# Texas Round 2 Wiki

## 1NC

### 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

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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.

### K Neolib

#### Antitrust is steeped in a procedural logic that contains a substantial mistrust of the administrative state – the affirmatives reform buys into this logic and believe the judicial order can and should dictate the structure of our society

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Sandeep Vaheesan, “The Twilight of the Technocrats’ Monopoly on Antitrust?,” The Yale Law Journal Forum, 6/4/18, <https://www.yalelawjournal.org/pdf/Vaheesan_ir9dchg8.pdf>.

ii. antitrust law is not and cannot be “apolitical”

Antitrust law is unavoidably political. Of course, the enforcement of antitrust law should not be political in the popular sense: the President and the heads of the Department of Justice Antitrust Division and Federal Trade Commission should not employ the antitrust laws to reward their friends and punish their enemies.22 Rather, antitrust is political in its content. In designing a body of law, Congress, federal agencies, and the courts must answer the basic questions of whom the law benefits and to what end. Answering these questions inherently requires moral and political judgments. These fundamental questions do not have a single “correct” answer and cannot be resolved through “neutral” methods or decided with an “apolitical” answer.23

Antitrust regulates state-enabled markets, which cannot be separated from politics. The history of antitrust law shows competing visions of both the law’s aims and its methods, suggesting there is no “apolitical,” universal concept of antitrust. Rather than aspire for an impossible utopia of “apolitical” antitrust, we must decide who should determine the political content of the field—democratically-elected representatives or unelected executive branch officials and judges.

A. Markets Cannot Be Divorced from Politics

A market economy is the product of extensive state action and so is inevitably political. The conception of the market as a “spontaneous order” is a useful construct for defenders of the status quo because it lends legitimacy to the current order and suggests that intervention is futile.24 This model, however, is a myth and bears no correspondence to actual markets. Most fundamentally, state action supports a market economy through the creation and protection of property rights25 and the enforcement of contracts.26 As sociologist Greta Krippner writes, “there can be no such excavation of politics from the economy, as this is the sub- stratum on which all market activity—even ‘free’ markets—rests.”27 In addition to property and contract law, examples of state action necessary for the contemporary U.S. economy to function include corporate and tort law (typically established and enforced by state governments), intellectual property, protection of interstate commerce, banking regulation, and monetary policy (generally con- ducted at the federal level).

Antitrust law, therefore, is a governmental action that shapes the power of state-chartered corporations and the scope of their state-enforced property and contractual rights. This regulation of state-enabled markets makes antitrust inherently political. Moreover, in formulating antitrust rules, lawmakers must determine whom the law seeks to protect. Antitrust law could conceivably protect consumers, small businesses, retailers, producers, citizens, or large businesses. But even identifying the protected group or groups does not fully resolve the question. For instance, if consumers are antitrust law’s sole protected group, how should the law protect consumers? Antitrust could protect consumers’ short- term interest in low prices or their long-term interests in product innovation or product variety, just to name a few possibilities.28

Given the foundational role of state action—and therefore politics—in a market economy, the choice of objective in antitrust law is not between intervention and nonintervention. Rather, antitrust law must choose between different con- figurations of state action and different sets of beneficiaries.29 More concretely, we must decide, openly or otherwise, whose interests antitrust law should protect.

B. The History of Antitrust Law Reveals the Unavoidability of Politics

The history of antitrust law further demonstrates the political nature of the field. Although Congress has not modified the antitrust statutes significantly since 1950,30 the content of antitrust has changed dramatically since then. Even the consumer welfare model has not banished political values from the field. While the range of debate within the community of antitrust specialists is narrow, the continuing disagreement over the interpretation of consumer welfare reveals the inescapability of political judgment.

Antitrust law today is qualitatively different from antitrust law fifty years ago. In the 1950s and 1960s, the courts and agencies interpreted antitrust law to advance a variety of objectives. The Supreme Court held that the antitrust laws promoted consumers’ interest in competitively-priced goods,31 freedom for small proprietors,32 and dispersal of private power.33 The Court held that business conduct injurious to competitors could give rise to antitrust violations, irrespective of the effects on consumers.34 It also interpreted congressional intent to be that a decentralized industrial structure should override possible economies of scale gained from greater consolidation of economic power.35 Recognizing this goal of decentralization, the federal judiciary adopted strict limits on business conduct with anticompetitive potential, including mergers36 and exclusionary practices.37

Since the late 1970s, however, the Supreme Court, along with the Department of Justice and Federal Trade Commission, has reduced the scope of the antitrust laws. With a rightward shift in the composition of the Supreme Court under the Nixon Administration and in the leadership at the federal antitrust agencies under the Reagan Administration,38 these institutions curtailed the reach of antitrust law, scaling back its objectives39 and rewriting legal doctrine to preserve the autonomy of powerful businesses—all in the name of protecting consumers.40

Even the adoption of the consumer welfare model has not somehow banished politics from antitrust. Instead, it has underscored the unavoidability of politics in the field. Despite being the prevailing goal of antitrust for nearly four decades now, the meaning of consumer welfare is still not settled. The two primary schools of thought on consumer welfare disagree on a fundamental question—who are the beneficiaries of antitrust law? One holds that actual consumers, as understood in the popular sense, should be the principal beneficiaries of antitrust law.41 The rival camp holds that both consumers and businesses should be the beneficiaries of antitrust law, and that whether a dollar of economic sur- plus goes to a consumer or a monopolistic business should be of no concern to the federal antitrust agencies and courts.42 C. Who Should Decide the Political Content of Antitrust?

Because the objective of antitrust law is thus bound up with political judgments and values, seeking an “apolitical” antitrust jurisprudence is futile at best and a cynical effort to conceal political choices at worst. The choice is not be- tween “apolitical” antitrust and “political” antitrust; rather, lawmakers must decide between different political objectives. Once the inevitably political valence of antitrust law has been acknowledged, we can turn to the key question of whether unelected officials at the antitrust agencies and federal judges (collectively “the technocrats”) or democratically-elected members of Congress should decide this political content.43

Over the past forty years, technocrats have dominated antitrust law.44 Leadership at the Department of Justice and Federal Trade Commission as well as Supreme Court Justices have rewritten much of antitrust law.45 They have ignored or distorted the legislative histories of the antitrust laws and have even overridden Congress’s legislative judgments.46 By restricting private antitrust enforcement, the Supreme Court has also limited the ability of ordinary Ameri- cans to influence the content of antitrust law.47

While the antitrust technocrats have been on the march, Congress has been dormant. Its antitrust activities have been confined to secondary issues.48 This combination of technocratic hyperactivism and legislative lethargy has created, in the words of Harry First and Spencer Waller, “an antitrust system captured by lawyers and economists advancing their own self-referential goals, free of political control and economic accountability.”49 Although proponents of technocratic antitrust may characterize it as “pure” or “scientific,” the reality is quite different as big business interests and their representatives dominate debate within this cloistered enterprise.50

This congressional indifference to antitrust is not inevitable. Despite pro- longed quietude, Congress could become an active player in antitrust again. Some members of Congress are showing a renewed awareness of the field and an interest in reasserting control over the content of the antitrust statutes.51 The most democratically accountable branch of the federal government may be poised to take the lead on antitrust in the coming years, reclaiming authority over a technocracy that has not answered to the public in decades.

iii. the consumer welfare model is not anchored in congressional intent and reflects a narrow conception of monopoly and oligopoly

Given that consumer welfare antitrust is a political choice, this model can be evaluated against alternatives on a level playing field. Consumer welfare is not “above politics.” It is a political construct that features at least two serious deficiencies. First, the consumer welfare model contradicts the legislative histories of the principal antitrust statutes; the courts and federal antitrust agencies have instead substituted their own political judgments for those of Congress. Second, the consumer welfare model represents an impoverished understanding of corporate power. It focuses principally on one aspect of business power—power over consumers—and ignores other critical manifestations.

Congress’s original vision for the antitrust laws, one that recognizes both the economic and the political impacts of monopoly, is a superior alternative to the consumer welfare philosophy. As the enforcers and interpreters of statutory law in a democratic polity, federal antitrust officials and judges should follow the congressional intent underlying the antitrust laws. Furthermore, commentators, legislators, and policymakers should recognize that controlling the power of large businesses over not only consumers but also competitors, workers, producers, and citizens is essential for preserving at least a modicum of economic and political equality in a democratic society.

A. In Passing the Antitrust Laws, Congress Expressed Aims Much Broader than Consumer Welfare

The consumer welfare model of antitrust is not true to the intent of Congress. An extensive body of careful research has shown that Congress had several objectives when it passed the Sherman, Clayton, and Federal Trade Commission Acts.52 The Congresses that passed these landmark statutes recognized that eco- nomics and politics are inseparable. Congress originally sought to structure markets to advance the interests of ordinary Americans in multiple capacities, not just as consumers. Consumer welfare antitrust reflects, at best, a selective reading of this legislative history and, at worst, an intentional distortion of this historical record. Contrary to Robert Bork’s historical analysis, the legislative histories show no congressional awareness, let alone support, for interpreting consumer welfare as the economic efficiency model of antitrust, one nominally indifferent toward distributional effects.53

In passing the antitrust statutes, Congress aimed to protect consumers and sellers from monopolies, oligopolies, and cartels, as well as defend businesses against the exclusionary practices of powerful rivals.54 Key members of the House and Senate condemned the prices that powerful corporations charged consumers as “robbery”55 and “extortion.”56 The debates reveal similar solicitude for farmers and other producers who received lower prices for their products thanks to powerful corporate buyers.57 In addition to consumers and producers, Congress aimed to protect another important group of market participants: competitors. In enacting the antitrust statutes, Congress sought to restrain large businesses from using their power to exclude rivals.58 Congress recognized the political power of large corporations and aimed to curtail it through strong federal restraints. Indeed, the political power of these corporations represents a running theme in the legislative histories of the anti- trust laws. A number of speakers in the course of the debates pointed to the power wielded by these big businesses over government at all levels.59 In the debate over the Clayton Act, one Congressman declared that the trusts were commandeering ostensibly democratic political institutions.60 Senator John Sherman warned his colleagues that “[i]f we will not endure a king as a political power[,] we should not endure a king over the production, transportation, and sale of any of the necessaries of life.”61

B. The Consumer Welfare Model Reflects an Impoverished Understanding of Corporate Power

Focusing solely on harms to consumers and sellers, the consumer welfare model embodies an emaciated conception of corporate power. With its foundation in neoclassical economics, the consumer welfare model privileges short- term consumer interests. The neoclassical representation of the market—commonly known through supply-and-demand diagrams—presents a static picture of a market and does not account for long-term dynamics. As the default analytical guide for consumer welfare antitrust, the neoclassical model, with its focus on quantification, prizes short-term price harms to consumers and sellers and discounts longer-term injuries.62

