-one** facilities. Despite the factors fueling deals, healthcare companies are going to see **more M&A activity** is due to the **growth vector** it can bring to a business.

M&A trends triggered by COVID-19

Several significant trends may characterize a robust M & M&A market for the rest of 2021 and beyond. First of all, we can expect **more megadeals** (transactions of at least $5 billion) in 2021, from pharma companies acquiring early-phase products and private equity acquisitions. With larger companies leading in this area, this activity will come even as company valuations have increased from their COVID-19 lows. The increase in megadeals in the second half of 2020 helped total U.S. deal value bounce back strongly going into 2021.

In addition, companies pursuing stock-for-stock mergers to gain scale comprised many of the largest corporate M&A transactions. Scale has always been important, and the pandemic has proven that you have to be **large enough** in order **to survive**. **Scale** and **more access** to capital markets have been a **considerable benefit** for larger companies. As the pandemic rages on, corporates remain focused on accessing capital, strengthening positions, and **investing in scale**, and consolidations **should continue** in sectors powered by technology and **healthcare**.

Private equity firms should continue to contribute to 2021 M&A volume meaningfully. In 2020, sponsor-backed transactions comprised 26 percent of M&A activity - the highest since before the financial crisis. In fact, by the end of 2020, financial sponsors had a record $2.9 trillion of capital. Last year, we saw many traditional private-equity funds investing across the capital structure to provide companies with cash during a challenging time.

Looking ahead

Looking later in 2021 and beyond, as vaccinations increase and business conditions in COVID-impacted sectors improve, companies will likely focus more on spending to accelerate growth, scale, and digitize their businesses.

As the global economic rebound aims for more growth this year, those **low-interest rates** will continue to make borrowing cheaper than ever before. This, along with the prospect for companies’ **renewed confidence** to spend, could create **more deals**, especially in **healthcare**-related business. So, M&A remains one of the most attractive ways to achieve growth, which should make 2021 a busy year…

**Consolidation is necessary to preserve rural hospitals, but pharma scrutiny deters them**

**Kaufman 20** – chair of Kaufman, Hall & Associates LLC

Ken Kaufman, "Removing Antitrust Barriers to Solve the Rural Health Care Crisis," Morning Consult, 1-2-2020, https://morningconsult.com/opinions/removing-antitrust-barriers-solve-rural-health-care-crisis/

Almost 120 rural hospitals have closed since 2010, and an estimated **21 percent** of rural hospitals are at **high risk of closure**.

The high number of financially stressed hospitals is creating a **crisis of access** for rural communities and a potential **crisis of quality** and patient safety, as these hospitals **struggle to secure** **sufficient** clinical and technological **resources**. These struggles can be even more difficult in towns that could once support two hospitals but can **no longer do so**.

A **solution** to the rural health crisis that promotes **partnerships** with larger health systems addresses two critical needs. First, it enables a **rational, equitable approach** to a fundamental restructuring of rural health care resources. Second, it provides **access to sufficient financial resources** to ensure that rural communities are able to benefit from the same resources available elsewhere.

Antitrust impediments to a system-based approach

Current **antitrust law makes it difficult** for individual hospitals or health systems to **collaborate on efforts** to restructure delivery of essential services within a rural health care market. These efforts can, however, be pursued among facilities owned by a **single health system**, enabling a rational and equitable distribution of services across the health system’s network of facilities and the communities they serve.

The Federal Trade Commission and Department of Justice have themselves acknowledged the **value** of a **system-based approach** to rural health. In their 1996 “Statements of Antitrust Enforcement Policy in Health Care,” the agencies created a **safe zone** for mergers of certain hospitals with a low bed size and low patient census with other hospitals.

The agencies recognized that these hospitals often “will be the only hospital in the relevant market” and that “mergers involving such hospitals are **unlikely** to **reduce competition substantially**.” They also recognized that “rural hospitals … are unlikely to achieve the efficiencies that larger hospitals enjoy. Some of these cost-saving **efficiencies** may be **realized** … **through a merger**.”

The situation becomes **more difficult** when a community has two hospitals that do not fall within the safe zone and it can **no longer support both**. Such markets will be considered highly concentrated, and an attempt to merge the hospitals **likely will be challenged** by the federal agencies.

Several states have tried to overcome the likelihood of an antitrust challenge by granting certificates of public advantage to health systems that want to come together to more effectively pool resources and rationalize services within a rural market. But these efforts also are being challenged by the federal agencies.

The **threat** of **antitrust enforcement** actions **throws a chill** over health system-led efforts to make the **rural health care** delivery system **more rational**, economically viable and equitable. For example, the systems that combined to form Ballad Health went through a two-year process to secure the COPA that ultimately allowed their merger.

They willingly accepted state oversight of their efforts to rationalize health care delivery. Yet, they now face an order by the FTC to provide extensive information for a study on the impact of COPAs, even though long-term benefits will not be apparent just a year after the merger. The effort and **ongoing scrutiny** these systems take on certainly might **dissuade other health systems** from pursuing a **similar route**.

Rethinking competition in rural health care markets

The FTC and DOJ must revisit an approach that prioritizes competition over access to care and the quality and financial sustainability of the rural health care delivery system. The agencies have themselves acknowledged that competition among hospitals may not be a **practical reality** in rural communities.

The rural health care crisis is **happening now**; there is not time for multiyear studies of the impact of efforts to rationalize and improve rural health care. Health systems that **understand** and **are willing** to take on the challenges of rural health care markets should be **given the opportunity** to do so.

**Rural hospital closures cause massive food spikes**

**Alemian 16** – President & CEO of Alemian & Associates

David Alemian, "Rural Healthcare Is a Matter of National Security," HCPLive, 11-8-2016, https://www.hcplive.com/view/rural-healthcare-is-a-matter-of-national-security

Rural health organizations are already struggling with enormous turnover rates and costs that run up into the millions of dollars each year. The additional financial burden of penalties from Medicare and Medicaid will put many rural health organizations at risk of going out of business. If **too many** rural health organizations go **out of business**, it then becomes a matter of **national security** and here’s why:

In most rural communities, the healthcare organization is the **largest employer**. When the largest employer goes out of business, the **community collapses** and **people move away**. What was once a thriving community then **becomes a ghost town**. Rural America **produces the food** that feeds the rest of the country.

What will happen when our **amber waves of grain turn to desert wastelands** because there is **no one to work our great farmlands**? As the source of food dries up, and store shelves empty, the price of food will go **through the roof**. As food prices go up, hyperinflation will become a reality, and our printed money will **become worthless**. Almost **overnight**, Americans will **begin to go hungry** because they won’t be able to afford to put food on the table.

**Food insecurity causes conflict and war – continued US leadership is key and no one fills the vacuum**

**Flowers**, director of the Global Food Security Project and the Humanitarian Agenda at the Center for Strategic and International Studies (CSIS), **‘18**

(Kimberly, “Keeping it Stable: The Connection Between Hunger and Conflict,” January 31, <https://www.georgetownjournalofinternationalaffairs.org/online-edition/2018/1/31/keeping-it-stable-the-connection-between-hunger-and-conflict)>

Although achieving this SDG’s targets in totality is unlikely, a global focus on reducing poverty, malnutrition, and hunger around the world **remains essential** both as a universal moral value in a world of inequalities, and as an important contributor to economic growth and **national security**. The United States has been a **global leader** in **addressing the root causes** of hunger and poverty through **agricultural development**, including President Obama’s leadership role in creating the L’Aquila Initiative at the 2009 G8 summit in Italy. The initiative emerged in **response to a food price crisis** and resulted in a promise by donors to provide $22 billion in agricultural development assistance over three years.

It is **more critical now than ever** for leaders within the Trump administration to continue to leverage that progress, starting with gaining a better understanding of the complexity of global food insecurity and its inherent connection with conflict. As food insecurity is both a cause and a consequence of conflict, addressing food insecurity goes well beyond a moral obligation; **it is a national security imperative.**

A lack of access to food can **spark unrest** among civilian populations, particularly when triggered by food **price spikes**. Hungry populations are more likely to express their discontent with unresponsive or corrupt leadership, perpetuating a **cycle of political instability** and further undermining long-term economic development. In addition, governments and non-state actors alike can **use food as a strategic instrument of war**, as witnessed in instances spanning from Sudan’s civil conflict in the 1990s to President Bashar al-Assad’s war-torn Syria today. In Syria, all sides have used food as a tool to **control** and **expel** populations. ISIS has used food resources as both a source of **funding** and a lure for **recruitment**. Food **weaponization** further **underscores the importance of United States** action to protect food security abroad and recognize strategies employed to transform a basic necessity into a military tool.

Today, between 1.2 and 1.5 billion people live in fragile, conflict-ridden states. These conflicts have pushed over 56 million people into crisis and emergency levels of food insecurity. The U.N. estimates that 65 million people are internally displaced within their own countries or are refugees in other countries. These numbers continue to rise as conflicts and violence **escalate across the world,** in countries like **Yemen**, South **Sudan**, and **Syria**, causing social and economic devastation. Meanwhile, the number of people dependent on humanitarian assistance has mushroomed. Projections indicate that by 2030, more than two-thirds of the world’s poor could be living in fragile countries.

The international community is increasingly recognizing the **linkages** between **food insecurity** and **political instability.** Sharp rises in global food prices in 2007 and 2008 sparked riots and street demonstrations in more than 40 countries across the world. Since political leaders started paying attention to this connection, there has been notable progress in increasing international attention and funding to address the root causes of hunger and poverty. The United States has dedicated roughly $1 billion to agricultural development since 2010 through its global food security programs. Thanks to the bipartisan Global Food Security Act that passed in July 2016, multiple U.S. agencies are implementing a global food security strategy that reduces poverty, bolsters resilience, and improves nutrition.

Even the U.S. intelligence community has noticed food security challenges. In November 2015, the National Intelligence Council released an assessment that linked food insecurity to political instability and conflict. The report states that the overall risk of food insecurity in many countries, **compounded** by demographic shifts and constraints on key resources such as land and water, **will increase** during the next decade. The assessment concludes that in some countries, declining food security will contribute to social disruptions and **large-scale political instability** or conflict. The intelligence community’s highlighting of the importance of food security as a diplomacy tool and security strategy broadens the number of stakeholders who are tracking, responding to, and mitigating food insecurity. It is no longer solely a focus for policymakers in the development space.

After nearly a decade of progress, global hunger is again on the rise. A U.N. report on food security and nutrition released last year estimates that 815 million people, or 11 percent of the global population, are chronically malnourished, an increase of nearly 40 million people over the previous year. Conflict and climate change are the two primary causes of this reversed trend. More than half of those experiencing extreme hunger live in countries affected by protracted conflict. Droughts and natural disasters also pose a serious threat to food security, particularly to smallholder farmers vulnerable to a volatile climate.

The 2017 State of Food and Agriculture report explains that conflict and climate change are responsible for rising global hunger levels. Smallholder farmers around the world will be forced to adjust to changing rainfall patterns and severe droughts and floods, which will directly impact their crops and incomes. Many weeds, pests, and pathogens are influenced by climate and thrive in warm conditions. Severe floods can wipe out fields and block market transportation routes, reducing smallholders’ abilities to maintain a sustainable income. Researchers, including those at the National Academies of Science, conclude that human-induced climate change and drought is one of the root causes of Syria’s conflict. Climate change thus places an added burden on countries with limited resources already struggling to feed their populations, as declining agricultural growth and incomes can create displacement and heighten hunger.

Food insecurity and climate change are not the sole cause of the conflict in Syria, but their contribution to the country’s instability cannot be ignored. Investing in international development programs and humanitarian **assistance** that fosters agricultural-led growth and **strengthens the resilience** of vulnerable people can **create peace**, improve lives, and **reduce conflict.** U.S. foreign policy priorities should include strengthening the health and prosperity of those less fortunate before a crisis occurs because our investments can help prevent a crisis in the first place. As Former Secretary of Defense Robert M. Gates said, “Development is a lot cheaper than sending soldiers.”

### DA Innovation

#### There’s a wave of M&A now – companies doubt rule changes will affect them now

David French and Sierra Jackson, Reuters, July 12, 2021, Analysis: Dealmakers see M&A rush, then chills, in Biden's antitrust crackdown

Dealmakers expect a new wave of transformative U.S. mergers and acquisitions (M&A), as companies rush to complete deals before President Joe Biden's antitrust push takes shape, to be followed by a slowdown when regulators start cracking down.

Biden signed a sweeping executive order on Friday to bolster competition within the U.S. economy. This included a call for regulatory agencies to increase scrutiny of corporate tie-ups which have left major sectors such as technology and healthcare dominated by few players. read more

The order came amid an unprecedented M&A frenzy, as companies borrow cheaply and spend mountains of cash they have accumulated on transformative deals to reposition themselves for the post-pandemic world. Almost $700 billion worth of U.S. deals were announced in the second quarter, the highest on record.

The dealmaking bonanza is set to continue, as companies seek to take advantage of the time window during which regulators frame precise rules to implement Biden's order, advisers to the companies said. The M&A slowdown will come only when regulators implement the rule changes, possibly in two years or more, they added.

"The order itself will be less likely to have a chilling effect on strategic M&A than the potential chilling effect of a significant increase in the number of prolonged investigations and merger challenges brought by the agencies," said Michael Schaper, partner at law firm Debevoise & Plimpton.

Spokespeople for the White House and the two main antitrust regulators, the Federal Trade Commission (FTC) and the U.S. Department of Justice (DoJ), did not immediately respond to requests for comment.

Dealmakers were bracing for a tougher antitrust environment under Biden even before last week's executive order. Last month, the DoJ sued to stop insurance broker Aon's (AON.N) $30 billion acquisition of peer Willis Towers Watson (WTY.F). And Biden tapped Lina Khan, an antitrust researcher who has focused her work on Big Tech's immense market power, to chair the FTC.

#### Expanding scope of antitrust liability brings that to a halt—undermines dynamism and global competitiveness

Thierer 21– Adam Thierer is a senior research fellow with the Mercatus Center at George Mason University. Author of several books on antitrust law; former president of the Progress & Freedom Foundation, director of Telecommunications Studies at the Cato Institute, and a senior fellow at the Heritage Foundation.

(Adam Thierer, 2-25-2021, "Open-ended antitrust is an innovation killer," TheHill, https://thehill.com/opinion/technology/540391-open-ended-antitrust-is-an-innovation-killer)

Antitrust reform is a hot bipartisan item today, with Democrats and Republicans floating proposals to significantly expand federal control over the marketplace. Much of this activity is driven by growing concern about some of the nation’s largest digital technology companies, including Facebook, Google, Amazon and Apple.

Unfortunately, the calls for more bureaucracy and regulation emanating from all corners of the political world could have an unintended consequence: discouraging the sort of vibrant innovation and consumer choice that made America’s tech companies household names across the globe.

Sen. Amy Klobuchar (D-Minn.) is leading one charge. Klobuchar, who chairs the Judiciary Subcommittee on Antitrust, Competition Policy and Consumer Rights, recently introduced the “Competition and Antitrust Law Enforcement Reform Act.” This sweeping measure seeks to expand the powers and budgets of antitrust regulators at the Federal Trade Commission and the Department of Justice. It also includes new filing requirements and potentially hefty civil fines.

The most important feature is the proposed change to the legal standard by which regulators approve business deals. It would allow the government to stop any deal that creates an “appreciable risk of materially lessening competition,” and it also defines exclusionary behavior as, “conduct that materially disadvantages one or more actual or potential competitors.”

These may sound like simple, semantic tweaks, but – much like some of the other policy ideas currently circulating – they would upend decades of settled law and create a sea change in U.S. antitrust enforcement. This change could undermine business dynamism, innovation and investment in ways that inhibit the global competitiveness of U.S. businesses.

Critics of merger and acquisition (M&A) activity by large tech firms include not only Sen. Klobuchar but also Republicans such as Sen. Josh Hawley (R-Mo.). Hawley recent offered an amendment to a budget bill that would preemptively prohibit mergers and acquisitions by dominant online firms. Klobuchar and Hawley believe that M&A skews the market in favor of today’s largest firms, entrenching their market power and discouraging innovation.

History teaches a different lesson. Consider DirecTV and Skype, both once considered innovative market leaders in their respective fields of satellite TV and internet telephony. Both firms stumbled, however, and they might not even be with us today without creative business deals. DirecTV has been partially or fully controlled by Hughes Electronics, News Corp., Liberty Media and now AT&T. Skype has swapped hands multiple times, moving from eBay, to a private investment firm and now to Microsoft.