Furthermore, the consumer welfare model legitimizes the existing distribution of resources by focusing on change to the status quo. Current antitrust law measures consumer welfare by changes in prices paid; what a person can pay, though, depends on both her willingness-to-pay for goods and services and her existing wealth. By this definition, a rich person who pays more for a luxury good due to a cartel suffers an antitrust harm, but a poor person who has no income and is unable to afford necessities cannot suffer antitrust harm from a monopoly. A wealthy consumer commands power in the market; a poor consumer, in comparison, has little or no clout in the market.63

The consumer welfare model, moreover, affords little or no importance to corporations’ ability to dictate the development of entire markets. Antitrust practitioners and scholars are wont to remind each other and critics that the antitrust laws “protect[] competition, not competitors.”64 Although the expression is arguably empty,65 it is taken to mean that harm to actual and prospective competitors alone is of no import to the antitrust laws. This doctrinal cornerstone is a political choice,66 which gives monopolists and oligopolists the power to dictate who participates in a market and on what terms.67 Under consumer welfare antitrust, businesses can use their muscle to exclude rivals and strangle economic opportunity so long as this exclusion is not likely to injure consumers. In practical terms, consumer welfare antitrust grants big businesses broad latitude to engage in private industrial planning. 68

For the consumer welfare school, the hegemonic power of large corporations is also of no consequence. Monopolistic and oligopolistic businesses across the economy use their power to seek and win favorable political and regulatory de- cisions.69 The ongoing—and frenzied—contest between states and cities to at- tract Amazon’s second headquarters is indicative of a giant business’s weight. In recent years, the concentrated financial sector has offered a vivid example of corporate political power in action.71 Leading banks helped trigger a worldwide economic crisis through their fraud and reckless speculation, and yet they defeated subsequent political efforts to control their size and structure and man- aged to preserve their institutional power.72 An influential analysis of congressional decision making suggests that the United States today is closer to an oligarchy than a democracy—the wealthy and large businesses wield tremendous political clout, whereas most ordinary people have little or no influence.73 Large businesses also set the parameters of political debate through control of the me- dia,74 sponsorship of supportive figures and organizations,75 and marginalization of critical voices.76 Consumer welfare antitrust itself is, at least in part, a product of big business’s reaction against the relatively vigorous antitrust pro- gram of the postwar decades.77

With its narrow analytical frame, the consumer welfare model of antitrust accepts and legitimizes many forms of state-supported corporate power. Under consumer welfare antitrust, large corporations have the freedom to enhance their power through mergers and monopolistic practices that hurt competitors and citizens. Viewed as part of the overall landscape of state-enabled markets, consumer welfare antitrust is not an apolitical choice, but a charter of liberty for dominant businesses.

#### That locks in the capture of our institutions which makes extinction inevitable – its try or die to transition to a more accountable government

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With each passing day, reports on global climate change become increasingly bleak. Recent research has affirmed that the glaciers are melting faster than anticipated1, and that acidification, with its catastrophic effect on ocean ecosystems, is also proceeding faster than feared2. As the concentration of atmospheric carbon continues to rise, so does the likelihood we’ve passed the tipping point for irreversible climate change.3

When one looks at other critical earth ecosystems, the danger is equally apparent. Soil is being destroyed.4 Fresh water shortages are wracking several continents and leaving billions of people without reliable access to clean drinking water.5 Fish stocks are plummeting.6 Oceans are clogged with plastic garbage.7 Biodiversity is disappearing at an alarming rate.8 In the face of this full-spectrum ecological assault, a growing number of scientists have been saying that the collapse of civilization is now unavoidable.9

Stopping the destructive effects of industrial, capitalist civilization has now become the defining challenge of our age. If we don’t radically change our society’s course within the next 30 years, then a deep collapse and protracted Dark Age are all but assured. In order to confront this challenge, we need to understand what is causing civilization’s crisis, and most importantly, how the crisis can be resolved. At stake is nothing less than a viable future on this planet.

The Five Horsemen of the Modern Day Apocalypse

In my book, Radical Transformation: Oligarchy, Collapse, and the Crisis of Civilization, I argue that industrial civilization is being driven toward collapse by five key forces – related to terminal dysfunction within its ecological, economic, socio-cultural, and political sub-systems:

Dissociation: globalized production and distribution systems disrupt people’s ability to put their own actions, and the actions of elites, into a coherent causal and ethical framework. Actions by individuals, institutions, and systems of governance are therefore disconnected from their effect on the natural world and on other peoples. Without this critical feedback, even well-intentioned actors can’t make rational and ethical choices regarding their behaviour.

Complexity: the world-spanning nature of industrial capitalist civilization, and the massive number of interrelationships it represents, make predicting the effect of any given change on the system as a whole devilishly difficult. Disastrous tipping points loom in several of civilization’s systems – from the collapse of ocean ecology to the threat of nuclear war. In addition, because the crisis cannot be contained in one part of the globe, the dysfunctions can’t be dealt with in isolation.

Stratification: a profoundly unequal distribution of wealth – both globally and within nations – leads to mass human poverty, displacement, and to premature death through disease and continuous warfare. Stratification also leads to political instability, eroding a society’s social cohesion and undermining decision-making structures.

Overshoot: the economic practices of industrial capitalism are exceeding ecological limits. Our civilization is critically degrading the biosphere, burning through non-renewable energy sources, and shifting the entire climatic balance.

Oligarchy: in states worldwide, political decision-making is controlled by a numerically small, wealthy elite. This form of government serves to lock in patterns of conflict, oppression, and ecological destruction.

Societies as Decision-Making Systems

Each of the horsemen presents a significant threat to civilization’s viability. However, oligarchy is particularly important as it deals with a society’s decision-making systems. In his 2005 book Collapse: How Societies Choose to Fail or to Succeed, geographer Jared Diamond argued that many past civilizations have collapsed due to their inability to make correct decisions in the face of existential threats.10 Diamond drew on the work of archaeologist Joseph Tainter, who in his 1998 book The Collapse of Complex Societies, argued that civilizations fail due to a constellation of factors.11

To Tainter, the ultimate mistake failed civilizations made was to continually solve problems by adding social complexity, and as a result, increasing the society’s energy needs. Eventually, Tainter argued that civilizations encounter a “thermodynamic crisis” in which they are unable to sustain an energy-intensive level of complexity. The result is collapse – ecological devastation, political upheaval, and mass population die-off.

The tendency for societies to collapse under excessive energy demands is an important insight. However, what Tainter and Diamond failed to appreciate is how oligarchy is an even more fundamental cause of civilization collapse.

Oligarchic control compromises a society’s ability to make correct decisions in the face of existential threats. This explains a seeming paradox in which past civilizations have collapsed despite possessing the cultural and technological know-how needed to resolve their crises. The problem wasn’t that they didn’t understand the source of the threat or the way to avert it. The problem was that societal elites benefitted from the system’s dysfunctions and prevented available solutions.

Oligarchic Control in “Democratic” States

Citizens in countries such as Canada, the United States, Australia, or the Eurozone members, would generally consider themselves to be living in democratic societies. However, when the political systems of Western democracies are scrutinized, clear and pervasive signs of oligarchy emerge.

A 2014 study by American political scientists Martin Gilens and Benjamin Page revealed that the great majority of political decisions made in the United States reflect the interests of elites. After studying nearly 1,800 policy decisions passed between 1981 and 2002, the researchers argued that “both individual economic elites and organized interest groups (including corporations, largely owned and controlled by wealthy elites) play a substantial part in affecting public policy, but the general public has little or no independent influence.”12

Today, oligarchic control over decision-making, and its catastrophic ecological effects, have never been clearer. In the U.S., Donald Trump and his billionaire-dominated cabinet are seeking to dismantle the Environmental Protection Agency13, to question climate science14, and to pursue a policy of “American energy dominance” that will dramatically expand production of fossil fuels.15

U.S. energy companies are also having a profound impact on domestic energy policy by accelerating the development of hard-to-access fuel sources through hydraulic fracturing, deep-sea oil drilling, and mountain-top removal coal mining.16 At the same time, fossil fuel oligarchs are working overtime to dismantle green energy initiatives, such as the Koch brothers’ war on the solar industry in Florida, and in other cities across the continent.17

In Canada, often thought of as more progressive than its southern neighbor, the situation hasn’t been much different. Under prime minister Stephen Harper’s two terms, the Canadian state became an unapologetic cheerleader for extracting some of the world’s dirtiest oil –Tar Sands bitumen. Harper accelerated Tar Sands production, leading to the clear-cutting of thousands of acres of boreal forest, the diversion of millions of gallons of freshwater, and the creation of miles of toxic tailings ponds, filled with water contaminated by the bitumen extraction process.18

Like the Trump administration, the Harper government silenced federal climate scientists.19 The government also targeted environmental charities and non-profits, using funding cuts and the threat of audits to undermine climate advocacy.20 When a movement of national outrage swept Harper from power in 2015, Canadians were hopeful that climate change would once more be taken seriously. However, the new government of Justin Trudeau, while embracing the international discourse on global warming, has shown a continued allegiance to the fossil-fuel oligarchy by committing over $7 billion in federal funds to purchase the failing Kinder-Morgan Trans Mountain pipeline.21

What is To Be Done?

To create a sustainable future, we must first learn the lessons of the past, and what archaeological research shows is that throughout history, civilizations that have been captive to the interests of an oligarchic elite have all collapsed.22 Today’s industrial, capitalist civilization is trapped in this same deadly cycle.

As long as a self-interested elite controls decision-making in modern states, we will be far too late to avoid the effects of steadily contracting ecological limits. In addition, we will be unable to avert the downward spiral of economic crisis, conflict, and warfare that will result as oligarchs scramble to maintain their wealth and power in the face of dwindling resources and mounting crisis.23

Breaking free from this destructive pattern will require us to take political and economic power back from the 1% and return it to the hands of citizens. This means that advocates for ecological sustainability must move far beyond individual actions, lobbying, or reform of existing political and economic institutions. If we are to have a chance, we must ensure that governments make decisions based on the public good, not on private profit.

Radically transforming industrial, capitalist civilization won’t be easy. It will require movements for environmental sustainability, social justice, and economic fairness to come together, and to realize their common interest in dismantling the system of oligarchy and building a democratic, eco-socialist society.24 This “movement of movements” must put aside sectarian squabbles, and finally realize that the goals of economic justice, human rights, and ecological sustainability are all intrinsically linked.

Such changes may seem like a tall order, but hope can be found in the deepening struggle being waged to protect our fragile ecosystems. First Nations groups are leading this charge and beginning to win some important victories. The inspiring Water Protectors of Standing Rock were able to disrupt the Dakota Access Pipeline in the face of intense government oppression.25 In Canada, Several British Columbia First Nations recently won an impressive court victory in their opposition to the Trans Mountain pipeline.26

If successful grassroots struggles can be linked with equally hopeful movements for real political change, then there is hope for the future. However, if we continue on with “business as usual” – hoping that change will come from lifestyle choices and the interchangeable representatives of elite political parties, then the future looks grim indeed.