These were complex deals, and some didn’t work, leading to divestitures. But each was a learning experience that illustrated how dynamic media and technology markets can be with firms constantly searching for value-added arrangements that serve their customers and shareholders. If we make this type of activity presumptively illegal, we’re imagining that government bureaucrats are better suited to make these calls than businesspeople and the consumers who choose whether or not to buy the product.

Worse yet, legal tests like those Klobuchar proposes – “conduct that materially disadvantages potential competitors” – are remarkably open-ended and could be easily abused. The system will be gamed by opponents of deals for business reasons. They will claim that their own failure to attract investors or customers must all be the fault of more creative rivals. That’s a recipe for cronyism and economic stagnation.

Those who worry about today’s largest tech giants becoming supposedly unassailable monopolies should consider how similar fears were expressed not so long ago about other tech titans, many of which we laugh about today. Just 14 years ago, headlines proclaimed that “MySpace Is a Natural Monopoly,” and asked, “Will MySpace Ever Lose Its Monopoly?” We all know how that “monopoly” ceased to exist.

At the same time, pundits insisted “Apple should pull the plug on the iPhone,” since “there is no likelihood that Apple can be successful in a business this competitive.” The smartphone market of that era was viewed as completely under the control of BlackBerry, Palm, Motorola and Nokia. A few years prior to that, critics lambasted the merger of AOL and TimeWarner as a new corporate “Big Brother” that would decimate digital diversity and online competition.

GOP divided over bills targeting tech giants

Today, we know these tales of the apocalypse ended up instead becoming case studies in the continuing power of “creative destruction.” New innovations and players emerged from many unexpected quarters, decimating whatever dreams of continued domination the old giants once had.

Today’s biggest players face similar pressures, and it’s better to let rivalry and innovation emerge organically, not through the wrecking ball of heavy-handed antitrust regulation.

#### Large-firm dynamism is the only way to maintain tech leadership vis-à-vis china—key to competitiveness and AI

Lee, senior lecturer at the University of Hong Kong Faculty of Business and Economics, ‘19

(David S., “Antitrust action risks holding back US tech giants in competition with China,” <https://asia.nikkei.com/Opinion/Antitrust-action-risks-holding-back-US-tech-giants-in-competition-with-China>)

But the administration should not forget the law of unintended consequences -- effective antitrust measures could stifle the ability of American tech companies to compete with their Chinese challengers. Presumably, that is the last thing the America First president wants to see.

While antitrust has been used to regulate technology companies before, perhaps most notably Microsoft two decades ago, its application against Amazon.com, Facebook, and Google seems different.

For the last half-century or so, U.S. antitrust law has been underpinned by the concept of maximizing consumer welfare, frequently measured by price to consumers. In regulating big technology companies today, however, a new paradigm has emerged, dubbed "hipster antitrust."

Hipster antitrust looks beyond traditional economic harm and includes wider effects such as wage inequality, data privacy intrusions, and sheer size as grounds to invoke the law.

But the wider the antitrust authorities reach, the more likely they are to damage the tech giants' global competitiveness. This applies especially in the key field of artificial intelligence, where the U.S. and China are world leaders.

AI is the engine powering the Fourth Industrial Revolution and the fuel for that engine is data, lots of data. Such data can only be collected at scale, which conflicts with hipster antitrust notions of size. If American antitrust measures compel large technology companies to shrink or in the extreme, to break up, then the U.S. will find itself at a disadvantage to China.

The idea of size is one of many fundamental differences separating Chinese and American technology ecosystems. Chinese government leaders have clearly grasped that scale matters for the technologies they want to dominate, such as artificial intelligence, as well as for the type of digital governance Beijing is striving to implement.

In the U.S., however, the economic value attached to scale is offset by deep-rooted concerns about privacy, bullying behavior and unfair political and social influence. Senator Elizabeth Warren of Massachusetts, a popular Democratic Party candidate for the 2020 presidential election, wrote: "Today's big tech companies have too much power -- too much power over our economy, our society and our democracy."

But in China this is not a hot-button political issue. In a recent fintech course I helped lead comprised of students from different countries, mainland Chinese students considered privacy differently than peers elsewhere. Though aspects of privacy are important to Chinese users, many readily understand there are trade-offs in operating on technology platforms.

Chinese technology platforms such as Alibaba and Meituan have developed so-called "super apps" that serve the same functions that users in the West might find by going to different applications on their devices.

Super apps are designed to be convenient to users so they can handle everything from ride hailing, shopping, food purchases, and payment, all without leaving the digital confines of a single app. This has become the dominant way Chinese citizens consume online. With the most internet users in the world, approximately 750 million, super apps also provide Chinese technology companies an incredible amount of data.

In his book, "AI Superpowers: China, Silicon Valley, and the New World Order," technology executive and investor, Kai-Fu Lee outlined four factors necessary to win the AI race: talent, computing speed, data, and government policy. Though the U.S. has an advantage in many areas, that lead is shrinking, and if China does overtake the U.S. in artificial intelligence, it will likely be a result of advantages in data and government policy.

This combination of data and government policy is perhaps best exemplified by SenseTime, widely considered the world's most valuable artificial intelligence startup. SenseTime boasts world leading facial recognition, which is enhanced because it reportedly has access to Chinese government databases, a rich source of data to further develop models.

Chinese companies like SenseTime have excelled in facial recognition, with some reports estimating that there are almost ten times as many Chinese facial recognition patents filed as American. Chinese surveillance technology is already used in the U.S., including New York City.

This widening gap will have broader implications beyond surveillance, security, and policing. Facial recognition technology will also serve as a biometric identifier for finance, retail, and health. With China moving forward aggressively both domestically and abroad in its use of such technologies, American competitors who are pursuing facial recognition, such as Amazon and Google, may not be able to close the growing competitive chasm.

So while American politicians may see antitrust investigations into large technology companies as necessary, there could be a significant impact on America's ability to compete with China.

Google's former CEO, Eric Schmidt forecast last year that China and the United States would lead the bifurcation of the internet into two spheres. Evidence of this splintering is already apparent. What remains undetermined, however, is which of those spheres will dominate.

Large Chinese technology companies, for example Alibaba Group Holding, are already setting-up far-flung outposts by partnering with and investing in local, non-Chinese technology companies around the world. This form of Chinese technological expansion allows Chinese big tech to shape user privacy norms, establish global networks, and attract more users into their ecosystems, all of which leads to increased user activity and ultimately more data.

While China aggressively expands its technological reach and hones its ability through mining evermore data, it is important that U.S. regulators understand that aggressive antitrust sanctions would risk inhibiting American companies from maintaining the scale necessary to compete with their Chinese rivals.

AI supremacy will be a defining feature of superpower status. And if future researchers one day examine how the U.S. lost the war for artificial intelligence, the hindsight of history may show that the current antitrust debate was the fatal turning point.

#### Failure to beat China in tech incentivizes escalatory nuclear postures that make extinction inevitable

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Matthew Kroenig and Bharath Gopalaswamy, "Will disruptive technology cause nuclear war?," Bulletin of the Atomic Scientists, 11-12-2018, <https://thebulletin.org/2018/11/will-disruptive-technology-cause-nuclear-war/>

Rather, we should think **more broadly** about how new technology might affect global politics, and, for this, it is helpful to turn to scholarly international relations theory. The dominant theory of the causes of war in the academy is the “bargaining model of war.” This theory identifies rapid shifts in the balance of power as a primary cause of conflict.

International politics often presents states with conflicts that they can settle through peaceful bargaining, but when bargaining breaks down, war results. Shifts in the balance of power are problematic because they undermine effective bargaining. After all, why agree to a deal today if your bargaining position will be stronger tomorrow? And, a clear understanding of the military balance of power can contribute to peace. (Why start a war you are likely to lose?) But shifts in the balance of power muddy understandings of which states have the advantage.

You may see where this is going. New technologies threaten to create potentially destabilizing shifts in the balance of power.

For decades, stability in Europe and Asia has been supported by US military power. In recent years, however, the balance of power in Asia has begun to shift, as China has increased its military capabilities. Already, Beijing has become more assertive in the region, claiming contested territory in the South China Sea. And the results of Russia’s military modernization have been on full displayin its ongoing intervention in Ukraine.

Moreover, China may have the lead over the United States in emerging technologies that could be decisive for the future of military acquisitions and warfare, including 3D printing, hypersonic missiles, quantum computing, 5G wireless connectivity, and artificial intelligence (AI). And Russian President Vladimir Putin is building new unmanned vehicles while ominously declaring, “Whoever leads in AI will rule the world.”

If China or Russia are able to incorporate new technologies into their militaries before the United States, then this could lead to the kind of rapid shift in the balance of power that often causes war.

If Beijing believes emerging technologies provide it with a newfound, local military advantage over the United States, for example, it may be more willing than previously to initiate conflict over Taiwan. And if Putin thinks new tech has strengthened his hand, he may be more tempted to launch a Ukraine-style invasion of a NATO member.

Either scenario could bring these nuclear powers into direct conflict with the United States, and once nuclear armed states are at war, there is an inherent risk of nuclear conflict through limited nuclear war strategies, nuclear brinkmanship, or simple accident or inadvertent escalation.

This framing of the problem leads to a different set of policy implications. The concern is not simply technologies that threaten to undermine nuclear second-strike capabilities directly, but, rather, any technologies that can result in a meaningful shift in the broader balance of power. And the solution is not to preserve second-strike capabilities, but to preserve prevailing power balances more broadly.

When it comes to new technology, this means that the United States should seek to maintain an innovation edge. Washington should also work with other states, including its nuclear-armed rivals, to develop a new set of arms control and nonproliferation agreements and export controls to deny these newer and potentially destabilizing technologies to potentially hostile states.

These are no easy tasks, but the consequences of Washington losing the race for technological superiority to its autocratic challengers just might mean nuclear Armageddon.

### Innovation

#### Biotech innovation is happening now – momentum from COVID will continue

Perieteanu & Brooks 21 - Ph.D. serves as the Director of Biopharmaceutical Services for SGS Toronto & Managing Editor

Alex Perieteanu & Kristin Brooks, “A New Era of Vaccine and Biologic Drug Development: As a result of COVID-19, unprecedented investments in vaccines, diagnostics, and treatments have had a tremendous impact on the Biotechnology industry,” 01-12-21, https://www.contractpharma.com/contents/view\_online-exclusives/2021-01-12/a-new-era-of-vaccine-and-biologic-drug-development/

The Biopharmaceutical industry has achieved remarkable success and innovation these past few years, namely the first CAR-T cell therapy and antibody drug conjugate (ADC) approvals. Significantly, the global pandemic has fueled vaccine innovation with the rapid acceleration of RNA based COVID vaccines.

Currently, nine ADCs have received market approval, and in July 2020, the U.S. FDA approved the third CAR-T cell therapy, Tecartus, a cell-based gene therapy for treatment of mantle cell lymphoma (MCL). Additionally, to date, Pfizer-BioNTech’s COVID-19 Vaccine and Moderna’s COVID-19 Vaccine have been approved by the FDA for emergency use.

Along with these advances, there has been a significant increase in outsourcing, particularly related to vaccine manufacture and fill finish, as well as drug research and development, analytical services, and manufacturing.

As the number of advanced therapy medicinal products (ATMPs) in development continue to grow, new production strategies are helping to address the inherent development and manufacturing challenges associated with these therapies.

Alex Perieteanu, Ph.D., Director of Biopharmaceutical Services at SGS Life Sciences discusses the future of vaccines and biologics, how the pandemic is impacting outsourcing and operations, and the challenges and advances in manufacturing cell therapies. –KB

Contract Pharma: With the current COVID climate what do you anticipate for the future of vaccines and biologics?

Alex Perieteanu: As an outcome of COVID-19, we’ve entered a new era of vaccine and biological drug development. The pandemic has demanded unprecedented investment into vaccines, diagnostics, and treatments. In a relatively short period of time, this has had a tremendous impact on the Biotechnology industry and the momentum is likely to continue. Looking at vaccines alone, we’ve seen a rapid acceleration in LNP-mRNA based approaches, a promising technology, but one that had yet to mature to commercialization. That is, until recently, two COVID-19 vaccines have recently received FDA emergency use authorization (EUA) to combat COVID-19.

CP: How has the pandemic impacted outsourcing and operations?

AP: Many organizations have had to carefully evaluate outsourcing strategies, internal capacities, priorities, and risks. It’s of little surprise that we’ve seen an increase in demand across the board. Whether it be for high priority activities related to Covid-19, supply chain diversification, or whether it is simply due to a needing to strategically outsource in order to manage internal capacities.

CP: What capabilities will be needed down the road?

AP: A very difficult question, as almost everything is in demand. With a tidal wave of COVID-19 related investigational new drug applications (INDs), the ability to support GMP level manufacturing as well as analytical testing, is and will be in high demand. Capabilities and experience in the nucleotide and vector-based delivery space (viral and non-viral) are going to be highly sought after in the near term and will continue until the market adjusts to an increased demand.

CP: Are there specific geographical markets that are key?

AP: This pandemic has had a global impact. All markets with established capabilities are likely to see rapid growth in the sector; however, with such high demand, regions or nations whom otherwise do not have significant local production capabilities may look to fund, or partially nationalize some basic levels of production in order to ensure long term supply.

CP: In what services areas are you seeing the most growth?

AP: Development, clinical trials, and manufacturing are all integral parts of bringing a molecule to market, and one cannot be done without the other. We’re seeing proportional growth in all areas.

CP: With the advances in cell and gene therapies, what type of growth do you anticipate? Is the industry positioned to accommodate future growth?

AP: Cell and gene therapies, or advanced therapy medicinal products (ATMPs) offer groundbreaking new opportunities for the treatment of disease or injury. While only a relatively small number of ATMPs have received regulatory approval, the number of active INDs in this category is expected to break 1,000 by the end of 2021.

With a promise to revolutionize medicine, ATMPs are very likely to become a staple in 21st century medicine. The industry has been adapting to the emergence of ATMPs with significant investments in product development, and manufacturing technology. Ultimately, vector delivery systems, complexity of manufacturing, an evolving regulatory landscape, and finally cost remain at the crux these emerging technologies.