#### In response to the crisis we face, a new form of governance and markets is needed – focusing on anti-domination in antitrust and politics rejects systems of power that allow social strife to continue in the name of markets

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Kate Jackson, “All the Sovereign’s Agents: The Constitutional Credentials of Administration,” *William & Mary Bill of Rights Journal*, 8 July 2021, pp. 2-7, https://papers.ssrn.com/sol3/papers.cfm?abstract\_id=3813904.

We face no less than four urgent crises: an ongoing pandemic1; racial injustice and its consequent civil unrest2; an economic depression approaching the pain inflicted in 1929; and the accumulating, existential threat of climate change.4 Citizens must rely on their state to tackle these burning perils.5 Yet critics both left 6 and right 7 would tear down its institutional capacity to do so. Some denounce the exercise of administrative power as illiberal, unconstitutional and obnoxious to the rule of law.8 Others impugn it as undemocratic, paternalistic, and corrupt.9 Yet without some kind of agent to carry out collective solutions, these perils may very well proceed unabated.

Pushing an anti-administravist agenda, libertarians continue their “long war”11 against government agencies by insisting that they are an unconstitutional fourth branch of government. For them, administration is a kind of “absolutism”12 that violates the separation of powers and defies the principle of limited government.13 They contend that agencies’ discretionary rulemaking offends the liberal commitment to the rule of law. 14 Accordingly, they would punt agencies’ responsibility for social, economic, and environmental problems to courts and legislatures. 15 Regulation would thus be placed at the mercy of an undemocratic judiciary who increasingly “weaponizes” the First Amendment in favor of big business16 – or of a Congress whose already inefficient decision-making is crippled by hyperpolarization17 and distorted by the kind of material inequalities that the welfare state is meant to ameliorate. 18

Conservatives with a more authoritarian inflection seek to recall administration from its constitutional exile by subsuming it under presidential power. 19 Such critics would lend administration some democratic credentials by bootstrapping them to the president’s electoral accountability. Yet ridding agencies of their independence by placing them under the discretion of the president grants the president personal control over agency policymaking and adjudication without the checks provided by Congress, the courts, or an independent civil service.20 It thus, arguably, solves a separation-of-powers problem by introducing a new one.21 More ominously, empowering the president with the patina of democratic legitimacy emits a strong whiff of Schmittian politics.22 The prospect of a largely unbound executive officer claiming a popular mandate to hire and fire civil servants on a whim should alarm any that followed the Trump Administration’s treatment of refugees, civil protestors, polluters, and political cronies.

Agency power likewise fares poorly in the hands of the left. 23 They blame administrative technocracy for a variety of social and political ailments: the reification of social differences and the juridification of human nature24; corruption, privatization and regulatory capture25; the depoliticization of economic issues and the subsidization of globalized financial capitalism26 and, ultimately, the constellation of conspiratorial populist politics currently threatening liberal democratic states.27 Their preferred solutions include democratizing agency decision-making28 and constraining Congress’ capacity to delegate its lawmaking function. 29 While their interventions are welcome, they may deprive government of the nimble expertise necessary to address environmental and economic crises.30 Moreover, as illustrated by the president’s extraordinary powers to shape national immigration policy despite its “notoriously complex and detailed statutory structure,” increasing the amount of formal legislation may only expand agencies’ enforcement discretion.31 Agency democratization, furthermore, risks reproducing, perhaps under the cover of ostensible public consensus, the same social, economic and political inequalities that distort Congressional lawmaking. 32

In this essay, I contend that this multi-pronged anti-administravist attack stands upon shaky conceptual foundations. Each builds atop a theory of constitutionalism that embraces a too-literal conception of popular sovereignty.33 It is a conception that posits that there is, in fact, a “people” with a sovereign “will.” It is a “will” that can be clearly identified (through elections); straightforwardly transcribed (through lawmaking); mechanically applied (by administrators) and constrained (by judges). 34 But in a country of hundreds of millions, the diverse multiplicity of citizens could never find a common will.35 It is even more impossible that it could ever be accurately expressed through the lawmaking of elected representatives.36 As a result, critics of administration often grant statutory lawmaking more democratic credentials than it deserves. 37 The non-delegation doctrine purports to prevent the delegation of something that simply may not exist.

Critics commit another mistake when they invoke a theory of constitutionalism that analytically divides functions that cannot, as either a moral or empirical matter, be disentangled. First, they incorrectly posit two separate, autonomous processes: the collective formation of ends (lawmaking) and the implementation (execution) and application (adjudication) of those ends. 38 But we cannot presume that judges and administrators can mechanically apply and enforce the law without importing into the process their own value-laden, and therefore political, judgments.39 “They who will the end will the means” is a naïve argument that occludes the power wielded by unelected actors.40 It is also a mistake to presume that the legislative branch concerns itself only with value-laden final ends, and not with the means required to execute them.41 Indeed, most of our most bitter political fights are fights conducted precisely over means: how best to grow the economy; how best to care for the sick; how best to mitigate climate change, etc. 42 As a result, the theories overemphasize and distort the purpose of separating powers.43

Critics commit yet another mistake when they divorce the constitutional functions of (1) protecting rights and limiting government power, and (2) providing the decision-making procedures necessary for democratic will-formation. 44 They isolate elections and lawmaking from the process of enforcing rights and the rule of law – as if they have nothing to do with one another. Yet quarantining rights from democracy requires reliance on an outsourced moral order external to the political system itself – a reliance inappropriate for contemporary secular polities.45 They therefore lend judges too many liberal credentials while denying any to mechanisms of popular feedback.

Rather than critiquing agencies for violating the separation of powers, for their over-reliance on unelected technocrats, or for their indifference to universalizable legal principles, I argue that administration does indeed carry constitutional liberal democratic credentials – credentials borne out by political theory’s “representative turn.”46 By understanding agencies as embedded in a system of representative democracy that aims to set the conditions by which citizens can relate to each other as political equals, we can assess the legitimacy of government agencies without any “idolatrous”47 commitments to a fictitious popular sovereign or legal formalism. I suggest that agency institutions should be measured against the notion that popular sovereignty demands not consensus and consent, but instead institutions that permit citizens to understand themselves as co-equal participants in the collective decision-making process.

This essay will proceed as follows. Part I situates administrative agencies in an understanding of liberal democratic constitutionalism that (A) eschews outmoded notions of popular sovereignty and (B) natural law. It will then (C) explain how adequately conceived notions of the separation of powers and the rule of law cannot serve as indefeasible objections to administration. Part II makes a positive case for agency authority by drawing from the insights gained from political theory’s representative turn. It will first (A) define this important intellectual development and then (B) explain how administrative agencies might fit comfortably within a representative system. The essay (C) concludes by showing how theories of representation can inform some enduring debates in administrative law and suggesting some changes that might enhance the legitimacy of agency action.

PART I: ADMINISTRATION, POPULAR SOVEREIGNTY AND RIGHTS

Democracy promises the rule of “we the people.”48 Democratic citizens, possessing inalienable rights, are to come together, deliberate,49 and jointly create the laws that bind them. The administrative agency, with its unaccountable expert technocrats, policymaking autonomy, and immunity from micromanaging judicial review, looks like an unwelcome uncle at the constitutional dinner table.

Intuitively, these knee-jerk objections cannot be quite correct. Agencies carry some obviously democratic credentials. As Adrian Vermeule points out, they are, after all, the creation of statutory lawmaking.50 At least as early as 1798, Congress has delegated coercive rule-making power to Federal bureaucracy on matters as diverse as tax inspections, territorial governance, veterans’ pensions, mail delivery, intellectual property, and the payment of public debts.51 In McCullough v. Maryland,52 the U.S. Supreme Court interpreted the “necessary and proper” clause53 to anticipate Congress’ desire to create such agencies – in this case, a national bank. Bruce Ackerman,54 in his seminal work, argues that our contemporary agencies carry Constitutional credentials. Many were birthed through multiple hyperpolitical elections and constitutional challenges within the courts. Further, from their very inception, agencies struggled internally to accommodate their actions to constitutional requirements.55 The Administrative Procedure Act56 (“APA”), for example, imposes upon agencies principles of due process and the rule of law.57

Regardless, if democratic lawmaking is to shape the community of those that make it, there must be some kind of agent or instrumentality to carry it out.58 A Congressional decision to levy a tax is meaningless without an Internal Revenue Service to collect it.59 Yet it is impossible to imagine that such agencies might operate like mindless, loyal robots. Whether performed by court or administrator, the application of laws will inevitably involve controversial policy judgments.60 Lawmaking is, by its nature, always more abstract than we would like. Such “general propositions do not,” noted Justice Holmes, Jr. in his influential Lochner v. New York61 dissent, “decide concrete cases.” The required elaboration almost always imports values that are not clearly and unambiguously identified in any statutory text.62 The task of accommodating administration to constitutional democracy cannot, therefore, aim at eliminating the agency costs implicit in the application of law. It can only seek to understand how they might comfortably fit within a constitutional order.

The next two sections will elaborate upon these intuitions. Many objections to agency power presume antiquated conceptions of sovereignty and rights. They juxtapose the will of a powerful organ-body sovereign63 against a governed mass of subjects who hold an array of pre-political liberties that require judicial protection. This all-powerful body is thought to be represented by Congress64 as the commissioned agent (or embodiment?) of the popular sovereign. To preserve citizens’ natural, pre-political liberties, this agent of the popular sovereign is constrained by a separation of powers, checks and balances, a Bill of Rights, etc. – each policed by independent courts capable of identifying and enforcing citizens’ inalienable liberties.65 If this is indeed the rubric of the liberal democratic constitutional state, it is difficult to see how agencies pass constitutional muster. They are not Congress – and so their policymaking cannot be legitimate expressions of the popular will. They often avoid substantial judicial review, and so they might violate natural liberties with impunity. Fortunately, this rubric is wrong.

A. The Mind and Body of the Democratic Sovereign

True, for much of modern Western history, sovereignty, understood as the supreme, absolute and indivisible power to make law, was thought to be held by a specific body: the one wearing the crown.66 To constitute and justify public power, Hobbes, for example, imagined a state of nature full of individuals authorizing and relinquishing their natural liberties to a “Mortall God,”67 i.e., the modern corporate state, represented (or re-presented) in the flesh-and-blood bodies of the king or legislature.68 During the democratic revolutions, radical69 theorists merged the monarch with her subjects.70 They imagined “the people” not only replacing the king as sovereign, but also governing itself as a subject, thereby creating an identity between ruler and ruled. Rousseau’s volonté générale71 serves as a model for this kind of logic.72 Montesquieu, whose thinking influenced the American founders,73 likewise held that the “people as a body have sovereign power” in a republic.74 Even A.V. Dicey, despite his fame as a rule of law scholar, believed that a representative legislature would “produce coincidence between the wishes of the sovereign and the wishes of the subjects.”75 It is a sovereign-subject hat trick: the ruled become the ruler, the democratic “people,” understood as a body, a “unitary macro-subject,”76 come to occupy what was once occupied by the body of the king. Carl Schmitt likewise endorsed a scrupulous identity between governed and governor - with homogenizing and fascist implications.77 For Schmitt, it was impossible to imagine a leader speaking with the voice of the people unless the people themselves first sang in perfect harmony.