#### Challenges from generics means less drugs can ever get returns – ruins innovation

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Joanna Shepherd, August 28 2018, “CONSOLIDATION AND INNOVATION IN THE PHARMACEUTICAL INDUSTRY: THE ROLE OF MERGERS AND ACQUISITIONS IN THE CURRENT INNOVATION ECOSYSTEM,” Journal of Healthcare Law and Policy, https://digitalcommons.law.umaryland.edu/cgi/viewcontent.cgi?article=1356&context=jhclp

Third, while facing increased competition from generics and pressure to reduce prices from PBMs, drug companies have also experienced significant increases in both the costs of drug development and the risks of product failures. Since the 1962 Amendments to the Federal Food, Drug, and Cosmetic Act, the FDA has continued to increase the requirements for new drug approvals. For example, whereas clinical trials in the 1970s typically enrolled only 2,000 patients, trials in the 1990s regularly enrolled over 5,000 patients.31 Similarly, the costs of recruiting patients, the length of the clinical trial period, and the number and complexity of clinical tests used in clinical trials have increased over time.32 These more stringent requirements, along with the more complex science associated with specialized medications, have significantly increased the costs of drug development and FDA approval and in turn lengthened the time to market, driving up the cost of investment. The most current estimates indicate that it now costs approximately $2.6 billion to develop and bring each new drug to market.33 Those costs were estimated to be only $179 million in the 1970s, 34 $413 million in the 1980s,35 and $900 million in the 1990s and early 2000s.36 In contrast, it costs generic manufacturers only one to two million dollars to bring a drug to market.37 Moreover, only about ten percent of brand drugs that begin clinical trials are eventually approved by the FDA. The most recent study to track FDA approval rates found that the approval rate varied by trial phase: phase I had a 64.5% success rate, phase II had a 32.4% success rate, phase III had a 60.1% success rate, and the FDA approved 83.2% of applications that passed phase III.38 Ultimately, of 100 drugs that begin Phase I trials, only ten drugs will eventually be approved.39 Thus, despite dramatic increases in research and development (R&D) spending, drug approval rates have increased little in recent decades.40 Even after FDA approval, pharmaceutical manufacturers increasingly face patent challenges that reduce the likelihood that drugs will achieve commercial success. Hatch-Waxman actively incentivizes generic companies to challenge the validity of brand-name patents by creating a pathway for such challenges and by offering a lucrative incentive to the first generic manufacturer that files a challenge claiming that the brand patent is either invalid or will not be infringed by the new generic (known as a Paragraph IV challenge).41 If the generic company wins or settles the patent litigation, it receives a 180-day exclusivity period during which the FDA will not approve any other generic versions of the drug, a period in which the first generic can earn substantial profits.42 Paragraph IV challenges have exploded in recent years; whereas only 9 percent of drugs facing generic entry in 1995 were challenged, 81 percent of drugs facing generic entry in 2012 were challenged.43 Moreover, Paragraph IV challenges are occurring earlier in the life of brand drugs. Drugs entering the market as generics in 1995 faced their first challenge 18.7 years after original launch.44 By comparison, drugs entering the market as generics in 2012 saw only 6.9 years between market launch and the first Paragraph IV challenge.45 These challenges threaten a drug’s commercial success and cost pharmaceutical companies significant legal fees.46 Moreover, the Leahy-Smith America Invents Act in 2012 gave generics a new administrative venue to challenge patents, the inter partes review (IPR).47 In contrast to Hatch-Waxman litigation that occurs in federal district court, IPR proceedings culminate in a trial before the Patent Trial and Appeal Board (PTAB) of the U.S. Patent and Trademark Office. IPR was expected to offer a more efficient and less costly alternative to Hatch-Waxman’s litigation pathway, but important differences between PTAB trials and district court litigation create significant advantages for generic patent challengers.48 The PTAB applies a lower standard of proof for invalidity than do district courts in Hatch-Waxman litigation.49 It is also easier to meet the standard50 of proof in a PTAB trial because there is a more lenient claim construction standard and a substantially limited ability to amend patent claims.51 Moreover, on appeal, PTAB decisions in IPR proceedings are given more deference than district court decisions.52 Finally, while patent challengers in district court must establish sufficient Article III standing, IPR proceedings do not have a standing requirement, allowing any member of the public other than the patent owner to initiate an IPR challenge.53 These advantages for patent challengers have led to significantly different patent invalidation rates in PTAB trials compared to rates in district court litigation. 54 Whereas patents challenged in district court are invalidated in less than 40%55 of cases, IPRs have resulted in patent invalidations in a shocking 70% of cases. 56 The intensifying competition from generics, expanding power of PBMs, escalating R&D costs, and increasing risk of patent challenges mean that many new pharmaceuticals will never attain commercial success. Even for the 10 percent of drugs that receive FDA approval, only 20 percent will ever earn enough revenue to cover the growing R&D costs. 57 Moreover, the likelihood that a drug will become profitable has decreased over time as both the risk of failure and the costs of development have increased.58 The average lifetime revenues for new drugs are lower now than at any point in the last 25 years.59 These shocks have put many pharmaceutical firms under significant economic stress, motivating consolidation as a means to streamline costs and provide new sources of revenue.

#### Investment in vaccines won’t happen in the world of the affirmative – can’t make a profit

Xue and Ouellette 20 – JD/PhD Candidate at Stanford University. Lisa Larrimore Ouellette is a Professor of Law and the Justin M. Roach, Jr. Faculty Scholar at Stanford Law School, as well as a Senior Fellow at the Stanford Institute for Economic Policy Research.

[Qiwei Claire Xue](javascript:;) and [Lisa Larrimore Ouellette](javascript:;), May 18 2020, « Innovation policy and the market for vaccines,” Journal of Law and the Biosciences, https://academic.oup.com/jlb/article/7/1/lsaa026/5838028?login=true#237984410

As noted above, the comparatively anemic vaccine development pipeline may have multiple root causes, including the underlying science and the legal distinctions discussed in Part II, both of which vary across vaccines. But even if a potential vaccine and a drug candidate have the same likelihood of success and the same expected period of monopoly protection, vaccines generally differ from therapeutic drugs along two dimensions, as illustrated in [Figure 1](javascript:;): (1) they are preventatives rather than treatments; and (2) they are durable goods with long-term effects rather than repeat-purchase products.

These dimensions are really continuous spectra rather than discrete boxes: some vaccines may have therapeutic as well as preventative benefits,[144](javascript:;) and although most vaccine sequences do not exceed three doses, a few require more regular doses.[145](javascript:;) But we think focusing on the polar ends of each spectrum helps illuminate the relevance of these dimensions, including the extent to which incentives are inadvertently tilted toward certain technologies.[146](javascript:;) Also worth noting is that both cures (durable treatments) and prophylactic drugs (repeat-purchase preventatives) do confer some of the benefits of vaccines and suffer from some of the same distortions.

In this part, we explain why these properties render vaccines less profitable than treatments, whether biological or small-molecule, all else equal. These two attributes combined suggest that on both the supply and demand sides of the vaccine market, private incentives do not coincide with social welfare maximization.

Suppose a pharmaceutical company is considering developing a product targeted toward a particular virus. The company’s research team informs management that there are two products that seem scientifically promising: a new drug that would treat people infected with the virus when taken daily, and a vaccine that would prevent people from contracting the virus in the first place. The firm holds all the relevant IP for each product over an equal period,[147](javascript:;) and both have the same likelihood of success. Developing both the vaccine and the drug would create the risk of having one product cannibalize the market for the other, so management decides to pursue only one of these options.[148](javascript:;) How does it choose, and how might that private choice differ from the one a social planner would make?

A profit-maximizing firm should consider the risk-adjusted development cost and the expected return if the project is successful. As described in Section III.A, vaccines may be somewhat more expensive to develop than therapeutic drugs, although there is little reliable data on actual development costs. This difference could mean that vaccines are simply costlier from a social welfare perspective. As discussed in Section III.B, however, preventatives usually have greater positive externalities, such that society will often prefer the firm to focus on the vaccine, all else equal.

Even if the costs of developing the drug and vaccine were equivalent, the profit side of the equation also skews incentives toward the drug. Section III.C considers how expected returns will be affected by effects described in the behavioral economics literature on consumer preferences, while Section III.D considers economic effects that apply even absent consumer irrationality.

A. Development Cost

When compared with therapeutic drugs—particularly small-molecule drugs—biologic vaccines may be more expensive to design and test.[149](javascript:;) The difference is not just that vaccines are all complex biologics: as discussed above, because preventatives are generally tested on healthy individuals rather than sick patients, a larger study population may be needed to observe a statistically significant effect, and there is a lower tolerance for adverse side effects.[150](javascript:;) However, the ability to rely on surrogate endpoints such as the presence of antibodies helps reduce clinical trial costs.[151](javascript:;) It is not obvious which of these are most important.

Unfortunately, data on the relative expense of vaccine versus small-molecule development are spotty. Estimates for the cost of vaccine development typically range in the hundreds of millions for clinical trials—well above most lower bounds on small-molecule clinical trial costs, but also within most upper bounds.[152](javascript:;) Estimates that include failed attempts and opportunity costs range in the low billions, again comparable to estimates for small-molecule drug development.[153](javascript:;) One review suggests this literature ‘implies the average capitalized costs are likely not statistically different from one another.’[154](javascript:;)

Nevertheless, the possibility that preventatives are costlier to produce is worth keeping in mind for the remainder of this article. If preventatives are simply more expensive to develop than treatments and thus costlier from a social welfare perspective, then society should prefer that firms focus on treatments, all else equal. But as discussed in the following section, preventatives have net social benefits that, based on current evidence, seem likely to outweigh their difference in costs.

B. Net Social Benefits and Externalities

Although vaccines may cost more to develop than therapeutics, they also have the potential to provide far greater benefits to society. These benefits for individuals other than the vaccinated patient—known as positive externalities or spillovers—could justify the extra costs of development from a social welfare point of view. However, to the extent that private actors are not able to capture them, these benefits may also contribute to substantial distortions in vaccine innovation markets.

As we explain in this section, the health economics literature has documented large positive consumption externalities of vaccines due to their preventative nature.[155](javascript:;) Furthermore, as durables, vaccines can be on aggregate less costly to distribute and administer, since they need to be given only once (or a handful of times) per person. The WHO notes that vaccines are ‘accessible to even the most hard-to-reach and vulnerable populations.’[156](javascript:;) Together, these factors contribute to the understanding in public health that vaccines are ‘among the most cost-effective health interventions.’[157](javascript:;)

#### The private sector can’t innovate anything.

**Mazzucato 15** (Mariana Mazzucato –RM Phillips Chair in the Economics of Innovation at the Science Policy Research Unit (SPRU) at the University of Sussex. Previously she has held academic positions at the University of Denver, London Business School, Open University, and Bocconi University. <KEN> “Chapter 1: From Crisis Ideology to the Division of Innovative Labour,” in “The Entrepreneurial State: Debunking Public vs. Private Sector Myths,” *PublicAffairs*. Revised Edition. ISBN 978-1-61039-614-1)

THE BUMPY RISK LANDSCAPE

As will be explained in more detail in the next chapter, innovation economists from the ‘evolutionary’ tradition (Nelson and Winter 1982) have argued that ‘systems’ of innovation are needed so that new knowledge and innovation can diffuse throughout the economy, and that systems of innovation (sectoral, regional, national) require the presence of dynamic links between the different actors (firms, financial institutions, research/education, public sector funds, intermediary institutions), as well as horizontal links within organizations and institutions (Lundvall 1992; Freeman 1995). What has been ignored even in this debate, however, is the exact role that each actor realistically plays in the ‘bumpy’ and complex risk landscape. Many errors of current innovation policy are due to placing actors in the wrong part of this landscape (both in time and space). For example, it is naïve to expect venture capital to lead in the early and most risky stage of any new economic sector today (such as clean technology). In biotechnology, nanotechnology and the Internet, venture capital arrived 15–20 years after the most important investments were made by public sector funds.

In fact, history shows that those areas of the risk landscape (within sectors at any point in time, or at the start of new sectors) that are defined by high capital intensity and high technological and market risk tend to be avoided by the private sector, and have required great amounts of public sector funding (of different types), as well as public sector vision and leadership, to get them off the ground. The State has been behind most technological revolutions and periods of long-run growth. This is why an ‘entrepreneurial State’ is needed to engage in risk taking and the creation of a new vision, rather than just fixing market failures.

#### No matter the future pandemic, humanity can adapt and find new solutions – we get better at it every single time

Pinker et Al. 20 – Steven earned his BA from McGill and his PhD from Harvard. Currently Johnstone Professor of Psychology at Harvard, he has also taught at Stanford and MIT. He has won numerous prizes for his research, his teaching, and his books, including [The Language Instinct](https://stevenpinker.com/publications/language-instinct-19942007), [How the Mind Works](https://stevenpinker.com/publications/how-mind-works-19972009), [The Blank Slate](https://stevenpinker.com/publications/blank-slate-20022016), [The Better Angels of Our Nature](https://stevenpinker.com/publications/better-angels-our-nature), [The Sense of Style](https://stevenpinker.com/publications/sense-style-thinking-persons-guide-writing-21st-century), and [Enlightenment Now](https://theopenscholars.com/pinker/publications/enlightenment-now-case-reason-science-humanism-and-progress). He is an elected member of the National Academy of Sciences, a two-time Pulitzer Prize finalist, a Humanist of the Year, a recipient of nine honorary doctorates, and one of Foreign Policy’s “World’s Top 100 Public Intellectuals” and Time’s “100 Most Influential People in the World Today.”

Benjamin M. Seitz, Athena Aktipis, David M. Buss, Joe Alcock, Paul Bloom, Michele Gelfand, Sam Harris,  Debra Lieberman, Barbara N. Horowitz, Steven Pinker,  David Sloan Wilson, and Martie G. Haselton, November 10 2020, “The pandemic exposes human nature: 10 evolutionary insights,” Proceedings of the National Academy of Sciences of the United States of America, https://www.pnas.org/content/117/45/27767

Many people have trouble reconciling the demonstrable fact of **human progress—**that, over time, we have become healthier, better fed, richer, safer, and better educated—with the constraints of human biology. Some fear that, if the mind has evolved as a complex structure, then progress would be impossible, because “you can’t change human nature.” Therefore, either there cannot be such a thing as progress or there cannot be such a thing as human nature.

But these are confusions which arise from misconceptions of human nature and of human progress ([85](https://www.pnas.org/content/117/45/27767#ref-85), [86](https://www.pnas.org/content/117/45/27767#ref-86)). Among the adaptations making up human nature is the triad of faculties that adapt us to the **“cognitive niche”** ([87](https://www.pnas.org/content/117/45/27767#ref-87)): know-how, which allows us to understand the physical world and try out new ways to manipulate it to our advantage; language, which allows us to share and recombine these ideas; and sociality, which gives us the motive to coordinate ideas and actions with our fellows for mutual benefit. Among the brainchildren of these faculties are **inventions that magnify their own power**, including the printed and electronic word and institutions of science and governance, which allow knowledge to accumulate over generations. When people deploy knowledge to improve their lives, retaining and combining the innovations that work and discarding those that don’t, p**rogress can take place.**

That’s all that progress consists of. It is not, contrary to conceptions of Herbert Spencer and other Victorians ([88](https://www.pnas.org/content/117/45/27767#ref-88), [89](https://www.pnas.org/content/117/45/27767#ref-89)), a mystical evolutionary force that propels us ever upward. On the contrary, the forces of nature tend to grind us down, including the inexorable increase in physical disorder and the evolutionary conflicts between parasites and hosts, predators and prey, and conspecifics and one another. It’s only the application of hard-won knowledge that allows us to eke out local and provisional advances against the constant challenges to our well-being.

Among these challenges are outbreaks of infectious disease. Bouts of outbreak over millennia were the selective pressure that led to the evolution of our innate, adaptive, and behavioral immune systems.

Yet it was **our cognitive adaptations that led to the recent conquest of the infectious disease**s that felled our ancestors in great numbers. They allowed us to discover vaccination, sanitation, antisepsis, antibiotics, antivirals, and other advances in public health and medicine that have dramatically extended life expectancy.

So it should come as no surprise, and is no refutation of the fact or the possibility of progress, that another infectious pathogen has launched an offensive against us; that is in the very nature of life. Yet the biology of Homo sapiens gives us good reasons to expect that **the disease will be subdued** in its turn—not as an inevitable step in some march of progress, but if (and only if) we redouble the commitment, which human evolution enables but does not guarantee, to the development and application of scientific knowledge to improve human well-being.

#### No biodefense impact – can’t engineer anything

--“select agents” are dangerous infectious agents

Eckard **Wimmer 18**. Prof @ Stony Brook University. 2018. “Synthetic Biology, Dual Use Research, and Possibilities for Control.” Defence Against Bioterrorism, Springer, Dordrecht, pp. 7–11. link.springer.com, doi:10.1007/978-94-024-1263-5\_2.

Listed below are some constraints that show how in the US the development of dangerous infectious agents, referred to as “select agents”, is controlled – perhaps misuse even prevented – through technical and administrative hurdles: I. Re-creating an already existing dangerous virus for malicious intent is a complex scientific endeavor. (i) It requires considerable scientific knowledge and experience and, more importantly, considerable financial support. That support usually comes from government and private agencies (NIH, NAF, etc.), organizations that carefully screen at multiple levels all applications for funding of ALL biological research. (ii) It requires an environment suitable for experimenting with dangerous infectious agents (containment facilities). Any work in containment facilities is also carefully regulated. II. Genetic engineering to synthesize or modify organisms relies on chemical synthesis of DNA. Synthesizing DNA is automated and carried out with sophisticated, expensive instruments. The major problem of DNA synthesis, however, is that the product is not error-free. Any single mistake in the sequence of small DNA segments (30–60 nucleotides) or large segments (>500 nucleotides) can ruin the experiment. Companies have developed strategies to produce and deliver error free, synthetic DNA, which investigators can order electronically from vendors, such as Integrated DNA Technologies (US), GenScript (US) or GeneArt (Germany). This offers a superb and easy way to control experimental procedures carried out in any laboratory: the companies will automatically scan ordered sequences in extensive data banks to monitor relationship to sequences of a select agent. If so, the order will be stalled until sufficient evidence has been provided by the investigator that she/he is carrying out experiments approved by the authorities. The entire complex issue of protecting society from the misuse of select agents has been discussed in two outstanding studies [11, 12]. III. Engineering a virus such that it will be more harmful (more contagious, more pathogenic) is generally difficult because, in principle, viruses have evolved to proliferating maximally in their natural environment. That is, genetic manipulations of a virus often lead to loss of fitness that, in turn, is unwanted in the bioterrorist agent.