There are flaws in this equation. The “people,” understood literally, cannot rule. They do not possess a primordial collective will existing outside and independent of their political institutions.78 Moreover, the entire population of a diverse community of hundreds of millions cannot be present within those institutions. Nor can that population ever find a unanimous general will, a non-controversial understanding of the common good, no matter how constrained and qualified their public reasoning or how universal and general its aspirations.79 Thus, no coherent popular will can obtain even after undertaking the decision-making processes of political institutions.80 Just as the contractual “meeting of the minds” is a legal fiction of private law,81 a popular “meeting of the minds” is a political fiction of public law. As a result, despite the democratic revolutions, the old gap between ruler and ruled remains.82 In other words, the merger between governed and governor attempted by the democratic revolutions did not remove the danger of heteronomy,83 even if the offices of government might be staffed by elected representatives and even as constitutional systems split powers and limited legal authority.84 Some (body) would wield public power, and the rest would be subject to its rules. Even Rousseau downgraded the popular sovereign to a silent, passive actor that left the actual business of governing to functionaries.85 Like the client of a travel agent, Rousseau’s democratic citizen was meant only to approve or disapprove the prepackaged plans presented by ministers.86

Lawmaking under constitutional liberal democracy is thus not a question of ascertaining the existence of some non-existent popular “will” to be left in the hands of loyal fiduciaries in government87 to carry out like mindless automatons. Nor is it comprised of the dictates of a caesarist leader purporting to speak with the unified voice of the sovereign people.88 Instead, it a question of developing transparent and accessible collective decision- making procedures that ensure that all citizens can understand themselves as equal participants in their collective ordering; that ordinary people are involved in public life and have a say in their collective destiny.89 They do not rule. Rather, they are equal players in the game of representative democracy.90

Thus, although contemporary notions of constitutional liberal democracy ascribe the highest legitimate source of authority to “the people,” they do not understand “the people” as a reified, homogenous whole with an identifiable will that pre-exists whatever governing apparatus might be laid atop it. Though “popular sovereignty” is a political fiction, it is a useful one – at least if it is used as a standard of justification and critique, not as a proper noun. It is an aspirational, regulative idea intended to depersonalize and distribute public power in a way that serves the entire community.91 It is a Kantian “as if” principle.92 Namely, if we try to think like a popular sovereign might think, if such a thing could ever exist, we will orient our public reasoning not towards our individual self-interest alone, but in terms of inclusivity, human equality and the public good.93 Because if the sovereign is a “we,” then governing involves more than the interests and preferences of single individuals. We will therefore demand that political institutions remain accountable and accessible to popular complaints. We will adopt a Weberian politics of responsibility, remembering that our decisions might inflict unforeseen costs upon others.94

This figurative idea of popular sovereignty also unlocks the closed doors of power and forces the inclusion of voices previously ignored.95 Whosoever happens to be governing at any given time, that person is not “the people” precisely because “the people” cannot ever be present. As a result, anyone denied an audience can appeal to popular sovereignty as they seek admission to political decision-making. Importantly, popular sovereignty demands, as French philosopher Claude Lefort96 notes, that this place of power remain an empty one – or at least one with a revolving door – where no body at all is permitted to rule permanently. For to fill that void would allow for a part to speak on behalf of the whole. “We the People” might become, as political theorist Nadia Urbinati notes, “Me the People.”97 It would thus force homogeneity upon plural societies as leaders with controversial viewpoints purport to represent everyone as they make and implement policy. Moreover, the usurpation of this space would undermine the depersonalization of power inherent in the idea of a fictional popular sovereign and, importantly, the rule of law and not of men.98 If the place of power remains empty because all citizens contribute in some way to lawmaking, then we can credibly claim that it is law, not our politicians, who rule.

As a result, it can be no objection to agency policymaking that it usurps authority from the popular sovereign. Because if we take popular sovereignty literally, so, too, do elected representatives. They likewise cannot logically or credibly speak with the voice of the sovereign people.99 Thus, insofar as theories of non-delegation and legislative primacy rely on an organ-body theory of popular sovereignty,100 they are misplaced. Attacks against the “technocratic” power wielded by administrative officers may likewise overstate the democratic credentials of the Congressional legislation against which such power is compared – and found wanting. Indeed, it is at least possible that administrative agencies can be made consistent with the requirements of constitutional popular sovereignty.101 Namely, the question is whether and to what extent they operate according to procedures that allow citizens to understand themselves as co-equal participants in shaping agency action. Finally, that independent administration is “headless” is not, as feared by contemporary New Deal critics, fascist or totalitarian.102 It may in fact be a necessary precondition for liberal democracy. A Leviathan with a single head with a single mouth, purporting to speak for all, can be monstrous indeed.

### CP Presumption

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

#### It’s competitive – “prohibit” means “ban” – CX was explicit that they allow some P4D

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)

### 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 antitrust expansion deters and prevents necessary mergers**

**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.”

### CP Private Action

#### Text: The United States federal government should allow relevant agencies to sue to enjoin anticompetitive reverse payment settlements and recover single damages.

#### Counterplan avoids private enforcement---private suits are an inextricable part of antitrust liability---public enforcement is sufficient

McCarthy et al., GC & Chief Legal Officer of Womble Bond Dickinson (US) LLP, ‘07

(Eric, Allyson Maltas, Matteo Bay and Javier Ruiz-Calzado, “Litigation culture versus enforcement culture A comparison of US and EU plaintiff recovery actions in antitrust cases,” <https://www.lw.com/upload/pubContent/_pdf/pub1675_1.pdf>)

In comparison, in the European Union, private enforcement actions are rare and play less of a role than public enforcement in the fight against anti-competitive behaviour. Several obstacles hinder actions for damages in member state national courts, including a plaintiff’s limited access to evidence, the unavailability of class actions and the potential that the plaintiff may have to pay the defendants’ costs if the plaintiff loses the case. To address these obstacles and the great diversity of damages actions among the member states, the European Commission recently published a green paper on Damages Actions for Breach of the EC Antitrust Rules.3 The green paper examines those aspects of EU litigation practice that have led to a pronounced underdevelopment of private damages actions in the EU. Since its publication in December 2005, the green paper has sparked significant debate within the international antitrust community about the role of private enforcement of EC Treaty competition law and about damages actions in particular. The general expectation is that private damages actions will emerge (albeit slowly) in the European Union. This article compares the state of plaintiff recovery actions in antitrust cases in the US with that of the EU and explores why the United States is more litigious than the EU.

Private antitrust damages actions in the US

Rightly or wrongly, the United States has earned the reputation of having a ‘litigation culture’ that permeates its entire legal system.4 If that is true, it certainly earned its stripes this past year in the area of antitrust litigation. Although the number of civil cases filed in the United States dropped by 10 per cent from 2004 to 2005, the number of antitrust civil filings, almost all of which were initiated by private plaintiffs, rose by 8.8 per cent.5 In the first six months of 2006, the number of antitrust class actions doubled over the same period in 2005.6 Some experts speculate that “[h]ard-charging regulators, a more aggressive plaintiffs[’] bar, and the implementation of [CAFA]” may contribute to the increase in antitrust litigation.7 But in all likelihood, the explanation is far more elementary. As discussed in greater detail below, the pot of treble damages available to plaintiffs in the United States, as well as pro-plaintiff discovery and procedural rules, make private damages extremely easy and attractive to pursue.

The treble damages remedy

In 1914, the US Congress passed the Clayton Act, codified at 15 USC sections 12-27. Section 4 of the Act extends the Sherman Act’s prohibitions on anti-competitive behaviour and, most notably, allows “any person who shall be injured in his business or property by reason of anything forbidden in the antitrust laws” to sue for and “recover threefold the damages by him sustained”.8 Treble damages were designed to deter illegal conduct, deprive antitrust violators of the “fruits of their illegal activities” and provide compensation to victims of wrongdoing.9

The Clayton Act’s treble damages provision is not without its critics.10 Many practitioners and policy makers contend that trebling damages creates too great an incentive for plaintiffs to sue. Additionally, they argue, treble damages actions can result in a windfall to plaintiffs. Furthermore, some believe that large fines and the potential for criminal penalties create just as much of a deterrent against violations, without the need for treble damages.11 Nonetheless, the ability of a US private plaintiff to recover treble damages is so sacred and well protected that earlier this year the First Circuit held in Kristian v Comcast Corp12 that, although Comcast could contract with its subscribers to arbitrate antitrust claims, the arbitration agreements could not bar treble damages because “the award of treble damages under the federal antitrust statutes cannot be waived”.13

Although exceptions to the treble damages provision remain few and far between, congress enacted the Criminal Penalty Enhancement and Reform Act (CPERA) in June 2004. CPERA eliminates the treble damages remedy for corporations that qualify for amnesty under the Department of Justice’s Amnesty Programme.14 Under CPERA, a corporation must report its own anti-competitive behaviour to the DoJ and enter into the Corporate Leniency Programme.15 If a private plaintiff sues the corporation for the same behaviour, the civil court may assess single damages against the participating corporation, but only if the judge in the civil action determines that the corporate defendant is cooperating with the civil claimant by providing a full account of the conduct, furnishing all potentially relevant documents, and securing testimony, depositions and interviews from employees.16

Discovery and evidence

Plaintiffs enjoy broad discovery rights in the United States under the Federal Rules of Civil Procedure. These rules provide significant incentives for plaintiffs to file damages suits, even if they have very little factual bases for the underlying claims. At the outset of a case, the parties are obliged to make certain disclosures to one another, including the name of each individual “likely to have discoverable information” and a description by category and location of all documents in the party’s possession or control that it may use to support its claims or defences.17 Thereafter, during the fact-finding or discovery period, plaintiffs may seek a defendant’s business documents through written requests18 as well as answers to questions through written interrogatories.19 Plaintiffs may also ask questions of a defendant’s employees (regardless of seniority), who must sit for depositions and testify under oath.20 Moreover, plaintiffs may seek documents and testimony from non-parties with relative ease.21

Armed with such easy access to a defendant’s or non-party’s documents and employees, plaintiffs with limited evidentiary bases for their lawsuits may be inclined to sue and go on ‘fishing expeditions’ to discover facts to support their case.