### Cost

#### Their standard won’t deter deals – crafty lawyers will construct agreements that comply with the law but maintain the social harms

Crane 10 – Professor of Law, University of Michigan.

Daniel Crane, 2010, “"Per Se Illegality for Re er Se Illegality for Reverse Payment Settlements?" Re yment Settlements?" Review of view of "Unsettling Drug Patent Settlements: A Framework for Presumptive Illegality,” University of Michigan Law School, https://repository.law.umich.edu/cgi/viewcontent.cgi?article=1020&context=reviews

So antitrust rules that focus on "reverse payment" settlements as a category run the risk of creating false positives, but they also run the risk of creating false negatives to the extent that they focus the inquiry on the direction in which consideration flows-a not terribly helpful spot. It is often not hard to structure a branded-generic settlement in a way that does not involve reverse payments but still involves the key ingredients of social cost-the cessation of meaningful competition between the two firms and a low probability that a court would have enjoined the generic on patent infringement grounds. Scott Hemphill's empirical research on patent settlements following some of the early negative decisions (like the Sixth Circuit's Cardizem decision holding reverse payments per se illegal)' shows that creative lawyers are capable of crafting settlement agreements that have the same effects as the most pernicious reverse payment cases but would pass unscathed under a rule focusing on reverse payments.8 Indeed, I have little doubt that if the Rush bill passes, antitrust lawyers will make a bundle of money restructuring patent settlement agreements to comply with the law. Here are some suggested reverse payment ban avoidance schemes:' \* Branded retains Generic to become its exclusive manufacturing and distribution agent for the branded's authorized generic. Utilizing its newfound freedom under Leegin,o Branded sets the resale price of the generic at an appropriate price-discriminatory discount off the branded price but nonetheless a monopoly price. Branded continues to collect monopoly rents by making generic pay an exorbitant royalty or annual lump-sum fee. If Generic can't afford the payments up front, Branded provides financing. \* Branded grants Generic an exclusive license to manufacture and distribute under the patent in Canada. Generic charges a monopoly price in Canada (so no one bothers re-importing), Branded charges a monopoly price in the U.S. There doesn't need to be any explicit agreement that Generic won't enter the U.S.-they get the point. \* The Schering scheme" -Generic licenses or sells Branded some worthless other drug for which Branded pays Generic some huge price. Investment bankers are paid to say the drug was worth it. Good luck litigating this as a reverse payment case-something like this worked in Schering. I could go on, but the basic point is that the creativity of high-paid New York lawyers exceeds the foresight of anyone drafting legislation in this area. As much as I agree with Mike that patent settlements involving the cessation of competition between branded and generic firms are a big problem, the focus on reverse payments is off the mark.

#### 0 internal link to prices – drugs are a mere 10% of total healthcare expenditures, their ev only says biologics are a large part of that 10% NOT that its more

CHQPR 20—(data from a survey by the American Hospital Association). Center for Healthcare Quality and Payment Reform. 2020 (last cited date). “3. The Cost of Rural Hospital Services”. https://ruralhospitals.chqpr.org/Costs.html#The\_Cost\_of\_Delivering\_Rural\_Health\_Clinic\_and\_Primary\_Care\_Services. Accessed 7/27/21.

The Largest Categories of Direct Service Costs

A core group of six services constitute the majority of direct patient service costs at small rural hospitals:

the Emergency Department,

inpatient services,

the laboratory,

radiology,

drugs and medical supplies, and

the Rural Health Clinic (if the hospital operates an RHC).

At the very smallest hospitals, these six core services represent nearly 80% of the hospital’s total direct patient service costs. Larger hospitals are more likely to offer other services, such as surgery and maternity care and to have larger numbers of patients receiving those services, so a smaller share of total costs at larger hospitals will be associated with the six core services, but the core services still represent two-thirds or more of direct patient service costs.

Graphical user interface, application

Description automatically generated

#### But those deficits are inevitable thanks to tax cuts and new social programs

Sloan and Podkul 21 – Allan Sloan, formerly a ProPublica editor at large and a Washington Post columnist, has been writing about business for almost 50 years. He has won seven Loeb Awards, business journalism’s highest honor, in four different categories (including lifetime achievement) in four different decades for five different employees. Write for The Wall Street Journal's financial investigations and projects team.

Allan Sloan and Cezary Podkul, January 14 2021, “Donald Trump Built a National Debt So Big (Even Before the Pandemic) That It’ll Weigh Down the Economy for Years,” ProPublica, https://www.propublica.org/article/national-debt-trump

One of President Donald Trump’s lesser known but profoundly damaging legacies will be the explosive rise in the national debt that occurred on his watch. The financial burden that he’s inflicted on our government will wreak havoc for decades, saddling our kids and grandkids with debt.

The national debt has risen by almost $7.8 trillion during Trump’s time in office. That’s nearly twice as much as what Americans owe on student loans, car loans, credit cards and every other type of debt other than mortgages, combined, according to [data](https://www.newyorkfed.org/microeconomics/hhdc.html) from the Federal Reserve Bank of New York. It amounts to about $23,500 in new federal debt for every person in the country.

The growth in the annual deficit under Trump ranks as the third-biggest increase, relative to the size of the economy, of any U.S. presidential administration, according to a calculation by a leading Washington budget maven, Eugene Steuerle, co-founder of the Urban-Brookings Tax Policy Center. And unlike George W. Bush and Abraham Lincoln, who oversaw the larger relative increases in deficits, Trump did not launch two foreign conflicts or have to pay for a civil war.

The National Debt Increased Under Trump Despite His Promise to Reduce It

Daily total national debt from 2009 to present.

Economists agree that we needed massive deficit spending during the COVID-19 crisis to ward off an economic cataclysm, but federal finances under Trump [had become dire even before the pandemic](https://www.washingtonpost.com/business/2019/03/12/trump-vowed-eliminate-debt-years-hes-track-leave-it-least-percent-higher/). That happened even though the economy was booming and unemployment was at historically low levels. By the Trump administration’s [own description](https://www.whitehouse.gov/briefings-statements/president-donald-j-trump-promoting-fiscally-responsible-pro-american-2020-budget/), the pre-pandemic national debt level was already a “crisis” and a “grave threat.”

The combination of Trump’s 2017 tax cut and the lack of any serious spending restraint helped both the deficit and the debt soar. So when the once-in-a-lifetime viral disaster slammed our country and we threw more than $3 trillion into COVID-19-related stimulus, there was no longer any margin for error.

Our national debt has reached immense levels relative to our economy, nearly as high as it was at the end of World War II. But unlike 75 years ago, the massive financial overhang from Medicare and Social Security will make it dramatically more difficult to dig ourselves out of the debt ditch.

The Debt to GDP Ratio Is the Highest It's Been Since World War II

Federal debt held by the public as a percentage of gross domestic product since 1900.

Falling deeper into the red is the opposite of what Trump, the self-styled “King of Debt,” said would happen if he became president. In a March 31, 2016, [interview](https://www.washingtonpost.com/news/post-politics/wp/2016/04/02/transcript-donald-trump-interview-with-bob-woodward-and-robert-costa/) with Bob Woodward and Robert Costa of The Washington Post, Trump said he could pay down the national debt, then about $19 trillion, “over a period of eight years” by renegotiating trade deals and spurring economic growth.

After he took office, Trump predicted that economic growth created by the 2017 tax cut, combined with the proceeds from the tariffs he imposed on a wide range of goods from numerous countries, would help eliminate the budget deficit and let the U.S. begin to pay down its debt. On July 27, 2018, he [told Sean Hannity](https://www.foxnews.com/politics/on-trade-policy-trump-is-turning-gop-orthodoxy-on-its-head) of Fox News: “We have $21 trillion in debt. When this [the 2017 tax cut] really kicks in, we’ll start paying off that debt like it’s water.”

Nine days later, he tweeted, “Because of Tariffs we will be able to start paying down large amounts of the $21 trillion in debt that has been accumulated, much by the Obama Administration.”

That’s not how it played out. When Trump took office in January 2017, the nonpartisan Congressional Budget Office [was projecting](https://www.cbo.gov/system/files/2019-04/52370-outlookonecolumn_1.pdf) that federal budget deficits would be 2% to 3% of our gross domestic product during Trump’s term. Instead, the deficit reached nearly 4% of gross domestic product in 2018 and 4.6% in 2019.

There were multiple culprits. Trump’s tax cuts, especially the sharp reduction in the corporate tax rate to 21% from 35%, took a big bite out of federal revenue. The CBO estimated in 2018 that the tax cut would increase deficits by about $1.9 trillion over 11 years.

Meanwhile, Trump’s claim that increased revenue from the tariffs would help eliminate (or at least reduce) our national debt hasn’t panned out. In 2018, Trump’s administration began hiking tariffs on aluminum, steel and many other products, launching what became a global trade war with China, the European Union and other countries.

The tariffs did bring in additional revenue. In fiscal 2019, they netted about $71 billion, up about $36 billion from President Barack Obama’s last year in office. But although $36 billion is a lot of money, it’s less than 1/750th of the national debt. That $36 billion could have covered a bit more than three weeks of interest on the national debt — that is, had Trump not unilaterally decided to [send a chunk](https://www.desmoinesregister.com/story/money/agriculture/2019/07/25/trump-trade-war-farm-bailout-iowa-farmers-payments-hardship-aid-relief-china-corn-soybean/1825721001/) of the tariff revenue to farmers affected by his trade wars. Businesses that struggled as a result of the tariffs also paid fewer taxes, offsetting some of the increased tariff revenue.

By early 2019, the national debt had climbed to $22 trillion. Trump’s budget proposal for 2020 [called it](https://www.whitehouse.gov/briefings-statements/president-donald-j-trump-promoting-fiscally-responsible-pro-american-2020-budget/) a “grave threat to our economic and societal prosperity” and asserted that the U.S. was experiencing a “national debt crisis.” However, that same budget proposal included substantial growth in the national debt.

By the end of 2019, the debt had risen to $23.2 trillion and more federal officials were sounding the alarm. “Not since World War II has the country seen deficits during times of low unemployment that are as large as those that we project — nor, in the past century, has it experienced large deficits for as long as we project,” Phillip Swagel, director of the CBO, [said](https://www.cbo.gov/publication/56052) in January 2020.

#### Sticky pricing means increased competition can’t reduce drug prices – only direct regulation of prices can solve

Rosenthal 18 – Elisabeth Rosenthal, a former New York Times correspondent, is the author of “An American Sickness: How Healthcare Became Big Business and How You Can Take It Back,” and editor in chief of Kaiser Health News.

Elisabeth Rosenthal, June 21 2018, “Why Competition Won’t Bring Down Drug Prices,” The New York Times, https://www.nytimes.com/2018/06/21/opinion/competition-drug-prices.html

Martin Shkreli is in prison, but [Daraprim still costs $750 per pill](https://www.washingtonpost.com/national/health-science/for-shame-pharma-bro-shkreli-is-in-prison-but-daraprims-price-is-still-high/2018/05/04/ade40860-4f7b-11e8-85c1-9326c4511033_story.html?utm_term=.9ded22efafdf). Heather Bresch [was hauled before Congress](https://www.nytimes.com/2016/09/22/business/mylan-chief-to-insist-epipen-is-priced-fairly-at-house-hearing.html), but EpiPens still cost three to six times more than they did in 2007. Every week we hear of a new outrageous drug price increase. In polls, [some 80 percent](https://www.kff.org/health-costs/press-release/poll-drug-companies-have-more-influence-in-washington-than-nra/) of Americans say that government should do more to curb drug prices.

Having proclaimed just before his inauguration that drug makers were “getting away with murder,” President Trump last month [issued a 50-point blueprint](https://www.federalregister.gov/documents/2018/05/16/2018-10435/hhs-blueprint-to-lower-drug-prices-and-reduce-out-of-pocket-costs) to bring down prices, mainly by injecting more competition — and a dose of public shaming — into the market.

Though the document was light on specifics, containing more than 130 questions, it included proposals for speeding the development and sale of generics, strengthening insurers’ negotiating clout, and making pricing more transparent.

The administration apparently hopes that, with a nudge and prod, the market will control pharmaceutical pricing excesses. If history is a guide, it won’t.

Competition may work well to lower the prices of baguettes and cars. But it has **proved to have limited impact** on American health care, especially when it comes to expensive interventions like prescription drugs.

Exhibit A would be Novartis’s cancer drug Gleevec, a miracle when it was approved by the Food and Drug Administration in 2001. It turned a deadly form of leukemia into a treatable disease. Today, people who are in remission after two years of taking the drug have [a normal life expectancy](https://www.cancer.gov/research/progress/discovery/gleevec).

When Gleevec came on the market, its list price was [about $26,000 a year](http://ascopubs.org/doi/full/10.1200/JOP.2016.019737). Today, there are several highly effective drugs in the same family on the market (sometimes called “sons of Gleevec”). The list price for each is about $150,000 annually. (Notably, Dr. Brian Drucker, the researcher who demonstrated that the drug could cure cancers, never got a patent and [never made money from it](https://www.nytimes.com/2009/11/03/science/03conv.html).)

What happened is that e**ach new entrant cost more than its predecessors**, and their makers then increased their prices to match the newcomer’s. When the first generic version entered the market in 2016, its list price was only slightly less, [about $140,000](http://www.ascopost.com/issues/may-25-2016/the-arrival-of-generic-imatinib-into-the-us-market-an-educational-event/).

This phenomenon, what economists call “**sticky pricing,”** is common in pharmaceuticals. It has raised the prices in the United States of drugs for serious conditions including multiple sclerosis and diabetes even when there are multiple competing drugs.

The problem is that **companies have decided it is not in their interest to compete.**

In situations where there can be only one winner, competing is a given. But a lot of life and a lot of business just isn’t like that, especially when a group of companies are all doing good business by selling a type of drug for a very high price. There’s cover in numbers.

When you’re driving on the highway where a speed limit is 55 and most everyone’s going 70, you’re likely to increase your speed, too. Why should you feel bad? Why would the cop single you out? Someone else in a flashy car is probably doing 90. (For drug makers, Mr. Shkreli would be the hot-dogger who gives others cover.)

The parties are not really colluding. Drivers aren’t calling one another up to agree to drive too fast; no manufacturers (one hopes) are sitting at a country club agreeing to keep their prices high. This makes drug makers difficult to prosecute under racketeering or restraint of trade laws.

#### No impact to deficits---sustained downward pressure on interest rates

Furman and Summers 19 – Jason Furman is an American economist and professor at Harvard University's John F. Kennedy School of Government and a Senior Fellow at the Peterson Institute for International Economics. On June 10, 2013, Furman was named by President Barack Obama as chair of the Council of Economic Advisers. Lawrence Henry Summers is an American economist, former Vice President of Development Economics and Chief Economist of the World Bank, senior U.S. Treasury Department official throughout President Clinton's administration, and former director of the National Economic Council for President Obama.

Jason Furman and Lawrence Summers, January 28 2019, “[Who’s Afraid of Budget Deficits?](http://larrysummers.com/2019/01/28/whos-afraid-of-budget-deficits/)” LarrySummers.Com, http://larrysummers.com/2019/01/28/whos-afraid-of-budget-deficits/

Economic textbooks teach that government deficits raise interest rates, crowd out private investment, and leave everyone poorer. Cutting deficits, on the other hand, reduces interest rates, spurring productive investment. Those forces may have been important in the late 1980s and early 1990s, when long-term real interest rates (nominal interest rates minus the rate of inflation) averaged around four percent and stock market valuations were much lower than they are today. The deficit reduction efforts of Presidents George H. W. Bush and Bill Clinton contributed to the investment-led boom in the 1990s.

Today, however, the situation is very different. Although government debt as a share of GDP has risen far higher, long-term real interest rates on government debt have fallen much lower. As shown in the table, in 2000, the Congressional Budget Office forecast that by 2010, the U.S. debt-to-GDP ratio would be six percent. The same ten-year forecast in 2018 put the figure for 2028 at 105 percent. Real interest rates on ten-year government bonds, meanwhile, fell from 4.3 percent in 2000 to an average of 0.8 percent last year. Those low rates haven’t been manufactured by the Federal Reserve, nor are they just the result of the financial crisis. They preceded the crisis and appear to be rooted in a set of deeper forces, including lower investment demand, higher savings rates, and widening inequality. Interest rates may well rise a bit over the next several years, but financial markets expect them to end up far below where they stood in the 1980s and 1990s. Federal Reserve Chair Jay Powell has noted that the Fed’s current 2.375 percent interest rate is close to the neutral rate, at which the economy grows at a sustainable pace, and financial markets expect that the federal funds rate will not rise any further.