Contingent fees

Plaintiffs that file antitrust damages actions in the United States routinely do so on a contingent fee basis. Under such an arrangement with counsel, the plaintiff client does not pay any fees to his or her attorney unless and until the plaintiff collects damages either by settling with the defendant or prevailing at trial. Typically, plaintiffs’ attorneys demand 33 per cent of the recovery as the fee.22 The result is a win for both client and attorney. The fee arrangements allow plaintiffs with limited funds the freedom to pursue their lawsuits without having to fund the litigation along the way. The plaintiffs’ attorney, on the other hand, is attracted to the prospect of treble damages, and thus a larger fee, and therefore is willing to front the litigation costs in the hopes of earning a sizeable fee at the conclusion of the suit.

Class actions

Class actions are the procedural device that enable one or more plaintiff members of a proposed class to sue on behalf of all similarly situated members of the same proposed class.23 Courts in the US have recognised that class actions can be appropriate mechanisms for promoting private enforcement of the antitrust laws.24 In this way, large numbers of potential claimants can prosecute their claims in a cost-efficient manner.25 The objective of any class action lawyer is to get the class certified. To do so, the court must find that the proposed class is “so numerous that joinder of all members is impracticable”, that there are “questions of law or fact common to the class”, that the “claims or defenses of the representative parties are typical of the claims or defenses of the class” and that the proposed class representatives “will fairly and adequately protect the interests of the class”.26 In addition, in most antitrust cases, the court must determine that the “questions of law or fact common to the members of the class predominate over any questions affecting only individual members” and that “a class action is superior to other available methods for the fair and efficient adjudication of the controversy.”27 Under rule 23, proposed class members are afforded the opportunity to decline to join or to ‘opt out’ of the class. But if the class is certified, all class members who do not affirmatively opt out are bound by the decision in the case and cannot pursue their claims individually. Class actions remain a popular means among plaintiffs’ lawyers to litigate antitrust conspiracy claims because they are regularly certified.

State indirect purchaser actions

In Illinois Brick Co v Illinois,28 the US Supreme Court held that, in order to maintain a claim for damages under section 4 of the Clayton Act, a plaintiff must have purchased the product in question directly from the alleged defendant-antitrust violator. The landmark decision thus precludes plaintiffs in a federal court from seeking alleged damages that were ‘passed through’ from the defendant down the chain of distribution in the form of overcharges. In direct response to Illinois Brick, many US state legislatures passed antitrust statutes that permit indirect consumers (ie, below the direct purchaser in the distribution chain) to sue the alleged violator. Today, 29 states permit such suits, or, alternatively, allow the state attorney general to pursue antitrust claims on behalf of indirect consumers.29 In these ‘Illinois Brick repealer’ states, as they are known, defendants face the real prospect of defending against lawsuits that mirror direct purchaser lawsuits pending against them in a federal court.

Huge jury verdicts and settlements

One natural result of the ease with which plaintiffs can pursue treble damages actions in the United States is huge jury verdicts in private antitrust cases. In Conwood v US Tobacco, the plaintiff manufacturer of moist smokeless tobacco (snuff) sued a competitor, the manufacturer of Copenhagen and Skoal, for unlawful monopolisation in violation of section 2 of the Sherman Act, among other claims.30

The jury awarded plaintiffs approximately US$350 million in damages, which, when trebled, resulted in an award that exceeded US$1 billion. The award is thought to be the largest antitrust jury verdict ever recorded.31

Additionally, the several aspects of US litigation highlighted above are a catalyst to settlement. Even before discovery begins, some defendants, confronted with the promise of invasive and expensive discovery, will choose to settle with plaintiffs in order to spare their employees from intrusive discovery and to save on exorbitant legal fees. Plaintiffs routinely extract large settlements from defendants after gaining access to corporate documents and information that, although not dispositive of any wrongdoing, are damaging or embarrassing enough to justify settlement. Similarly, class actions may contribute to settlement of private damages actions because, if certified, defendants do not want to risk losing at trial and therefore pay treble damages. The same is true for state indirect purchaser actions. Defendants often settle these suits in order to avoid duplicative litigation costs.32 Settlement is also preferable for many defendants in this situation who rightly fear the application of collateral estoppel if they are adjudicated liable in even one state.33

The ultimate risk of large jury verdicts inspire settlements even if the defendants litigate the cases for years and at great expense. In 1998, in In re NASDAQ Market-Makers Antitrust Litigation, MDL Docket No. 1023, plaintiffs settled with 37 defendants for a total of US$1.027 billion.34 And in 2003, on the eve of trial, defendant Visa USA settled with plaintiffs in In re Visa Check/Mastermoney Antitrust Litigation, 297 F Supp 2d 503, 506-508 (EDNY 2003) for approximately US$2 billion. Two days later, defendant MasterCard settled for approximately US$1 billion. The combined US$3.05 billion settlement has been described as “the largest antitrust settlement ever”.35 Private damages actions in the EU

In stark contrast to the United States, private damages actions in the EU are few in number and have never played much of an antitrust enforcement role. Although the European Court of Justice (ECJ) in 2001 explicitly recognised a right to damages for breaches of EC competition law,36 plaintiffs have pursued very few damages claims for violations of competition rules. According to a 2004 study (the Ashurst Study), private damages actions based on the violation of either EU or national antitrust rules are in a state of “total underdevelopment” due to various obstacles in bringing such lawsuits.37

To address these obstacles, the EC recently published a green paper, in which the Commission has sparked significant discussion on the present and future role of private enforcement in the EU. This section explores that role.

EU antitrust laws and enforcement

In the EU, there are two levels of antitrust laws and enforcement. The Commission enforces EU antitrust rules at the EU level, which is limited to public enforcement. At the member state level, however, national antitrust authorities and national courts apply both EU and national antitrust laws. Member states permit private enforcement, including damages actions, through national courts.38 Within this two-tiered system, national antitrust authorities and national courts may apply both EU and national antitrust laws, though substantively there is often little difference between the two.

Articles 81 and 82 of the European Community Treaty govern antitrust enforcement. The ECJ long ago decided that these provisions create rights for private parties that national courts must safeguard.39 In Courage v Crehan, the ECJ held that these rights include the right to damages,40 and recently it clarified that such a right includes compensation not only for actual loss, but also for loss of profit plus interest.41 Moreover, with the adoption of Regulation 1/2003,42 the Council of the European Union ‘modernised’ antitrust enforcement by including new procedural rules for the application of articles 81 and 82. In particular, by devoting specific provisions to national courts, the EU legislative branch has recognised the fundamental role that national courts play in the private enforcement of EU antitrust law for the first time since the inception of EU antitrust enforcement in the early 1960s.

The green paper

These developments, however, have not been sufficient to ensure an effective system of private antitrust enforcement, particularly damages actions, throughout 25 jurisdictions with very different legal traditions and markedly diverse substantive and procedural rules. According to the Ashurst Study, to date there have been only 28 successful private actions for damages for violations of the antitrust laws in the EU.43 More often than not, only single large companies that allege anti-competitive behaviour by dominant competitors have pursued private damages actions. For these well-financed plaintiffs, the damages that they seek are large enough to offset the trouble and costs of private litigation before a national court.

In light of the obstacles to private enforcement in the EU, the Commission published its green paper in 2005 to facilitate damages actions, enhance the overall effectiveness of antitrust enforcement and, ultimately, increase compliance with antitrust laws. In response to criticism from those practitioners who fear the adoption of a USstyle system that could lead to ‘excessive litigation’, the Commission has stated that the objective is that of building “an enforcement culture, not a litigation culture”, in which private enforcement would complement public enforcement.44 For each obstacle to damages actions, the green paper proposes several solutions, although the Commission has not yet indicated how it intends to implement any of these solutions (eg, by means of an EU Directive harmonising certain aspects of national law, or thorough ‘soft law’ such as Commission guidelines).

Amount of damages

Treble damages are not available in the EU. It is also not likely that they will be any time soon; the Commission notes that the US treble damages system can lead to “unmeritorious or vexatious litigation”.45 Instead, compensation is limited to the harm suffered, without the possibility of obtaining punitive or exemplary damages. Plaintiffs may thus usually recover only the loss actually incurred, as well as, in some countries, the loss of profits.46 The Ashurst Study, however, revealed that this system of limited recovery provides disincentives to private litigation.47 To provide balance, the Commission proposes to maintain the rule of single damages, while contemplating the possibility of awarding double damages in cartel actions.48 On this issue, it recognises that the addition of double damages will require the implementation of appropriate measures to avoid jeopardising the effectiveness of leniency programmes (eg, successful immunity applicants would be exposed to single damage recovery only).49

#### Expanding liability to private plaintiffs is bad---turns case and undermines solvency

Nuechterlein, JD, partner and co-leader of Sidley's Telecom and Internet Competition practice, and Muris, George Mason University Foundation Professor of Law, served from 2000-2004 as Chairman of the Federal Trade Commission, ‘21

(Jon and Timothy J., “Private Antitrust Remedies: An Argument Against Further Stacking the Deck,” March, <https://instituteforlegalreform.com/wp-content/uploads/2021/03/March-2021-Antitrust-Paper-FINAL.pdf>)

Advocates of expanding private antitrust remedies begin with the premise that “private enforcement deters anticompetitive conduct” and conclude, in the words of the Report, that legal “obstacles” to recovery by “private antitrust plaintiffs” should be eliminated to maximize deterrence.24 But even if the premise is true,25 the conclusion would not follow. The Report appears to assume that the more deterrence the law provides, the better, and that any “obstacles” to private recovery should thus be removed.26 But that position ignores the consequences of overdeterrence, including the prospect that firms will respond to the threat of draconian penalties in ways that reduce the threat of liability but that ultimately harm consumers.

Overdeterrence is a particular concern in antitrust doctrine because the line separating lawful from unlawful conduct can be blurred and much of the conduct falling on the lawful side of the line is socially beneficial. As economists William Baumol and Alan Blinder explain: One problem that haunts most antitrust litigation is that vigorous competition may look very similar to acts that undermine competition …. The resulting danger is that courts will prohibit, or the antitrust authorities will prosecute, acts that appear to be anticompetitive but that really are the opposite. The difficulty occurs because effective competition by a firm is always tough on its rivals.27

For example, excessive antitrust remedies for predatory pricing may not only deter firms from engaging in conduct that would ultimately be deemed unlawful, but also induce them to keep prices well above their costs and, in effect, hold a price umbrella over smaller, potentially litigious rivals. Such a regime would result in less competition and higher prices for consumers—the very outcomes the antitrust laws are designed to prevent.