Low interest rates mean that governments can sustain higher levels of debt, since their financing costs are lower. Although the national debt represents a far larger percentage of GDP than in recent decades, the U.S. government currently pays around the same proportion of GDP in interest on its debt, adjusted for inflation, as it has on average since World War II. The cost of deficits to the Treasury is the degree to which the rate of interest paid on the debt exceeds inflation. By this standard, the resources the United States needs to devote to interest payments are also around their historical average as a share of the economy. Although both real and nominal interest rates are set to rise in the coming decade, interest payments on the debt are projected to remain well below the share reached in the late 1980s and early 1990s, when deficit reduction topped the economic agenda.

Government deficits also seem to be hurting the economy less than they used to. Textbook economic theory holds that high levels of government debt make it more expensive for companies to borrow. But these days, interest rates are low, stock market prices are high relative to company earnings, and major companies hold large amounts of cash on their balance sheets. No one seriously argues that the cost of capital is holding back businesses from investing. Cutting the deficit, then, is unlikely to spur much private investment.

Moreover, the lower interest rates that would result from smaller deficits would not be an unambiguously good thing. Many economists and policymakers, including former Treasury Secretary Robert Rubin and the economist Martin Feldstein, worry that interest rates are already too low. Cheap borrowing, they argue, with some merit, has led investors to put their money in unproductive ventures, created financial bubbles, and left central bankers with less leeway to cut rates in response to the next recession. If the United States cut its deficits by three percent of GDP, enough to stabilize the national debt, interest rates would fall even further.

Some commentators worry that rising deficits don’t just slowly eat away at economic growth, as the textbooks warn; they could lead to a fiscal crisis in which the United States loses access to credit markets, sparking an economic meltdown. There is precious little economic theory or historical evidence to justify this fear. Few, if any, fiscal crises have taken place in countries that borrow in their own currencies and print their own money. In Japan, for example, the national debt has exceeded 100 percent of GDP for almost two decades. But interest rates on long-term government debt remain near zero, and real interest rates are well below zero. Even in Italy, which does not borrow in its own currency or set its own monetary policy and, according to the markets, faces a substantial risk of defaulting, long-term real interest rates are less than two percent, despite high levels of debt and the government’s plans for major new spending.

The eurozone debt crisis at the start of this decade is often held up as a cautionary tale about the perils of fiscal excess. But stagnant growth (made worse by government spending cuts in the face of a recession) was as much the cause of the eurozone’s debt problems as profligate spending. And countries such as those in the eurozone, which borrow in currencies they do not control, face a far higher risk of debt crises than countries such as the United States, which have their own currencies. Countries with their own currencies can always have their central bank buy government debt or print money to repay it; countries without them can’t.

Higher levels of debt do have downsides. They could make it harder for governments to summon the political will to stimulate the economy in a downturn. But saying that a country would be better off with lower debt is not the same as saying that it would be better off lowering its debt. The risks associated with high debt levels are small relative to the harm cutting deficits would do.

It’s true that future generations will have to pay the interest on today’s debt, but at current rates, even a 50-percentage-point increase in the U.S. debt-to-GDP ratio would raise real interest payments as a share of GDP by just 0.5 percentage points. That would bring those payments closer to the top of their historical range, but not i

## 2NC

### Prizes

#### The formula pays MORE to companies that produce cheap drugs which solves prices

Ganjour and Chernyak 11 – Afschin Gandjour is a medical doctor, health economist, and Gandjour received an M.D. from Hannover Medical School in Germany, an M.B.A. from Duke University, a Ph.D. in health economics from the University of Cologne in Germany, and an M.A. in philosophy from the University of Düsseldorf in Germany. He held faculty positions at the University of Cologne Medical School, Baylor College of Medicine, and Louisiana State University Pennington. Nadja Chernyak, Department of Public Health, Center of Health and Society, Heinrich-Heine University Düsseldorf, Düsseldorf, Germany.

Afschin Gandjour and Nadja Chernyak, October 2011, “A new prize system for drug innovation,” Health Policy, [https://www.sciencedirect.com/science/article/pii/S0168851011001114?via%3Dihub#](https://www.sciencedirect.com/science/article/pii/S0168851011001114?via%3Dihub)!

VBP = Value based pricing

The fundamental principle of the VBP approach is that costs of new medical technologies should not exceed their health benefits. The prize system we propose builds on this fundamental principle of VBP. Compared to existing pricing proposals we make specific suggestions on how to adjust health benefits for uncertainty in cost-effectiveness and equity considerations. Furthermore, we derive the WTP for health benefits from the cost-effectiveness ratio of palliative or nursing care, appropriate the full social value to the innovator, and discuss implications for generic price competition.

To further explain the VBP approach, consider that the relative efficiency of medical intervention is traditionally summarized as the incremental cost-effectiveness ratio (ICER) and assessed with reference to a threshold value for the WTP [[33]](https://www.sciencedirect.com/science/article/pii/S0168851011001114?via%3Dihub" \l "bib0165):(1)C1−C0E1−E0=ΔCΔE<λwhere C1 − C0 denotes incremental costs of the new therapy, i.e., additional cost compared to the current treatment pattern, E1 − E0 denotes incremental health benefit of the new therapy, i.e., the difference in health outcomes between the new therapy and the current treatment pattern, and λ is an acceptable price per unit of health outcome. Current treatment pattern is the appropriate comparator because this is the treatment being substituted in the real world. That is, only incremental costs and benefits compared to current treatment represent the real-world costs and benefits of the new therapy.

Note that with current treatment pattern as a comparator, a new therapy may be compared to several different alternatives including no treatment. Hence, incremental costs and benefits represent weighted averages with weights representing the current market share of the different comparators.

Traditionally, the price of a drug has been set by the manufacturer and is an input to the calculation of the ICER. Alternatively, a cost-effective drug price can be derived from a threshold analysis by setting the ICER equal to the acceptable price per unit of health outcome (λ) [[54]](https://www.sciencedirect.com/science/article/pii/S0168851011001114?via%3Dihub" \l "bib0270):(2)C1−C0E1−E0=ΔCΔE=λ

Decomposing the price of the new drug from its total costs yields:(3)C1−C0E1−E0=C1−p+P−C0ΔE=λwhere P is the price of the new drug and C1−p denotes costs induced by the new drug (i.e., costs of side effects, savings from avoiding morbidity, and costs from avoiding premature death). Rearranging Eq. [(3)](https://www.sciencedirect.com/science/article/pii/S0168851011001114?via%3Dihub" \l "eq0015) yields the maximum acceptable drug price:(4)P=ΔE⋅λ−(C1−p−C0)

As price P is a function of λ, the acceptable price per unit of health outcome is explicitly considered. The size of the reward is thus placed into the broader context of societal willingness/ability to pay for health improvements.

Independent of the threshold value λ chosen, innovators that develop drugs providing high incremental health benefits are generally more highly rewarded than firms that develop drugs offering only marginal improvements over existing treatments. Drugs that yield a lower benefit but demonstrate savings compared to existing treatments are also priced based on Eq. [(4)](https://www.sciencedirect.com/science/article/pii/S0168851011001114?via%3Dihub" \l "eq0020). Hence, incentives are created to develop cost saving therapies, which are equally or slightly less effective compared to the common practice.

#### Prizes are better for serendipitous innovation because more strategies can obtain the prize

Charlton 7 – Bruce Graham Charlton is a retired British medical doctor and was Visiting Professor of Theoretical Medicine at the University of Buckingham.

Bruce Charlton, 2007, “Mega-prizes in medicine: Big cash awards may stimulate useful and rapid therapeutic innovation,” Medical Hypotheses, sciencedirect.com/science/article/pii/S0306987706006827?via%3Dihub

Prizes are different both from process-funded and patent-seeking research. Prizes are essentially a way of funding research to solve specified problems in situations where the process of development is more a matter of R&D than pure science, but when the aimed-at product is unlikely to be patentable. Researchers have a strong incentive to solve the specified problem because receiving the prize is contingent upon achieving a solution. But prize-seeking researchers are free to solve the specified problem using ideas and approaches that may be scientifically mundane, technologies that are un-patentable, or technologies for which patents have expired.

Prizes tend to generate solutions which are incremental extensions, new applications or novel combinations of already existing technologies. The most famous example is the 1714 Royal Society of London 20 000 pounds Sterling prize for measurement of longitude to within five tenths of a degree [[3]](https://www.sciencedirect.com/science/article/pii/S0306987706006827?via%3Dihub" \l "bib3). This was eventually awarded to John Harrison in 1773, for designing a sufficiently accurate and robust clock. The delay in awarding the prize came from the fact that the Royal Society was looking for a ‘pure science’ answer to the longitude problem, while Harrison’s method was based on old science implemented by vastly-improved technology.

Indeed, this seems to be the usual way in which prizes are won. The general rule seems to be that prizes stimulate technology rather than science, accelerate R&D rather than generate paradigm-shifting breakthroughs. The prize winners for motorized flight, human powered flight, energy-efficient refrigerators and the ‘X prize’ for cheap space flight seem to confirm this pattern [[4]](https://www.sciencedirect.com/science/article/pii/S0306987706006827?via%3Dihub" \l "bib4).

The main use of mega-prizes in medicine would be to accelerate therapeutic progress in stagnant fields of research, to address urgent problems, and to do so even when effective solutions are neither scientifically ‘sexy’ nor necessarily money-making. Useful therapies for a disease may be even duller than Harrison’s clock appeared to the Royal Society, and may not be patent-protect-able, yet nonetheless extremely valuable to suffers from the disease.

#### Prizes solve better than patents because they can be given to strategies that aren’t patnentable – means a wider range of strategies will be utilized

Charlton 7 – Bruce Graham Charlton is a retired British medical doctor and was Visiting Professor of Theoretical Medicine at the University of Buckingham.

Bruce Charlton, 2007, “Mega-prizes in medicine: Big cash awards may stimulate useful and rapid therapeutic innovation,” Medical Hypotheses, sciencedirect.com/science/article/pii/S0306987706006827?via%3Dihub

For example, many specific types of cancer might be suitable for offering prizes. Shortly before he died of lymphoma, David Horrobin wrote an article in the Lancet calling for a more urgent and pragmatic approach to cancer therapy [[5]](https://www.sciencedirect.com/science/article/pii/S0306987706006827?via%3Dihub" \l "bib5). He speculated that there might already exist a variety of potentially beneficial (and non-toxic) nutritional and pharmaceutical interventions – supported by biochemical and animal experiments or case studies, but not yet refined or checked by clinical trials. Specific types of lifestyle advice and nursing care might also make a difference. Such interventions, if properly combined and sequenced, and tested in small and well-controlled trials, could rapidly and significantly help people with various malignancies. Yet such potentially beneficial treatments would probably not be patentable, and would also be regarded as scientifically mundane, so would be unlikely to be discovered with current mainstream research incentives. Mega-prizes might make the difference.

Perhaps sufficiently large amounts of money, and the prestige and publicity which would derive from winning a mega-prize, could mobilize research efforts to discover a whole range of scientifically un-glamorous but clinically-useful therapeutic breakthroughs. Such a strategy could provide realistic hope of speeding-up therapeutic advances for patients suffering from diseases for which, at present, little can be done.

#### The system rewards new uses of similar innovations and incentivizes investments in new applications

Ganjour and Chernyak 11 – Afschin Gandjour is a medical doctor, health economist, and Gandjour received an M.D. from Hannover Medical School in Germany, an M.B.A. from Duke University, a Ph.D. in health economics from the University of Cologne in Germany, and an M.A. in philosophy from the University of Düsseldorf in Germany. He held faculty positions at the University of Cologne Medical School, Baylor College of Medicine, and Louisiana State University Pennington. Nadja Chernyak, Department of Public Health, Center of Health and Society, Heinrich-Heine University Düsseldorf, Düsseldorf, Germany.

Afschin Gandjour and Nadja Chernyak, October 2011, “A new prize system for drug innovation,” Health Policy, https://www.sciencedirect.com/science/article/pii/S0168851011001114?via%3Dihub#!

However, the proposed prize system considers the cumulative nature of medical innovation and does not preclude approval of therapeutically similar innovations (me-too drugs) if they offer additional health benefits or cost savings. There have been concerns that therapeutic substitutes might crowd out drastic innovations by reducing the budget available for R&D. But different drug versions are often innovated in so-called R&D races, implying that therapeutically similar innovations are already in the ‘pipeline’ when the first drastic innovation enters the market [[10]](https://www.sciencedirect.com/science/article/pii/S0168851011001114?via%3Dihub" \l "bib0050). Thus, increased competition because of the race to be the first might further stimulate innovation and possibly speeds up commercialization. Moreover, even drugs with the same effectiveness can provide incremental benefits because of reduced side effects or improved compliance [[35]](https://www.sciencedirect.com/science/article/pii/S0168851011001114?via%3Dihub" \l "bib0175). In any case, the prize system considers as a comparator of a new drug the current treatment, which may be a recently approved drug or no treatment in case of market expansion.

### DA Healthcare

#### And the DA turns case – blanket limits on practices in healthcare creates huge private sector uncertainty dooming investment in new drugs

Abbott 21 – Alden Abbott is a Senior Research Fellow focusing on anti-trust issues. Before joining Mercatus, Mr. Abbott served as the Federal Trade Commission’s General Counsel from 2018 to early 2021, where he represented the Commission in court and provided legal advice to its representatives.

Alden Abbott, April 29 2021, “Lack of Resources and Lack of Authority Over Nonprofit Organizations Are the Biggest Hindrances to Antitrust Enforcement in Healthcare,” Mercatus Center, https://www.mercatus.org/publications/antitrust-and-competition/lack-resources-and-lack-authority-over-nonprofit

Existing Antitrust Statutes and Agency Guidance are Fully Adequate to Address Health Care Antitrust Issues, but Narrowly Targeted Legislation to Deal with Specific Abuses May Be Warranted

At this time, there are a variety of legislative proposals for far-reaching change in federal antitrust law. Respectfully, I do not believe that major statutory change in the antitrust field would be helpful. As I have argued recently, although a few marginal adjustments to the antitrust statutes appear appropriate, such as elimination of the nonprofit exception to FTC jurisdiction, the mainstream consensus consumer-welfare approach should be retained. Antitrust statutory amendments affecting such areas as burdens of proof, presumptions, merger and monopolization standards, and blanket limits on mergers applicable to certain categories of firms (among other possible changes being advanced) would transform enforcement norms and judicial analysis, generating enormous private-sector uncertainty. This uncertainty would tend to deter innovation, harming consumers and the American economy. The claims by some that broad-based sweeping changes are needed owing to reduced competition in the American economy and ineffective antitrust enforcement have been rebutted by sound economic analysis—at the very least, those claims have not been proven.

During my years as an executive in the FTC’s Bureau of Competition and as FTC general counsel, I became quite familiar with FTC antitrust development and policy research applicable to healthcare. In my opinion, the FTC staff possesses the legal tools (with the exception of the nonprofit limitation, discussed earlier) to fully investigate and take action against anticompetitive behavior in this sector. What’s more, the FTC has had an excellent enforcement track record, including in hospital mergers. It currently is addressing a broad range of healthcare-related activity. Existing agency guidance, including the 2020 Vertical Merger Guidelines, provide ample support for appropriate, evidence-based, economically sound enforcement. New general legislation is not needed.

Nevertheless, I recognize that targeted statutory amendments, narrowly tailored to address specific competitive healthcare sector problems, may be appropriate in certain circumstances. A good example is the newly minted CREATES Act, which deals with regulatory abuses that had allowed branded pharmaceutical companies to forestall competition from both generic drug and biosimilar producers. I testified in favor of the CREATES Act in 2017 before this subcommittee and in 2016 before the Subcommittee on Competition Policy, Antitrust, and Consumer Rights. There is an extensive literature on how regulated entities may manipulate the regulatory process to undermine competition, and the abuses dealt with by the CREATES Act present a prime example of such conduct.

Several scholars recently have advanced a number of additional legislative proposals to deal with perceived competitive problems afflicting healthcare. Professor Michael Carrier notably has called for legislation providing that pharmaceutical “pay for delay” settlements are presumptively illegal; authorizing the FTC to challenge pharmaceutical “product hopping”; allowing the FTC to challenge certain “patent thickets” (a particular issue in the area of biologic drugs); and limiting sham citizen petitions filed by brand-name drug producers with the FDA.

I will not comment in this testimony on the merits of these or other targeted healthcare-related proposals, which deserve serious scrutiny. I would, however, add a word of caution. Antitrust enforcement focuses on the specific facts of a case to determine whether conduct in the particular instance at hand is likely to undermine competition and reduce consumer welfare. But proposals that broadly seek to condemn a certain practice risk rendering illegal (and deterring businesses from pursuing) specific beneficial manifestations of that practice. Accordingly, before legislating, Congress should seriously weigh whether in attacking a particular practice, the benefits of eliminating targeted harmful conduct would likely be outweighed by the costs of condemning and deterring specific instances of such conduct that could have benefited consumers, including through innovation.

#### And the status quo gradualism of antitrust will solve the plan which means there’s only a risk of neg offense

Melamed 20 – Professor of the Practice, Stanford Law

A.Douglas Melamed, Antitrust Law and its Critics, *Antitrust Law Journal* Vol. 83 (2020), <https://www-cdn.law.stanford.edu/wp-content/uploads/2021/11/A.-Douglas-Melamed-Antitrust-Law-and-Its-Critics-83-ANTITRUST-L.J.-269-2020.pdf>

Antitrust law should retain its singular focus on economic welfare. To do so

effectively, it must remain faithful to its common law-like tradition of adapting in light of new learning and new experience. Antitrust law, and the executive and judicial institutions that enforce it, must grapple seriously with

worthy and empirically based ideas of the mainstream progressives; those of

the conservatives; and, to the extent they are focused on promoting competition and economic welfare, those of the populists as well.

#### Years of experience prove that kind of evolutionary updating will solve. Their authors make bankrupt assumptions—AND any reasons it wouldn’t the plan does not fix.

Melamed 20 – Professor of the Practice, Stanford Law

A.Douglas Melamed, Antitrust Law and its Critics, *Antitrust Law Journal* Vol. 83 (2020), <https://www-cdn.law.stanford.edu/wp-content/uploads/2021/11/A.-Douglas-Melamed-Antitrust-Law-and-Its-Critics-83-ANTITRUST-L.J.-269-2020.pdf>

On the surface, the populist critics, like the conservatives and mainstream progressives, are talking at least in part about whether antitrust law is well suited to promote its economic-welfare objective. They argue, in particular, that the "consumer-welfare standard" that has defined contemporary antitrust law is much narrower than suggested above and that it prevents antitrust law from effectively promoting economic welfare. They say, for example, that the consumer-welfare standard requires courts to pursue outcomes, a task for which they are not well-suited, instead of calling balls and strikes; 79 confines antitrust law to a singular focus on consumer prices; 80 is not able to address conduct that reduces innovation; 81 and focuses solely on consumers and ignores harm to suppliers.8 2 Nicolas Petit and I have argued elsewhere that each of these criticisms is incorrect. 83 In brief, antitrust is about proscribing anticompetitive conduct and does not call upon courts to measure or regulate welfare outcomes. Antitrust law has in the past effectively addressed harms to innovation; harms to suppliers, including in labor markets; and anticompetitive conduct that had nothing to do with prices and involved products sold for a zero monetary price. The common focus on pricing data and other perceived problems reflect limitations on available data and difficult problems of proof, not any conceptual restrictions arising from the consumer-welfare standard. These limitations and problems have been, and no doubt will continue to be, ameliorated by advances in economists' toolkit and legal doctrine.

#### Perception—companies do not expect immediate statutory/legal changes—enforcement only affects a small slice of deals

Zero 21 – Senior Reporter for Mergers & Acquisitions

Brandon Zero, "Antitrust Deal Scrutiny More Storm Than Fury," Mergers & Acquisitions, 8-4-2021, <https://www.themiddlemarket.com/news-analysis/threat-of-antitrust-deal-scrutiny-seen-more-storm-than-fury>

What’s the forecast for regulatory scrutiny of deals so far this year? There may be more cloud cover than storms on the M&A horizon. New antitrust scrutiny and a longer review time are potential looming threats, but they lack the lightning needed to actually block deals.

Let’s look at these twin threats and the risks they pose to dealmaking. President Biden’s executive order has spurred the Department of Justice and Federal Trade Commission to increase scrutiny of deals in a move that, “if implemented by regulators and upheld by the courts…could lead to the most robust antitrust enforcement in decades,” writes Debevoise & Plimpton lawyers in a recent note. But that’s a big ‘if.’ The attorneys write that actually intensifying competition review standards would require acts of Congress and/or litigation. Both regulatory agencies have mixed records in courts. And it’s unclear if Democrats will defy the political gravity that has historically weighed down incumbent presidents’ party performance in midterm elections to win a mandate to rewrite antitrust laws.

What about the other lingering storm cloud on the periphery? A frenetic M&A pace has overwhelmed oversight body the Federal Trade Commission to the extent that it’s warned companies the expiration of the standard 30-day waiting period is no longer an implicit approval of a deal, Bloomberg reports. That creates a threat of enforcement even after deals have closed.

Amidst the merger deluge, a few high-profile deals have been challenged, but context is king: the handful of challenged deals represent a small slice of the year’s record value of announced transactions.

For starters, some of the highest profile deals challenged by the new administration’s antitrust regime represent merger dynamics that have always drawn intense scrutiny. Aon Plc’s proposed $30 billion takeover of Willis Towers Watson (Nasdaq: WLTW), announced only five years after Willis Group’s $18 billion merger with Towers Watson, was challenged by the DOJ as taking the industry from three competitors to two. So called “3 to 2” mergers have always been a bright line for regulators. And the insurance investment bankers I’ve spoken to for a decade about industry consolidation have long steered clear of attempts to marry those players or Marsh & McLennan (NYSE: MMC) out of fear of this precise outcome.

There are wild cards that could skew my forecast. It’s true that zealous enforcement of vertical merger review guidelines has created unexpected scrutiny of some sectors, and that agencies’ evolving theories of harm could disproportionately put tech deals at risk. But on the whole, the latest policy announcements may well be more thunder than lightning**.**

#### No lasting change even if administrative stuff implemented

Wright, JD, PhD, University Professor and the Executive Director, Global Antitrust

Institute, Scalia Law School at George Mason University, former FTC Commissioner, ‘21

(Joshua D., “Lina Khan Is Icarus at the FTC,” July 13, WSJ)

All that has been overshadowed by an executive order aimed at competition and loaded with goodies, good intentions, new regulatory regimes and a blissful ignorance of unintended consequences (“Joe Biden, 20th Century Trustbuster,” Review & Outlook, July 10). Some of its pronouncements, like occupational-licensing reform, are to the good. But the FTC’s competition authority is about to become a free-for-all for the Biden administration to reshape the economy. One wonders how the Republicans going along with all this to “get Big Tech” are feeling right now; I’m guessing “played.” If not, they’ll catch up soon enough.

Imagining the FTC as Icarus flying without the constraints of history, economics or law is a fun thought experiment, but we’ve been here before. Ms. Khan’s initial steps are indicative of a regulatory overreach that will end with the FTC’s wings melting in the courts. This path does not lead to incremental, much less radical, change. I predict early headlines that appease a rabid base, frustration for FTC staff and a new, volatile partisanship at the agency, but actual results that leave unsatisfied the progressives aching for radical change.

#### Squo victories do not touch large firms—bops their link turn not our link

Nicole Goodkind, Fortune, Lina Khan is the face of the populist antitrust moment. But how much power does the FTC chair wield? June 30, 2021, https://fortune.com/2021/06/30/ftc-chair-lina-khan-populist-antitrust-movement-what-can-she-do-federal-trade-commission/

But the question of whether Khan will be able to rouse an agency that’s been in a state of semiconsciousness for nearly half a century remains.

Detractors argue that Khan is little more than a figurehead, meant to placate progressives and antitrust populists while the FTC remains largely ineffective. This week, a federal judge struck down an FTC complaint against Facebook, brought by Khan’s predecessor, that would have forced the company to divest from Instagram and WhatsApp. Khan and the FTC now have until July 29 to file a new complaint.

Amazon also tried to make the case on Wednesday that Khan should recuse herself from any FTC enforcement decisions involving the company—including the FTC review of its $8.45 billion acquisition of movie studio MGM—because of her previous statements that the company should be broken up.

There’s a dichotomy between popular groupthink around monopolies and what’s actually going on in the courts, said Aurelien Portuese, director of antitrust and innovation policy at the Information Technology and Innovation Foundation, a D.C. think tank that is partially funded by Big Tech. “There are a lot of proposals to depart from these principles of how you define the market and market demand. I think these attempts may very well be crushed many times in courts,” he said. Khan might be effective in precautionary rulemaking, he said, but that would largely impact smaller tech upstarts, not the Big Four.

Those interruptions, he argued, would stifle innovation and American entrepreneurship, giving China an upper hand (a similar argument was made when Microsoft faced antitrust charges in 1998).

Populist antitrust sentiment, said Portuese, is a trend that will soon fade: “I don’t see radical changes in the long run, because of the inevitable judicial review that entrepreneurs are subject to.”

**No radical action yet---Khan’s moved slowly and without controversy**

**Guilford 2/14** – Columnist for Reuters Breakingviews

Jonathan Guilford, "Lockheed deal flop is just antitrust amuse-bouche," Reuters, 2-14-2022, https://www.bloomberg.com/news/features/2022-02-09/there-are-now-1-000-unicorn-private-company-startups-worth-1-billion-or-more?utm\_campaign=news&utm\_medium=bd&utm\_source=applenews

Meanwhile, in areas that companies and their investors feared radical change, little has happened. The market priced in substantial antitrust risk to a variety of pharmaceutical mergers – all of which passed muster. The Department of Justice allowed media giant Discovery’s (DISCA.O) merger with WarnerMedia, even after members of Congress raised concerns.

Khan wants to enlarge the FTC’s notion of what constitutes an unacceptable merger, as shown by efforts to discard current guidelines for analyzing deals and start from scratch. Yet so far, there’s no evidence of a big shift. Instead Khan has moved deliberately, issuing enforcement actions at a relatively slow pace while racking up uncontroversial, bipartisan votes on deals.

**Especially health mergers are high now and only looking to increase**

**Orlov 9/28** – Managing Director in the Health Care Consulting Group

Bert Orlov, "Health Care M&A Activity on the Rise," EisnerAmper, 9-28-2021, https://www.eisneramper.com/health-care-m-and-a-hc-blog-0921/

In the health care market, a dramatic uptick in activity (acquisitions) by entrepreneurs and private equity (PE) firms in 2021 has already exceeded expectations. And early data points to a long-term trend in provider acquisitions (e.g., hospitals, physician practices, home care, telehealth). Here are some themes that were discussed at the Texas Society of CPAs 2021 Advanced Healthcare Conference Webcast:

While COVID-19 temporarily slowed PE activity in 2020, now, the pent-up demand exacerbated by the slowdown, plus the intrinsic movement toward exit strategies, shows the sector’s strong future. Furthermore, the pandemic itself will likely drive volume due to financial distress. And investor interest is returning stronger than ever.

In addition, for elderly providers and entrepreneurs, the aftermath of COVID-19 stress will likely drive exit/monetization strategies, and the industry is seeing exactly this pattern in dramatic growth in acquisitions in the physician practice sector.

The underlying drivers of consolidation, and thus PE activity, have only grown stronger. Consolidation will accelerate across all segments of health care due to needs for market power, economies of scale, and strong management to address increasing demands in technology and care management. Value-based purchasing will continue to expand as the Centers for Medicare and Medicaid Services (CMS) designs and implements new payment models, most particularly its emphasis on direct contracting (via entities known as DCEs).

Furthermore, integration of new technologies such as telehealth will require a move from the COVID-19 ad hoc approach to strategic positioning of patient care and operations to integrate new tools. Finally, long simmering issues such as management of chronic disease and behavioral health care will create new markets and management demands.

#### Courts limit Biden enforcement – any squo antitrust actions won’t take effect until 2023

Christopher et. Al. 7/26 – Paul Christopher is the Head of Global Market Strategy for Wells Fargo Investment Institute (WFII), a subsidiary of Wells Fargo Bank, N.A., which is focused on delivering the highest quality investment expertise and advice to help investors manage risk and succeed financially.

[Paul Christopher, CFA](https://www.wellsfargoadvisors.com/research-analysis/strategists/paul-christopher.htm), [Ken Johnson, CFA](https://www.wellsfargoadvisors.com/research-analysis/strategists/ken-johnson.htm), [Gary Schlossberg](https://www.wellsfargoadvisors.com/research-analysis/strategists/gary-schlossberg.htm), [Michael Taylor, CFA](https://www.wellsfargoadvisors.com/research-analysis/strategists/michael-taylor.htm), and [Michelle Wan, CFA](https://www.wellsfargoadvisors.com/research-analysis/strategists/michelle-wan.htm), “Policy, Politics & Portfolios,” Wells Fargo, https://www.wellsfargoadvisors.com/research-analysis/reports/policy/domestic-foreign-policies.htm

Antitrust laws are intended to help protect consumers from predatory corporate activity and promote fair competition in the open market. The intention of these laws and associated regulations is to help curb a range of business practices, including price fixing and monopolies. Without regulatory oversight, lawmakers' concern is that consumers would likely pay higher prices and have access to fewer choices of products and services.

Antitrust laws are comprised of three pieces of legislation enacted by Congress (see Sidebar 1). U.S. antitrust regulations are enforced by two federal agencies: the Federal Trade Commission (FTC) and the Department of Justice (DOJ). Yet, there are limits and potential delays to antitrust policy under current laws. At times, U.S. courts have struggled to interpret vague language and make rulings.

Biden acts

Earlier this month, President Biden signed an executive order (EO) initiating a broad-based approach to spur competition across sectors including Information Technology, Health Care, and agriculture. The EO includes 72 actions and recommendations across 12 federal agencies (see Sidebar 2).1 President Barack Obama issued a similar EO late in his second term, but few agencies responded to it. Recently appointed FTC Chair Lina Kahn appears poised to broaden oversight and enforcement of anti-competition laws. Yet, there are questions about the president’s authority over the FTC and the agency’s reach; certain measures will likely be blocked by courts.

In Congress, regulating Big Tech has garnered bipartisan support, but for different reasons. Democrats are focused on alleged anticompetitive practices while Republicans are concerned about the limitations on commentary and content on social media websites. Last September, Congress held hearings to investigate these allegations. In June, the House Judiciary Committee approved five of six proposed bills, mainly aimed at Big Tech platforms favoring proprietary products and services. Yet, even with bipartisan support, we believe the odds of passing meaningful antitrust legislation in the near term are slim as proposals for physical infrastructure and social spending take precedence. That said, we expect antitrust legislation to remain a priority for lawmakers ahead of midterms.

Investment implications

With the signing of the EO, we believe changes in regulatory oversight are likely. Successful antitrust litigation from lawmakers is a growing possibility, yet likely slow in coming. The DOJ suit filed last year is still scheduled for September 2023, demonstrating the snail-like pace of litigating antitrust cases.

We currently have a neutral tactical position on the Information Technology sector. This outlook aligns with our view that the path of regulation is unclear and will likely be delayed by court challenges. This trajectory may not affect the earnings of large firms with component businesses that could be flexible enough to maintain earnings growth as individual or spun-off companies. Thus, the cross-currents of regulation add uncertainty that balances against our view that the sector’s earnings will grow over the next 6 to 18 months.

#### Scope – modifying the scope of the Sherman act creates chilling fears of treble damages that cascade across the entire economy

Delrahim, JD, former Assistant Attorney General for the Antitrust Division of the United States Department of Justice, ‘20

(Makan, “Assistant Attorney General Makan Delrahim Delivers Remarks at IAM’s Patent Licensing Conference in San Francisco,” September 18, <https://www.justice.gov/opa/speech/assistant-attorney-general-makan-delrahim-delivers-remarks-iam-s-patent-licensing>)

It can be a serious mistake for a court to allow either type of claim to proceed under the Sherman Act. To understand why that is the case, one should consider the policies underlying Section 2 of the Sherman Act.