Proposals to slap another layer of deterrence on top of existing private remedies are particularly perverse because, as discussed above, the current U.S. regime is already overdeterrent, in that it subjects firms to unusually severe liability risks even for overt conduct subject to the rule of reason. If anything, Congress should consider aligning private antitrust remedies with remedies for analogous common law torts by, for example, limiting treble damages and one-way fee-shifting to cases involving hard-core violations that may elude detection, such as price-fixing cartels. In all events, Congress should not make a bad situation worse by ratcheting up the level of overdeterrence.

### CP FDA

#### The United States Food and Drug Administration should revoke biosimilar licenses in cases of reverse payment settlements.

#### The FDA should revoke licenses of biologic companies that engage in reverse payment settlements – that solves both price competition and innovation faster than the aff

Rutschman 20 - Assistant Professor of Law, Saint Louis University School of Law

Ana Santos Rutschman, “Regulatory Malfunctions in the Drug Patent Ecosystem,” Emory Law Journal, Volume 70 Issue 2, https://scholarlycommons.law.emory.edu/cgi/viewcontent.cgi?article=1405&context=elj\

The first signs of a contractual agreement resulting in the delay of competition between an original and follow-on biologic date back to 2016 and involved biologic drug Humira.33 That same year, the FDA approved the first Humira biosimilar. But, even though no biosimilars actually entered the market in the United States, it was not until 2019 that the first lawsuits were brought against the manufacturer of Humira and the biosimilar manufacturers potentially competing with it.34 Unless a legal intervention changes this landscape, there will be no biosimilar competition in the United States until 2023—five years after the first biosimilar to Humira entered the European market, and six years after that same biosimilar was approved by the FDA for commercialization in the United States.35

The legal interventions associated with anticompetitive behaviors of the type described above belong traditionally to the domain of antitrust law and policy. However, antitrust responses tend to lag in time, as exemplified in the case of Humira. While pay-for-delay can be configured as a core antitrust problem, this does not mean that antitrust law and antitrust regulators are or should be the sole entities capable of addressing anticompetitive behaviors in the biopharmaceutical arena. This Article explores the possibility of a more immediate response to problems posed by pay-for-delay in the context of biologics than the one that antitrust regulators like the FTC, or the application of antitrust law, can provide.

Because anticompetitive behaviors related to biopharmaceutical products arise in a “shared regulatory space,”37 it is worth asking if there are any other institutional players that are well placed to address pay-for-delay, without deviating from their mission and without interfering with unfolding, however slow, antitrust responses. This Article answers that question by identifying the FDA as the natural locus for an intervention that would curb pay-for-delay and incentivize motivated biosimilar manufacturers to bring their products to market. Known as an institutional catalyst for the production of information and as a player in the administration of innovation policy, the FDA acts also as the gatekeeper for biopharmaceutical products. In cases of pay-for-delay, a biopharmaceutical company elects to deliberately remain outside the market, going against the permissive gesture of the administrative agency approving a product at the request of that same company.

While it is a prerogative of the private company to refrain from commercializing its products, it is also a prerogative of the agency to withdraw approval if no manufacturing activity occurs within a reasonable period of time.39 In fact, after examining the regulatory framework for license revocation, this Article argues that the FDA has not only the ability, but also the obligation, to revoke biosimilar licenses in cases of pay-for-delay.

From a policy perspective, it is also desirable that the Agency do so. This solution eliminates some of the most troubling effects of the extended lag between anticompetitive settlements and antitrust litigation while triaging the marketplace for biosimilar competition.40 On the one hand, highly motivated players—in a field encompassing the most expensive drugs in the world—will seek regulatory approval from the FDA if they intend to come to market. On the other, players unwilling to engage in patent litigation, or motivated primarily by the prospect of pay-for-delay, are now discouraged from (mis)using the regulatory pathway and will reallocate their resources and strategic priorities accordingly. In fact, resource reallocation has already started to happen in the case of biosimilars to Humira: with so many biosimilars approved by the FDA waiting to enter the market in 2023, companies have started shifting research and development (R&D) funds away from biosimilars to Humira and into other types of biosimilars.42

In addition to increasing costs for patients and health systems, the detrimental effects of pay-for-delay in the context of biologic-biosimilar competition are likely to extend into other areas. In 2018, as the number of agreements between the manufacturer of Humira and biosimilar companies grew progressively larger, the FDA Commissioner noted that competition-restricting agreements targeting biosimilars are likely to produce long-term effects and affect the incentives for the development of new biosimilars: “[T]he net result is a lopsided playing field that disincentives biosimilar developers from making the sizable investment in bringing such products to market. I am concerned this will lead to reduced competition in the long-run and unsustainable costs for these treatments.”43

But so far, neither the Agency nor commentators have considered a solution hiding in plain sight: license revocation, a counterpart to the FDA’s power to grant licenses, monitor the production and commercialization of approved products, and use information generated in connection with these products. Because manufacturers entering into pay-for-delay agreements fail to generate meaningful information about their approved biosimilars, this Article argues that inaction due to pay-for-delay, if unjustified under certain principles,44 falls into the cases contemplated by law allowing the Agency to revoke market authorization.45 Moreover, the regulatory language is not merely enabling, but rather mandatory: the FDA “shall” revoke licenses for biologic products whose manufacture it cannot monitor and properly evaluate. The solution proposed in this Article is thus already embedded in the regulatory framework, needs no legislative intervention, and does not constitute an additional burden to an administrative agency that is already resource-constrained. Applying it, however, would have an immediate and important effect on the availability of less expensive versions of drugs that are critical to so many patients in the United States.

With several blockbuster biologics poised to start losing patent protections in years to come, finding ways to disincentivize pay-for-delay in this field becomes especially relevant. In arguing in favor of an FDA intervention to curb pay-for-delay, this Article does not seek to minimize the role and centrality of the antitrust apparatus, but rather to uncover a localized fix that can help in diminishing the frequency and impact of a specific type of anticompetitive agreement. In doing so, this Article contributes to the literature on pay-for-delay and other anticompetitive behaviors in the biopharmaceutical arena, as well as to the larger ongoing debate surrounding the limitations of long-established antitrust responses to competition issues.49 Additionally, it makes the case that the role of the FDA as a competition-distorting entity capable of providing fixes to intersecting regulatory problems should be further explored within the FDA-as-locus-of-incentives literature. Secondary contributions include a descriptive account of waves of patent expirations in the pharmaceutical space,51 a questioning and reframing of the licensing function of the FDA as an administrative agency, and analysis of regulatory language that reveals current frameworks to be more capacious than previously thought.53

### CP Presumption

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

#### It’s competitive – “prohibit” means “ban” – CX was explicit that they allow some P4D

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)

### Access

#### Presumption of illegality fails to deter reverse payment settlements – 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.

#### Generic entry won’t happen even without pay for delay: Sooooooo expensive

Timmis 15 - Northwestern University School of Law

Ryan Timmis, “The Biologics Price Competition and Innovation Act: Potential Problems in the Biologic-Drug Regulatory Scheme,” Northwestern Journal of Technology and Intellectual Property, Volume 13 Issue 2, Fall 2015, https://heinonline.org/HOL/Page?collection=journals&handle=hein.journals/nwteintp13&id=235&men\_tab=srchresults

A. Biosimilar Drugs Are Significantly More Expensive to Develop Than Chemical Generics

Biopharmaceuticals are inherently more costly to develop than chemical drugs. Further, they are difficult to manufacture in quantity, require precise manufacturing processes, and involve exorbitant start-up costs, such as the estimated $200 to $400 million required just to build the initial manufacturing plant. As a result, the production of a new biologic drug generally requires an investment of approximately $1.2 billion. In other words, developing a new biopharmaceutical drug costs double the estimated $802 million required to develop a new chemical drug. This cost difference is even greater when comparing biosimilars to generics. For instance, in Europe the cost of bringing a biosimilar to market ranges from $75 to $250 million, and requires between eight and ten years to develop. On the other hand, standard chemical-drug generics require only a few years and $1 to $2 million to develop, a mere fraction of its biologic counterpart.

There are two primary reasons for these high manufacturing costs: scientific challenges specific to biologic production and more burdensome data requirements. First, it is simply more difficult to make the sort of large molecules characteristic of biologic drugs. Virtually every aspect of production must be meticulously controlled and monitored to generate a useable product, with even minor temperature changes potentially ruining an entire batch of biopharmaceuticals. The medium of production and storage conditions are also essential to the final product. Impurities can arise from nearly any change in the manufacturing process, and because this process takes more time than that for chemical drugs, sometimes lasting up to nine months per batch, the likelihood of an impurity corrupting the batch increases. All of this is without accounting for the costs of materials, which are often 20 to 100 times more expensive than for conventional chemical drugs. Perhaps the biggest obstacle, however, is the cost of building, equipping, and qualifying the manufacturing plant, which generally costs between $250 million and $1 billion.

On top of the arduous manufacturing process, biosimilars will likely face additional data requirements relative to generics. Hatch-Waxman provides very specific data standards ANDAs must meet to show bioequivalence, which often suffice to gain FDA approval if met. 136 The BPCIA, by contrast, only states that the FDA shall require analytic, animal, and clinical studies, and provides no further guidance detailing what sort of similarity applicants must show. 137 Most likely, and lasting for the indefinite future, the FDA will determine this amorphous similarity requirement on a case-by-case basis, relying only on the relative state of knowledge about the reference product in question. 138 Given the immense costs associated with entering the biosimilar market, it is likely that only well-established companies with substantial extant resources will be able to do so at all. 139 Even then, as indicated by the FTC, it will likely only be for drugs with annual sales greater than $250 million. 140 Consequently, only the most profitable biologics are likely to face biosimilar competition. In the end, because niche markets and less profitable drugs are unlikely to spur the same degree of competition, high prices will remain the norm for biologics generally.

#### Alt cause to cartels AND no impact – cartel violence is caused by weak states, but it won’t ever collapse

Neil Couch, Brigadier, British Army, “Mexico in Danger of Becoming a Collapsed State. Reality or Exaggeration?” Defence Studies, 13:2, 152-191, ‘13

A ‘collapsed’ state, however, as postulated in the Pentagon JOE paper, suggests ‘a total vacuum of authority’, the state having become a ‘mere geographical expression’.16 Such an extreme hypothesis of Mexico disappearing like those earlier European states seems **implausible** for a country that currently has the world’s **14th largest economy** and higher predicted growth than either the UK, Germany or the USA; that has **no external threat from aggressive neighbours**, which was the ‘one constant’ in the European experience according to Tilly; and does not suffer the ‘**disharmony between communities’** that Rotberg says is a feature common among failed states.1/,1S

A review of the literature does not reveal why the JOE paper might have suggested criminal gangs and drug cartels as direct causes leading to state collapse. Crime and corruption tend to be described **not as causes but** as **symptoms demonstrating failure**. For example, a study for Defence Research and Development Canada attempting to build a predictive model for proximates of state failure barely mentions cither.19 One of the principal scholars on the subject, Rotberg, says that in failed states, ‘corruption flourishes’ and ‘gangs and criminal syndicates assume control of the streets’, but again as effect rather than trigger.20 The Fund for Peace Failed States Index does not use either of them as a ‘headline’ indicator, though both are used as contributory factors. This absence may reflect an assessment that **numerous states** suffer high levels of organised crime and corruption and nevertheless do not fail. Mandel describes the corruption and extreme violence of the Chinese Triads, Italian Mafia, Japanese Yakuza and the Russian Mob that, in some cases, has continued **for centuries**.21 Yet none of these countries were singled out as potential collapsed or failed states in the Pentagon’s paper. Indeed, thousands of Americans were killed in gang warfare during Prohibition and many people ‘knew or at least suspected that politicians, judges, lawyers, bankers and business concerns collected many millions of dollars from frauds, bribes and various forms of extortion’. Organised crime and corruption were the norm in the political, business, and judicial systems and police forces ran their own ‘rackets’ rather than enforcing the law.23 **Neither the violence nor the corruption led to state failure.**

### Econ

#### 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

#### 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.

### Innovation

#### 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:;)

## 2NC

### CP Prizes

#### CP weighs the cost-effectiveness with health benefits of the innovation to determine pay out – that creates proper incentives for truly innovative conduct there is no way to game this syste,

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#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#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#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#eq0020). Hence, incentives are created to develop cost saving therapies, which are equally or slightly less effective compared to the common practice.

#### The CP triggers research that may not be patentable which allows new entrants into research which solves

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#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#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.

#### Empirics prove that prizes trigger tons of investment in the specified technology

Kim and Schwartz 6 – Marhi Kim, Canadian lawyer, specializing in the field of Corporate/Commercial. Schwartz Professor of International Business and Trade Law, University of Manitoba Law School.

Marhi Kim and Bryan Shwartz, 2006, “Economic Prizes: A New Model for Pharmaceutical Innovations,” Asper Review of International Business and Trade Law , https://www.canlii.org/en/commentary/doc/2006CanLIIDocs543#!fragment/zoupio-\_Toc2Page1-Page10/BQCwhgziBcwMYgK4DsDWszIQewE4BUBTADwBdoAvbRABwEtsBaAfX2zgCYAFMAc0ICMjHvwEAGAJQAaZNlKEIARUSFcAT2gByTVIiEwuBMtUbtu-YZABlPKQBCGgEoBRADLOAagEEAcgGFnKVIwACNoUnYJCSA

An example of the successful use of tasteful marketing to further scientific advancement is the Ansari X Prize. The highly promoted Ansari X Prize135 offered $10 million to the first privately manned space vehicle to orbit the planet twice in two weeks. The X Prize created a high degree of public interest by announcing the competition with black-tie galas and keynote speeches from celebrities such as author Tom Clancy. It also boasts an impressive panel of members and endorsements from well-known celebrities such as Arthur C. Clarke, Dennis Tito, John Glenn, Buzz Aldrin, and Tom Hanks. The results speak for themselves. The $10 million prize resulted in intense competition between 27 teams from 7 countries and leveraged over $100 million in private investment. More importantly, it accomplished what it set out to do. In October of 2004, the first privately-manned spaceflight was launched and revolutionized the idea of low cost civilian spaceflights. Despite initial skepticism, but due to its overwhelming success, the X Prize is now considered the leading model for fostering innovation through competition. The element of healthy competition produced exceptional results, without damaging the integrity of the resulting innovation. Rather, the competition fostered greater awareness, education, and appreciation of science and enhanced the existing pool of scientific knowledge. The prize model in this proposal can bring similar advancement to innovation in healthcare, without compromising its integrity.

#### Government purchases can provide higher rewards than monopoly patent pricing which solves R&D

Kremer and Glennerster 4 – Michael Robert Kremer is an American development economist who is University Professor in Economics And Public Policy at the University of Chicago. Rachel Glennerster CMG is the chief economist at the Department for International Development, the UK's ministry for international development cooperation, after formerly serving on DFID's Independent Advisory Committee on Development Impact.

Michael Kremer and Rachel Glennerster, 2004, “Strong Medicine: Creating Incentives for Pharmaceutical Research on Neglected Diseases,” Princeton, https://www.jstor.org/stable/j.ctt1dr365r

Large-scale government purchases could, in theory, compensate for the private market failures that reduce both R&D incentives and use of vaccines already developed. But to address the market failures, governments would need to pay high prices to vaccine producers (often unpopular multinationals) and to subsidize delivery to consumers. Simply establishing intellectual property rights for vaccines and allowing private sales would lead to underconsumption of vaccines, while simply buying vaccines as cheaply as possible and subsidizing consumption would undermine R&D incentives. Because vaccine development is expensive while manufacturing additional vaccine doses at the margin is cheap, large government purchases at prices above manufacturing costs (but below monopoly prices) could make both vaccine producers and consumers better off than they would be in a market that allowed producers to sell at monopoly prices. If the government bought enough vaccine, manufacturers might be better off than with monopoly pricing. So government purchases could actually increase R&D incentives, even if the government paid less than the monopoly price. To see why large public purchases that expand the market and bring down the cost per person could make everyone better off, suppose that willingness to pay is proportional to income and that the government agrees to pay the vaccine manufacturer an amount equal to the sum of areas A, B, C, and D (figure 7) in exchange for enough vaccine for the entire population. If these purchases are funded by an income tax, with all people who would have paid the monopoly price paying just under that price and all others paying just over the actual production cost, both vaccine producers and the general public would be better off. The sum of areas D and E is the social benefit of the vaccine purchase program. This hypothetical government is not bargaining for the lowest possible price, but for a price that makes both producers and consumers better off. However, actual governments typically pay much less for two reasons. First, even if a government places a high value on having a vaccine, after developers have sunk their R&D investments, governments have every incentive to force prices down to a level that covers only manufacturing costs—and not the R&D expenses. This is known as the time-consistency problem in economics. Moreover, governments are typically in a position to drive very hard bargains because they often serve as primary purchasers of vaccines, as well as regulating pharmaceuticals and enforcing intellectual property rights. This helps explain why the value of all sales of childhood vaccines in low-income countries has historically been only $200 million annually (World Bank AIDS Vaccine Task Force 2000

### Hospitals

**Antitrust law expansion signals a novel, economy-wide shift in governmental approach that fundamentally changes the game---that’s contrasted with other areas of law, which don’t send broad signals**

**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.

#### Substantive legal focus—new substantive changes signal a trend throughout the economy

Crowell & Moring 20 – Contributions from: Shawn R. Johnson, partner and co-chair of Crowell & Moring's Antitrust & Competition Group; Wm. Randolph Smith, partner in (and former chair of) the firm's Antitrust & Competition Group; Jeane A. Thomas, partner in Crowell & Moring's Antitrust & Competition and Privacy & Cybersecurity Groups, and co-chair of the firm's E-Discovery & Information Management Practice; Andrew I. Gavil, senior of counsel in Crowell & Moring’s Washington, D.C., office and is a member of the firm’s Antitrust & Competition Group; Gail D. Zirkelbach, partner in Crowell & Moring's Government Contracts and Investigations groups; Alexis J. Gilman, partner in Crowell & Moring’s Antitrust & Competition Group; Jason C. Murray, co-chair of the firm's Antitrust & Competition Group; Lisa Kimmel, senior counsel in Crowell & Moring's Antitrust & Competition Group; Thomas De Meese, co-managing partner of the firm's Brussels office.

Crowell & Moring, "Antitrust in the Digital Age: How Antitrust Investigations into Big Tech Impact Companies in Every Industry," Regulatory Forecast 2020, 2-26-2020, <https://www.crowell.com/files/Regulatory-Forecast-2020-Antitrust-Cover-Story-Crowell-Moring.pdf>

“The antitrust world hasn’t seen an issue this large in decades. Unlike every major antitrust development of the past, a look into Big Tech involves companies that may not charge customers anything and whose assets involve private consumer data that may not be able to be transferred as part of a remedy,” says Shawn Johnson, a partner at Crowell & Moring and co-chair of its Antitrust Group in Washington, D.C. “And this is not just about Big Tech. In the end, all companies are becoming digital. From how we view the role of data privacy to so-called killer acquisitions, these investigations are going to impact a wide range of businesses for years to come.”

While an imminent breakup of any Big Tech firm is unlikely, the increased attention to antitrust issues has implications far beyond the handful of companies that dominate the news. These new developments could affect mergers, acquisitions, and business practices in virtually every sector. That’s because competitive advantage today is often reliant upon access to key data, to online platforms, and to cutting-edge technologies—and antitrust legal and regulatory action sets the rules for such access.

“This is a megatrend,” says Wm. Randolph Smith, a partner at Crowell & Moring in Washington, D.C., former chair of the firm’s Antitrust Group, and a former executive assistant to the chairman of the FTC. “A confluence of events, including political philosophy, economic impact, and missteps on issues like privacy, is creating a shift in antitrust focus and thinking that could reverberate into other sectors.”

So Big. So What?

Big Tech platforms stand accused of a multitude of sins: invasion of privacy; lax data security; unfair treatment of labor, content, or merchandise suppliers; bias against competitors; failing to vet dangerous products or content; and the acquisition of incipient competitors in an effort to squelch future competition, a phenomenon some have labeled killer acquisitions.

Many of these platforms have prospered because they provide a superior service at a lower cost, or for free. But they also have benefited from the “network effects” that tend to favor technology incumbents. Along the way they’ve collected vast quantities of data about customers or users that critics contend entrench their dominance. “Antitrust enforcers are struggling to figure out how to define and police the amount of market power these platforms have amassed, particularly with respect to the collection and use of personal data,” says Jeane Thomas, a Washington, D.C.-based partner in Crowell & Moring’s Antitrust and Privacy & Cybersecurity groups.

Within antitrust circles, a debate has emerged about whether current law and legal precedent suffice to address the alleged challenges presented by Big Tech platforms. For nearly 40 years, antitrust law has been dominated by the idea that consumer welfare is the ultimate goal of antitrust enforcement. Some critics have vigorously challenged that standard, especially when it comes to mergers and dominant-firm conduct, and blame what they view as weak antitrust enforcement for increased market concentration and market power. Others have sought to defend the standard, while still others are actively seeking to define a new middle ground that is at once economically grounded yet acknowledges that increased antitrust enforcement is warranted, notes Crowell & Moring senior counsel Andrew Gavil, a former director of the FTC’s Office of Policy Planning and a member of the firm’s Antitrust Group in Washington, D.C.