One crucial element in establishing any claim of unlawful monopolization under Section 2 is a showing that a defendant acquired, enhanced, or maintained monopoly power in the relevant market through anticompetitive conduct that is “exclusionary” or “predatory” in nature. I will focus on so-called “exclusionary” conduct—the umbrella concept often invoked by licensees bringing Section 2 claims premised on FRAND violations.

The term exclusionary conduct in antitrust law is potentially misleading because there is a difference under the Sherman Act between “lawful” and “unlawful” conduct that results in exclusion of a competitive alternative. In market economies, every rational business wants to exclude and defeat its competitors, and indeed antitrust law encourages fierce competition among companies aiming for as high a market share as they can achieve. That is why courts applying Section 2 are careful not to condemn “exclusionary” conduct that is driven by competition on the merits such as innovation. Most obviously, legitimate competition on the merits can be “exclusionary” in the sense that consumers choose a superior product or service. That conduct does not violate Section 2. By comparison, conduct that “excludes” a competitor by hindering its ability to offer a superior product or service, without offering any benefit to competition, likely would constitute a Section 2 violation.

When courts police the line between lawful and unlawful “exclusionary” conduct, a few themes emerge.

First, courts have recognized that not every type of conduct that may enhance a business’s market power is actionable, such as when the application of Section 2 would impose a duty that contravenes the policies of the antitrust laws themselves. For example, in Verizon Communications Inc. v. Law Offices of Curtis V. Trinko, the plaintiff alleged that Verizon refused to deal with a rival in order to limit competitive entry, thereby enhancing its monopoly position. The Supreme Court held that the claim did not satisfy Section 2 as a matter of law. That is because the claim would condemn a monopolist’s refusal to share its resources and effectively would create an antitrust duty to help a competitor. Such a duty, the Court explained, is in “tension with the underlying purpose of antitrust law, since it may lessen the incentive for the monopolist, the rival, or both to invest in those economically beneficial facilities.” The Court applied a legal rule, rather than a fact-specific rule, to protect conduct that may have an exclusionary, monopoly-enhancing effect.

Second, the Supreme Court has cautioned against antitrust standards that would create an unacceptable risk of “false positives” or condemnations of lawful pro-competitive conduct. As the Court has explained, “Mistaken inferences and the resulting false condemnations ‘are especially costly, because they chill the very conduct the antitrust laws are designed to protect.’” Judge Robert Bork, in his famous Antitrust Paradox, highlighted the same risk in the application of Section 2 theories, explaining with respect to exclusive dealing that “[t]he real danger for the law is less that predation will be missed than that normal competitive behavior will be wrongly classified as predatory and suppressed.”

This backdrop helps frame the question whether a unilateral refusal to license a lawful patent on “FRAND” terms after committing to do so constitutes a form of unlawful exclusionary conduct. A unilateral violation of a FRAND commitment should not give rise to a cause of action under Section 2 of the Sherman Act, even if a patent holder is alleged to have misled or deceived a standard-setting organization with respect to its licensing intentions. Applying Section 2 to this sort of unilateral conduct would contravene the underlying policies of the antitrust laws. This conduct may warrant remedies under contract law, but the important difference is that contract remedies do not involve the threat of treble damages that can deter lawful, pro-competitive conduct.

In the context of legitimate standard setting, the collective decision to incorporate a patented technology into a standard necessarily involves the “exclusion” of rival technologies. Moreover, as a result of having its technology incorporated into a standard, a patent holder may gain incremental market power beyond any power that holding a patent would already convey. By voluntarily participating in the standard setting process, however, owners of rival technologies and prospective licensees assume the risk that the outcome of that process may have an exclusionary effect where there are patents covering the “winning” technology. Simply winning selection by a standard setting process does not constitute unlawful exclusionary conduct under the antitrust laws. This is because that selection, regardless the reason for it, contributes to unification around a single standard, which creates interoperability benefits for consumers that could not be achieved without unification.

This form of lawful and pro-competitive exclusionary conduct should not be condemned as unlawful under the Sherman Act when a licensee believes that a patent-holder opportunistically has reneged on its commitment to license on “FRAND” terms and engaged in so-called “hold-up.” That is also true even where a patent holder never allegedly intended to license on the terms that a court ultimately determines are “FRAND.” I will explain why.

There is no duty under the antitrust laws for a patent holder to license on FRAND terms, even after having committed to do so. A FRAND commitment is a contractual representation that a patent holder will license on “fair,” “reasonable,” and “non-discriminatory” terms. It is not the same as a promise to pay a specific price in a final contract. Indeed, commentators have noted that by failing to specify a specific price, a FRAND commitment is an incomplete contract term.

To be clear, a FRAND commitment may create a duty under contract law to fulfill that obligation, and courts may be tasked with determining the relevant FRAND rate where parties disagree over this contract term. Section 2, however, is agnostic to the price that a patent-holder seeks to charge after committing to such a term. Breaking down “FRAND” by its component terms makes clear why this is so.

First, the Sherman Act does not police “fair” prices or competition; it protects the competitive process. Judge Easterbrook once asked, “Who says that competition is supposed to be fair, that we judge the behavior of the marketplace by the ethics of the courtroom? . . . When economic pressure must give way to fair conduct . . . rivals will trim their sails”; introducing conceptions of “fairness” into the Sherman Act “is to turn antitrust law on its head.”

Second, having undertaken a contractual duty to charge “nondiscriminatory” rates, the Sherman Act does not compel a patent-holder to abide by this promise. The Sherman Act is indifferent to price discrimination; indeed, in some circumstances price discrimination may be pro-competitive.

Third, the Sherman Act does not authorize courts to determine “reasonable” licensing rates. The Supreme Court has emphasized repeatedly that antitrust law does not recognize a cause of action that would “require[] antitrust courts to act as central planners, identifying the proper price, quantity, and other terms of dealing—a role for which they are ill-suited.”

It, therefore, would be a mistake to infer that a contractual FRAND commitment somehow establishes a duty under the antitrust laws to license on terms demanded by a licensee or that violations of an ambiguous FRAND term become an antitrust violation. Transforming such a contract obligation into an antitrust duty would undermine the purpose of the antitrust laws and the patent laws themselves, both of which serve the same goal of increasing dynamic competition by fostering greater investment in research and development, and ultimately in innovation.

Making the duty to license on FRAND terms enforceable under the antitrust laws would contravene the policies of the Sherman Act. As the Supreme Court recognized in Trinko, a business has no antitrust duty to deal with another company, and only in limited circumstances will a refusal to deal give rise to a potential antitrust claim. As then-Tenth Circuit Judge Neil Gorsuch explained in Novell v. Microsoft, following Trinko, a monopolist’s refusal to license its intellectual property is actionable under the antitrust laws only if it terminates a “presumably profitable course of dealing between the monopolist and the rival” and that termination is “irrational but for its anticompetitive effect.”

I would note that then-Judge Gorsuch’s standard echoes what the United States and FTC advocated to the Supreme Court in its amicus brief in the Trinko case. The brief stated:

Where, as here, the plaintiff asserts that the defendant was under a duty to assist a rival, the inquiry into whether conduct is “exclusionary” or “predatory” requires a sharper focus. In that context, conduct is not exclusionary or predatory unless it would make no economic sense for the defendant but for its tendency to eliminate or lessen competition.

That narrow window for a refusal to deal claim is irreconcilable with the broader contention that Section 2 obligates an SEP-holder subject to a contractual FRAND commitment to license its technology to any comer—much less on FRAND terms. An antitrust duty to license on FRAND terms would also contravene the patent laws’ policy of promoting innovation by offering incentives for holders of valid patents to seek the greatest rewards possible for their inventions.

To be clear, contract law may very well require an SEP-holder to deal with any willing licensee, but the Sherman Act does not convert FRAND commitments into a compulsory licensing scheme. It logically follows that there is no antitrust liability for proposing to deal at terms that are above FRAND rates.

Nor should an antitrust duty spring into being if a patent holder allegedly “deceives” an SSO when it commits to license on FRAND terms and its participants rely on that representation in deciding to adopt the technology. That is because Section 2 should not condemn a patent holder’s profit-maximizing intentions or aspirations at the time it makes a FRAND commitment, particularly where remedies are already available to an unhappy licensee or SSO participant.

Suppose that, hypothetically, the holder of a standard-essential patent knew upfront precisely what price would satisfy the vague definition of “FRAND” and planned to demand a much higher price after the SSO incorporated its technology into a standard. By making a legally binding commitment, a patent-holder acknowledges that it will be required under contract law to license at a rate determined by a court if a disagreement over that rate arises later. A licensee, for its part, understands that it can bring suit if a price does not fit its own subjective understanding of “FRAND.” Because both patent-holders and licensees participating in a standard-setting process recognize that the proper “FRAND” rate will be determined after the fact—in court, if necessary—there is therefore no meaningful ex ante “deception” that should give rise to an antitrust claim.

To be sure, having one’s technology incorporated into a standard, in some circumstances, may increase a patent-holder’s market power. The same could be said, of course, about a monopolist’s refusal to deal with a rival who might gain market share if it had access to the monopolist’s inputs. Even if this occurs as a result of a patent holder’s so-called “deception” about its licensing obligations, this is not the sort of market-power-enhancing conduct that Section 2 should reach because a cause of action for treble damages would impede the policies underlying the Sherman Act. Even worse, such a cause of action would “require[] the court to assume the day-to-day controls characteristic of a regulatory agency.”

More fundamentally, recognizing a Section 2 cause of action for violations of a FRAND commitment would create an unacceptable risk of “false positive” condemnations of pro-competitive conduct by licensees. The prospect of antitrust liability and treble damages for breaching a potentially vague FRAND term—or allegedly “misrepresenting” one’s intentions to offer some FRAND rate—threatens to chill incentives for innovators to develop new technologies that fuel dynamic competition.

Where contract law remedies exist to remedy and deter breaches of a FRAND commitment, the additional deterrence that Sherman Act remedies offer could deter lawful, pro-competitive conduct—that is, research and development by innovators who make careful cost-benefit calculations as to how much to invest in technologies that may not pay off. Demanding a high price for one’s patented technology is permissible, and expected, conduct in a free market negotiation. A Section 2 cause of action would skew the patent licensing bargain away from the bargaining outcome that a free market dictates.

In particular, where the parties have a subjective disagreement over the meaning of an incomplete contract term, a Section 2 remedy threatens the patent holder with the risk of enormously costly litigation and a possible treble damages award. Bargaining in the shadow of litigation, a patent holder would be wary that a high license demand could be penalized by a significant damages award, whereas a prospective licensee’s low-ball offer would do no such thing. Such a remedy would bestow any putative licensee with disproportionate negotiating power. In turn, the cost-benefit calculation for innovators would change and the prospect of additional dynamic competition likely would decline.

#### Current antitrust is evolutionarily adaptive—Inherently caps their harms, but the plan locks the economy into a straightjacket—Eliminates dynamism which nukes US competitiveness

COC 21 – U.S. Chamber of Commerce

The Role & Responsibility of Antitrust: What antitrust is and what it is not, September 20, 2021, <https://www.uschamber.com/regulations/the-role-responsibility-of-antitrust>

Antitrust learns from its mistakes, it adjusts based on deeper economic understandings. As the economics behind any given market becomes better understood conduct maybe viewed overtime as pro-competitive or anti-competitive.

Changes to antitrust law would stunt the growth of this evolution and lock our economy into an economic straight jacket that overtime will undermine U.S. competitiveness, which is at the core of our dynamic economy.

**Precedent – antitrust has been oriented around defense friendly standards for decades, the plan would reverse that trend**

**Wright**, JD, PhD, University Professor and the Executive Director, Global Antitrust

Institute, Scalia Law School at George Mason University, **and** **Mungan** is a Professor of Law, Scalia Law School at George Mason University, **‘21**

(Joshua D., and Murat C., “The Easterbrook Theorem: An Application to Digital Markets,” The Yale Law Journal Forum, Vol. 130, pp. 622-646)

Thirty-six years afer Judge Easterbrook’s seminal article, the Supreme Court has effectively **written** Easterbrook’s principal conclusion about error costs **into antitrust jurisprudence**. Less ideological campaign, more convergent evolution, this process has **spanned decades,** over a series of opinions, and includes the votes of **at least fourteen different Justices**. **Time and again**, when confronted with **deep questions in antitrust law**, those Justices, have **reached the same conclusion**: **false positives are more harmful than false negatives in antitrust.**13

This proposition has appeared in **a variety of antitrust contexts**, both **substantive** and **procedural**. A couple of years after Easterbrook’s article was published, the Court invoked systemic-error costs to justify its intervention in Brooke Group Ltd. v. Brown & Williamson Tobacco Corp., which raised the burden for plaintiffs alleging predatory pricing.14 Noting how rarely the Supreme Court reviewed the sufficiency of the evidence, Justice Kennedy, writing for six Justices, found the effort justified by “the benefits of providing guidance concerning the proper application of a legal standard and avoiding the systemic costs associated with further proceedings.”15 The Court placed **paramount importance** on the **“realities of the market”**16—like the likelihood of a breakdown in oligopoly discipline—which animated the Court’s **skepticism** about the odds of recovery from predatory pricing schemes.17 The Court’s answer, with the odds of a “real” case of predatory pricing so slim, was to tighten the legal standards to better filter false positives, in accordance with the economic balancing of error costs. The Court concluded the better course was **not to assign liability** to companies cutting prices because “[t]he **antitrust laws** then would be an **obstacle** to the chain of events most conducive to a breakdown of oligopoly pricing and the onset of competition.”18

#### Which is why the plan would cascade across the entire economy – because the congress modifies them so infrequently, when they do everyone takes notice

Tracy 21– Ryan Tracy and Brent Kendall, tech and legal reporters, respectively, in WSJ’s Washington Bureau

(Ryan Tracy and Brent Kendall, 3-12-2021, "Antitrust Law: What Is It and Why Does Congress Want to Change It? ," WSJ, <https://www.wsj.com/articles/antitrust-law-what-is-it-and-why-does-congress-want-to-change-it-11615554000>)

U.S. antitrust laws date back more than 130 years and affect every part of the economy. Democrats and Republicans are now considering the most significant changes in decades. Here's what you need to know about what might be coming:

What is antitrust law?

Antitrust laws are designed to protect and promote competition, guided by the principle that consumers are better off when companies battle for their business by offering better services and prices.

The laws date to the 1890 Sherman Antitrust Act, when powerful monopolies (then known as "trusts") in industries such as oil and railroads exercised huge influence over American trade. These laws bar price-fixing, market-rigging, monopolistic practices and mergers that pose a substantial threat to competition.

Why does Congress want to update the laws now?

Both political parties have been galvanized by concern that the nation's giant tech companies -- including Alphabet Inc.'s Google, Amazon.com Inc., Apple Inc. and Facebook Inc. -- hold unchecked power over the economy and American society, and don't have any true rivals in the sectors they dominate.

Are Democrats and Republicans in agreement?

To a degree, but they have different perspectives.

Democrats say the tech giants are a symptom of a broader disease, pointing to studies showing many U.S. industries have grown more concentrated. With fewer competitors, they say, big companies are tilting the scales in favor of the rich and powerful by, for example, paying their workers less or shutting off a path to startups that could offer better products.

Republicans generally aren't convinced concentration is a problem in and of itself, pointing out that operating at a large scale can allow big companies to cut prices. But they do worry about it in some industries. In social media, many in the GOP say, a lack of competition for Facebook, Google's YouTube and Twitter Inc. empowers those platforms to treat conservatives unfairly. (The companies deny political bias.) Republicans also see increased antitrust enforcement as a better approach than direct government regulation of the marketplace.

What changes are they considering?

Some of the proposals are relatively modest, including bigger budgets and new civil penalty power for antitrust enforcers at the Federal Trade Commission and the Justice Department.

Lawmakers have also proposed changes to legal standards to make it easier for enforcers to halt proposed mergers and business practices that threaten competition. And some have called for moving some of the FTC's enforcement authority into the Justice Department, rather than having the agencies share power.

There is also a bipartisan proposal to allow local news outlets to join to negotiate with dominant platforms such as Google and Facebook.

What are some of the tougher proposals?

Some lawmakers are calling for measures that would force technology companies to break apart widely used digital platforms from other business lines. This could force Amazon to separate its online marketplace, or Google to split off its search engine. Both companies operate many other businesses.

Existing lawsuits by the FTC, Justice Department and states could result in similar consequences for Google, and could force Facebook to shed its Instagram and WhatsApp units, but those remedies are years away at a minimum.

I've read about something called self-preferencing. What is that?

That is a practice in which companies such as Amazon and Google use proprietary platforms to promote their own products and services over those offered by competitors.

While Republicans generally aren’t in favor of breaking up big companies, a handful of GOP lawmakers say they are so concerned about the conduct of big tech platforms that they would be open to restricting self-preferencing.

That could mean a mandatory separation of certain business lines, such as Amazon dividing its e-marketplace from Amazon-made retail products or Google splitting its search engine from maps or travel.

Are the tech companies fighting back?

Yes. The tech giants and other big businesses are poised to fight many of the measures, which they see as threats to their bottom lines. Facebook and Amazon spent more on lobbying in 2020 than any other U.S. corporations, seeking to influence legislation on antitrust and other matters. The tech giants say that they face vigorous competition forcing them to constantly innovate, and that they have acquired large market shares because consumers love their products—arguments that they are now making in court.

Supporters of existing antitrust law say the current rules are sufficiently flexible for addressing the challenges presented by evolving technologies and other developments in the modern marketplace. They also say the current approach strikes a fair balance between policing markets and giving companies significant room to maneuver in the rough-and-tumble business world.

So what might happen?

Members of both parties support larger enforcement budgets and the news-industry proposal. In concept, both sides agree there might be a need for so-called interoperability and data portability rules to create more competition in the tech sector. These would allow consumers to move more easily between competing online platforms by, for instance, posting on multiple social-media sites at once or moving their shopping histories from one marketplace to another.

Some Republicans have also said they would join Democrats in supporting changes to legal standards—especially if they are targeted at the tech sector. In addition to self-preferencing, one potential area for compromise between the parties is a proposal to raise the legal burden for mergers by companies with 50% or greater market share.

Republicans would support a consolidation of enforcement agencies, but Democrats don’t appear interested.

What would the changes mean?

Even if Congress acts on only a couple of middle-of-the-road proposals, it could mark the biggest substantive changes in decades, as courts have been reading current antitrust laws more narrowly. Very large companies could have trouble getting deals approved. Tech giants could have to divest themselves of certain business lines.

If lawmakers, for example, make slight changes to reinforce broad government authority to successfully challenge mergers that threaten consumers, “that would signal to the courts that merger enforcement is important and that doubts should not always be resolved in favor of defendants,” said Wayne State University law professor Stephen Calkins.

#### The plans signal is especially huge because it has the congress OVERTURN established precedent

Pearlstein 20 – former business and economics columnist for The Washington Post and the Robinson professor of public affairs at George Mason University

Steven Pearlstein, "Facebook and Google cases are our last chance to save the economy from monopolization," The Washington Post, 12-18-2020, <https://www.washingtonpost.com/business/2020/12/18/google-facebook-antitrust-lawsuit/>

Keeping a close eye on both the antitrust cases and the legislative debate will be the members of the Supreme Court, including six conservative justices who have a well-documented hostility to government regulation of business. The century-old Sherman and Clayton acts are remarkably spare and concise statutes, which has meant that most antitrust law has been judge-made, based on the precedents laid down in individual cases. Any antitrust reform that might come out of Congress, however, is certain to be much more detailed and prescriptive than those earlier laws. Not only would such legislation erode the power and discretion of the court, but it would also likely overturn a number of recent precedents that have made it much more difficult for regulators to limit the size and business practices of dominant firms.

All that could well be playing out in Congress just as the court considers the inevitable appeals in the cases of U.S. v. Google and FTC v. Facebook. And it would hardly be unprecedented if some members of the Supreme Court were to consider the political and legislative consequences as they decide the fate of two companies with whom most Americans interact on a daily basis.

A similar dilemma faced Judge Learned Hand of the U.S. Court of Appeals in 1945 as he considered U.S. v. Alcoa. After the longest federal trial in history — two years — a district court judge had ruled against the government’s request to break up Alcoa, declaring that the company had legally obtained its 90 percent share of the aluminum market. Hand himself was an antitrust skeptic. But in a memo to his fellow appeals court judges, Hand recognized that the public would not accept a highly technical ruling that any such monopoly was benign.

“If we hold that [Alcoa] is not a monopoly, deliberately planned and maintained,” Hand wrote, “everyone who does not get entangled in the legal niceties … will quite rightly, I think, write us down as asses.”

In the end, the appeals court ruled that Alcoa had illegally monopolized the market for aluminum, and Hand’s opinion became one of the most influential, and controversial, in the history of antitrust. The cases against Google and Facebook will be no less consequential or contentious.

#### Employing normative considerations to justify expansion of the antitrust laws marks a seachange—Provides cover for others and cascades throughout the antitrust laws

Ohlhausen 15 – Commissioner, FTC

Maureen K. Ohlhausen, Federal Trade Commission, and Alexander P. Okuliar, Attorney Advisor to Commissioner Ohlhausen, COMPETITION, CONSUMER PROTECTION, AND THE RIGHT [APPROACH] TO PRIVACY, 80 *Antitrust Law Journal* No. 1 (2015), <https://www.ftc.gov/system/files/documents/public_statements/686541/ohlhausenokuliaralj.pdf>

B. CHOOSING THE RIGHT APPROACH

Rather than expanding antitrust law as some have proposed, we instead

recommend applying three screens to discern the best body of law to handle a

potential privacy issue. First, we suggest that the type of harm should continue

to guide the choice of law, as set out by Congress and developed by the agencies and courts for decades. That is, the application of competition law is

appropriate only where the potential harm is grounded in the actual or potential diminution of economic efficiency. If there is likely no efficiency loss

because of the conduct or transaction, another legal avenue for enforcement is

more appropriate and efficient. Second, the scope of the potential harm also

should aid in the choice of law. Antitrust laws are focused on broader macroeconomic harms, mainly the maintenance of efficient price discovery in

the markets, whereas the consumer protection laws are preoccupied with ensuring the integrity of each specific contractual bargain. These are complementary, but discrete, enforcement goals. Third, and finally, the available

remedies must be able to address effectively the potential harm. Enjoining a

merger may do little to prevent a privacy violation if the parties can simply

share the same consumer information under a contractual arrangement.

1. Focus on the Type of Harm

John Locke noted, “The great and chief end [ ] of . . . government, is the

preservation of [citizens’] property,” which includes their “lives, liberties, and

estates.”146 As we have shown, the government has over time pursued specific

laws narrowly tailored to address particular harms. This trend to more

nuanced and sophisticated legal mechanisms has allowed for deepened expertise and greater analytical precision in both competition and consumer protection. Splicing them together again, and using the modern antitrust laws, which

are empirically focused on economic efficiency, to remedy harms relating to

normative concerns about informational privacy contradicts the specialized

nature of these laws and risks distorting them

in ways that would leave both

the law and consumers worse off. The better approach would be to continue

the measured improvement of precise legal tools directed to specific harms.

A blended approach to antitrust that encompasses normative privacy concerns also would provide cover for the injection of other noncompetition factors into the analysis. As a normative matter, privacy is conceptually unsettled

and, depending on who you ask, could include other rights, like property

rights or human dignity.147 The introduction of these factors could shift antitrust law’s focus away from efficiency and alter its relatively predictable and

transparent application.

**Even if antitrust is concentrated in one sector, the new approach the plan adopts signals a broader economy wide shift in enforcement that chills conduct**

**Tyler 11/1** – Senior Legal Analyst at Bloomberg Law

Eleanor Tyler, "ANALYSIS: The Very Purpose of Antitrust Law Is At Issue in 2022," Bloomberg Law, 11-1-2021, <https://news.bloomberglaw.com/bloomberg-law-analysis/analysis-the-very-purpose-of-antitrust-law-is-at-issue-in-2022>

New Laws, Old Power Struggles

While antitrust has become a hot topic in the past few years, this year saw big legislative pushes in a number of key jurisdictions to revise or reform antitrust/competition law itself. Behind those proposed changes is a fundamental debate about what the laws should do and where the balance of power lies between lawmakers, enforcers, and courts.

Laws applicable to tech platforms have occupied most of the antitrust news headlines this year, but the new measures that enforcers are considering—or, in some cases, implementing—will often apply much more broadly (including the proposed U.S. legislation). And more importantly, the changed approach to market regulation reflected in these laws has policy implications for everyone. Antitrust is one of the few areas in U.S. law that talk openly about market power; attitudes about the balance of power between consumers and enterprises, big and small businesses, and government and private businesses are all involved in the debate.

Some laws will make it through the legislative gauntlet, and they will fundamentally shift investment patterns, and may even shift entrenched power in a few big markets. The long game of interpreting any new laws in the courts will begin shortly thereafter. All of that means uncertainty for market participants and enforcers alike.

#### Precisely because they overturn the 2011 Activas doctrine, firms across the economy see the plan as congress reclaiming authority back from the court

Pearlstein 20 – former business and economics columnist for The Washington Post and the Robinson professor of public affairs at George Mason University

Steven Pearlstein, "Facebook and Google cases are our last chance to save the economy from monopolization," The Washington Post, 12-18-2020, <https://www.washingtonpost.com/business/2020/12/18/google-facebook-antitrust-lawsuit/>

Keeping a close eye on both the antitrust cases and the legislative debate will be the members of the Supreme Court, including six conservative justices who have a well-documented hostility to government regulation of business. The century-old Sherman and Clayton acts are remarkably spare and concise statutes, which has meant that most antitrust law has been judge-made, based on the precedents laid down in individual cases. Any antitrust reform that might come out of Congress, however, is certain to be much more detailed and prescriptive than those earlier laws. Not only would such legislation erode the power and discretion of the court, but it would also likely overturn a number of recent precedents that have made it much more difficult for regulators to limit the size and business practices of dominant firms.

All that could well be playing out in Congress just as the court considers the inevitable appeals in the cases of U.S. v. Google and FTC v. Facebook. And it would hardly be unprecedented if some members of the Supreme Court were to consider the political and legislative consequences as they decide the fate of two companies with whom most Americans interact on a daily basis.

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### Costs

#### Because courts NEVER enforce antitrust law against tacit collusion– firms would just shift to these in the world of the aff

Vaheesan 13 – Special Counsel, American Antitrust Institute, Washington, D.C.; Duke University School of Law.

Sandeep Vaheesan, 2013, “Market Power in Power Markets: The Filed-Rate Doctrine and Competition in Electricity,” University of Michigan Journal of Law Reform, https://repository.law.umich.edu/cgi/viewcontent.cgi?article=1010&context=mjlr

Tacit collusion, also known as conscious parallelism, in oligopolistic industries has been one of the most intractable problems in antitrust law. It involves firms setting supracompetitive prices without any overt agreement or direct communication between them.24 In oligopolistic markets, the profits of firms are dependent on the expected behavior of their rivals. 24 ' Because of this strategic interaction, smaller players may, for example, recognize it is in their selfinterest to follow the prices of a market leader, all without ever directly communicating with each other.2 42 The result may be to mimic the price effects of a cartel without any overt communication-let alone agreement-between participating firms. 243 Noted antitrust scholars have debated what to do about tacit collusion in oligopolistic markets. Donald Turner, the head of the Antitrust Division at the Department of Justice in the Kennedy Administration and then-author of the leading antitrust treatise, thought that tacit collusion was a common problem in concentrated markets in the mid-twentieth century.24 He argued, however, that there is no satisfactory remedy for tacit collusion under Section 1-how could courts enjoin firms from ignoring the pricing decisions of their rivals?245 He said that courts should not impose Section 1 liability for tacit collusion "without more in the way of 'agreement' than is found in 'conscious parallelism."'2 46 Instead, he called on using Section 2 of the Sherman Act to reduce market concentration in oligopolistic markets as a means of addressing persistent tacit collusion. 247 Judge Richard Posner has presented a contrasting view, arguing that tacit collusion is not as prevalent as Turner claimed. According to Posner, tacit collusion is not an inevitable feature of oligopolistic markets; industry characteristics and practices often create strong incentives for undercutting the collusive price.248 As a consequence, Posner has said that tacit collusion is a product of "voluntary behavior" and should be addressed under Section 1.249 Thus, in his view, courts should look to market conduct and price effects in determining whether firms have colluded tacitly.2 50 Regarding appropriate remedies, Posner endorsed the use of private damages, civil and criminal penalties, and, in exceptional cases, divestitures but rejected judicial regulation of pricing behavior. 251 The courts have generally followed the Turner approach to tacit collusion. Although tacit collusion is not categorically legal under the antitrust laws, plaintiffs still face significant evidentiary hurdles in bringing a successful claim. The Supreme Court has long held that mere parallel behavior is legal under the antitrust laws.2 52 To establish an agreement under Section 1, the plaintiff must show the existence of "plus factors" in addition to the existence of parallel market conduct.2 53 The courts have not enumerated an exhaustive list of these factors, but some have been used repeatedly to establish liability in parallel conduct cases. An anticompetitive arrangement may be inferred if there is (1) proof that rivals did or could have communicated directly, (2) evidence of anticompetitive intent behind the parallel conduct, (3) behavior so complex as to be unlikely to occur without detailed communication among rivals, or (4) behavior that is unlikely to be rational in the absence of an agreement. 254 The 2007 Supreme Court decision Bell Atlantic Corp. v. Twombly raised the hurdles for plaintiffs trying to bring a successful tacit collusion claim.2 55 It held that a defendant's motion to dismiss in a conscious parallelism case must be granted unless a plaintiff can plausibly allege plus factors at the prediscovery stage in litigation.2 56 Given the present state of antitrust jurisprudence, tacit collusion in electricity markets may be persistent and yet incurable under the Sherman Act. The transparent pricing and repeated game nature of centralized wholesale power markets may simplify collusion among generators in RTO regions.2 57 The threat of quick detection and punishment make defection from such arrangements less profitable and consequently less likely than in other industries . 258 Tacit collusion in an industry conducive to it may make actual agreement on price or output unnecessary. 25 9 This is an important virtue from the perspective of suppliers. Even with the filed-rate doctrine, electricity market participants who engage in more overt forms of collusion face the risk of civil and criminal prosecution by the government.26 Generators may thus be able to engage in persistent parallel pricing above competitive levels without triggering any of the plus factors that could invite legal liability.

### Innovation

#### Even when companies can price gouge, the infectious disease market is still too small to incentivize investment. Competition would make that worse

Darrow, Sinha and Kesselheim 18 – Program on Regulation, Therapeutics and Law (PORTAL), Harvard Medical School and Brigham & Women’s Hospital. Dr. Darrow and Dr. Kesselheim are core members of CeBIL.

JONATHAN J. DARROW, MICHAEL S. SINHA, AND AARON S. KESSELHEIM, 2018, “When Markets Fail,” Food and Drug Law Institute, https://www.jstor.org/stable/pdf/26661184.pdf?refreqid=excelsior%3A84515439cd5ff06d02b861f156eb6d81

The infectious disease context presents an **entirely different type of challenge to the patent system**, one that derives not so much from pricing issues that prevent access once products are developed, but from a failure to sufficiently incentivize the development of new products in the first instance. This shortcoming arises because the incentive of high prices associated with patent exclusivity is inherently tied to market size and ability to pay,3 and not to public health value or future costs avoided by the health care system as a whole. Many infectious disease markets are small **and therefore do not offer sufficient profit potential**

**even under monopoly condition**s. In part because the market-based patent system more generously incentivizes investment in products outside the infectious disease context, such products accounted for 85% of new drugs approved by the U.S. Food and Drug Administration (FDA) between 1987 and 2016, while the share of antibiotics and other antimicrobial products, already small**, actually decreased over that time period (**Figure 1).4 Although antimicrobials have tremendous public health value and can in some cases be curative, sharp declines were seen in new antibiotic approvals, and vaccine approvals— perennially low—declined from a modest peak in 2006–2008 (Figures 2 and 3).5 Although antiviral approvals increased, these increases were driven **largely by drug discovery arising from public investment** in HIV/AIDS research (30 drugs), which receives more than $2 billion in annual federal research funding to supplement patent incentives.6 Spillover effects from HIV research also contributed to advances in adjacent disease areas, such as Hepatitis B and C (3 and 9 drugs, respectively).7 HIV and hepatitis products accounted for 42 (89%) of the 47 antiviral drugs approved since 1987. Similar levels of p**ublic investment have not been directed to antibiotic development.**