Yet the source of Big Tech’s alleged dominance may lie less in legal doctrine than in missed opportunities for more aggressive antitrust enforcement. Many important acquisitions by Big Tech companies in recent years have flown under the radar from an antitrust perspective, notes Johnson. Antitrust enforcers haven’t challenged these deals, likely because the acquired company was viewed as operating in an adjacent or differentiated space. But with the benefit of hindsight, it is likely that some of these companies would have developed into potential competitors, such that a killer acquisition had occurred. “The platforms are thinking 10 years ahead,” Johnson says.

“The current wave of concern about Big Tech mirrors previous eras when antitrust was in the spotlight, such as when supermarkets and shopping malls were hurting Main Streets across America,” says Smith. Beyond acquisitions, big company behavior can raise competitive concerns when the companies take measures to hold onto the power they already have. Or as Smith puts it, “It’s often not what you do to become king of the hill, it’s what you do to stay there” that attracts antitrust attention.

It’s far from clear, however, whether antitrust enforcement is the answer to the problems ascribed to Big Tech. A prime example is concern about the protection of privacy. “Traditionally, privacy concerns have played virtually no role in antitrust enforcement,” says Thomas. “But the platforms have grown so large that some users want, and to some extent need, to be on these platforms so much so that they feel forced to give up significant privacy in exchange.” Some markets might benefit from competitors that would do a better job protecting privacy.

“Privacy protection and competition protection are on a collision course,” Thomas says. If platforms are leveraging customer data to foreclose competition, a typical antitrust solution would be to require them to make that data available to competitors. But this might mean the sharing of personal data, which would be unacceptable to most people. One prominent platform has already withheld information from advertisers about how viewers are interacting with their ads— creating anticompetitive concerns—by saying it must conform with European and California privacy laws. “Regulators are going to have to make some policy choices to say whether or not we’re willing to trade off harm to competition to protect personal data,” Thomas says. “In any case, privacy protection may be better addressed through consumer protection laws, for example by forbidding platforms from collecting certain information or from using it in certain ways.”

Guidelines Ahead

With so many investigations underway, it might seem to some that the era of Big Tech is coming to an end. In reality, experts say, the course of change in 2020 is likely to be slow and incremental—though a change in the political balance of power in Washington could open the door to new legislation that would upend existing judicial precedent.

In January, the DOJ and the FTC jointly released new draft guidelines governing vertical mergers. The FTC has also said that it is developing additional digital platform enforcement guidelines as well as an addendum to 2006 horizontal merger guidelines that would address nascent competition and how the agency analyzes non-price effects of mergers. “Agency guidelines are significant for many reasons,” says Alexis Gilman, an antitrust partner at Crowell & Moring in Washington, D.C., and former head of the Mergers IV Division at the FTC. “They’re a useful road map of the agencies’ own analyses, which make them an important cue for companies that want to understand how the agencies might react to proposed deals. But they also influence how courts analyze issues, especially given the relative paucity of case law.”

But any litigants that choose to pursue an antitrust remedy in the courts—whether agencies, states, or private entities—will run into legal doctrines that have set a very high bar for plaintiffs, particularly standards relating to exclusion and the duty to deal with rivals, says Lisa Kimmel, a senior counsel in Crowell & Moring’s Antitrust Group in Washington, D.C., who formerly served as FTC attorney advisor on antitrust and competition policy matters for then-chairwoman Edith Ramirez. “The case law has been very defense-friendly for many years, especially for monopolization cases. Novel theories are unlikely to prevail under the existing state of antitrust law, which means there may be a disconnect between what U.S. enforcers want to do and what they can actually get done absent legislation that alters the status quo in the courts.”

With the courts and long-standing precedent acting as a backstop, a sea change in antitrust will likely require new laws from Congress. And substantive new laws are unlikely unless a bipartisan consensus coalesces around specific reforms or this year’s election results in single-party control of Congress and the White House, Gavil believes.

Ripple Effects

Regardless of whether this new wave of antitrust investigations results in a major change in law or legal doctrine, it could still have a significant effect on business well beyond Big Tech. That’s because it could impact the robust markets for data and disruptive technology that drive the economy in this era of digital transformation.

“The mere fact of the investigations is already affecting the market,” Gavil says. “It influences investors, venture capitalists, and innovators.” Potential competitors to the Big Tech platforms have been emboldened, the big platforms are more cautious, and some innovators who were looking forward to having their companies bought “could be disappointed.” The likely sources and shape of innovation may well change as a result.

#### Agency leverage—enforcers manipulate any new change to the max

Delrahim, Assistant Attorney General, Antitrust Division, United States Department of

Justice, ‘20

(Makan, “The Future of Antitrust: New Challenges to the Consumer Welfare Paradigm and Legislative Proposals,” 69 Cath. U. L. Rev. 657)

What does the future hold for consumer welfare standard? That’s up to us. No policy, no matter how sound, is immune to calls for change. Throughout history, when reformers fail in the legislative arena, they will turn to existing laws and regulations and try to manipulate them in ways never previously seen. I won’t mention specific examples, but we have seen this playbook when federal courts interpret or, more accurately, rewrite the law in head scratching ways and when agencies issue new regulations that strain the statutory text. Some reformers now seek to bring this playbook to the domain of antitrust law, which, if read broadly, could wield tremendous power over the economy. Unbridled, this power could do significant damage to the economic impulses that drive innovation, gains, and efficiency, and other pro-competitive outcomes for consumers.

Antitrust law may be particularly vulnerable to hasty change given its common law status and evolution in light of advancements and economic thinking. We will see in our lifetimes whether the pendulum will swing back and unravel the progress the field has made. What can practitioners, academics, judges, and enforcers do if they want to preserve the consumer welfare standard? First and foremost, we should not be complacent. Many deride the latest reform movement as “hipster” antitrust because advocates for abandoning the consumer welfare standard invoked a decades-old trust-busting era that we now consider antiquated and economically misguided. Labeling one’s opponents only go so far.

Winning the economic debate goes further, but not far enough. The modern antitrust reform movement is less concerned about economic soundness than it is about results. That means we must demonstrate to observers that we will pursue effective results whenever we find anticompetitive conduct. We must be vigilant to ensure that the biggest companies are minding the guardrails of competition. If we don’t act swiftly and certainly, then we risk looking impotent next to those who would punish monopolists just for being big. That approach, of course, is an axe where a scalpel is needed. If we don’t use our scalpel, we

shouldn’t be surprised to see the reformers sharpening their axes.

**That’s specifically true of hospital consolidation**

**Carroll et al. 21** – John D. Carroll is a partner in the Antitrust & Competition Practice Group; David Garcia is a partner and Office Managing Partner for Sheppard, Mullin, Richter & Hampton LLP, with a practice focused on antitrust litigation; Bevin Newman is a partner in the Antitrust and Competition Practice Group

John D. Carroll, David R. Garcia, and Bevin M.B. Newman, "Healthcare Antitrust Update: Key Antitrust Takeaways for Physician Groups," The National Law Review, 6-14-2021, https://www.natlawreview.com/article/healthcare-antitrust-update-key-antitrust-takeaways-physician-groups

Like other players in the healthcare industry, physician groups are facing **increased antitrust scrutiny** from the Biden administration, with the Federal Trade Commission (the “FTC”) and Department of Justice, Antitrust Division (the “DOJ”) (together the “Agencies”) continuing to **expand their enforcement** **focus** to include all types of transactions involving physician groups, including both traditional combinations, as well as so-called vertical combinations with health systems, payors, and private equity investors.

Many states’ attorneys general have also become more active investigators of physician transactions, as California, New York, Texas, and others have scrutinized numerous physician combinations, while the State of Washington recently passed legislation that requires a 60 day notice of provider transactions that involve at least seven providers.

Based on our experience in the marketplace, we expect physician groups to encounter more antitrust scrutiny of their transactions and collaborations as the provider sector **seeks to overcome** the challenges posed by the COVID-19 pandemic and physicians look to **innovative combinations** and collaborations to find solid economic footing. Physician groups should keep in mind the following three key takeaways as they navigate an increasingly challenging antitrust enforcement landscape.

Takeaway 1: Physician Consolidation Remains Enforcement Priority

Physician group mergers are often taking place in **local markets** that the Agencies may already **view to be concentrated** with respect to one or more specialties. One recent study estimates that in 2016, 40 percent of markets for primary care services and nearly two-thirds of specialty physician services markets were highly concentrated under the DOJ and FTC Horizontal Merger Guidelines, while other studies and analyses come to different conclusions.

In spite of what some may consider to be a steady ongoing pace of physician consolidation, antitrust enforcers frequently argue that there is little support for concluding that consolidation enhances quality, lowers costs, or improves outcomes.

The FTC, the most active federal antitrust enforcer in the provider sector, **seeks** to translate such **views into enforcement action** in the near term. In January, the FTC issued orders to six major health insurance companies to provide information that will enable the Agency to study the effects of physician group and healthcare facility consolidation over the past five years in several regions of the country. These orders follow on the FTC’s announcement last fall that it would expand and formalize its merger retrospective program, which the FTC has used with great success in the past to test and refine the economic models that it uses to make enforcement decisions and to challenge mergers.

**US food security is key to prevent global conflict escalation**

-Globalization = price spillover

**Hendrix**, PhD, Associate Professor, Josef Korbel School of International Studies, Affiliated with the Sié Chéou-Kang Center for International Security & Diplomacy, **‘16**

(Cullen S., “When Hunger Strikes: How Food Security Abroad Matters for National Security at Home,” April, https://www.thechicagocouncil.org/sites/default/files/Report\_When\_Hunger\_Strikes\_1604.pdf)

Feeding the world and teaching the world to feed itself is not just a humanitarian endeavor. It **is vital to US national security**. Food price– related unrest can have an **immense impact** on the **stability** of countries vital to US interests. Fortunately, the United States is well positioned to **lead the fight against food insecurity** across the globe. Even with increases in agricultural productivity, Africa and Asia have become **increasingly dependent on global markets** to satisfy their growing domestic demand for food. For example, Africa’s 20 most populous countries are all net grain importers. This **import dependence** has made these countries **more sensitive to food price volatility than ever** before. Food price shocks can act as a **catalyst** for both nonviolent and armed conflict. Particularly in urban areas of lower- and middle-income countries, high food prices and reduced access can trigger protests and rioting. For example, food price–related protests toppled governments in Haiti and Madagascar in 2007 and 2008. In 2010 and 2011, food prices and grievances related to food policy were one of the **major drivers of the Arab Spring.** Unrest in the Middle East and North Africa has led to upheaval in some of the **most strategically significant regions** to the United States. From 2007 to 2011, instability in **key oil-producing regions** led to fluctuations in global energy markets and fears the unrest would spread to other major oil exporters in the Gulf. Instability in the region has also exacerbated the **ongoing civil war in Syria**, contributing to **growing US-Russia tension**s and a massive refugee crisis in Europe. Because food insecurity can be **strongly linked to political instability**, the United States should rededicate itself to a program of research, knowledge transfer, and assistance in developing agricultural capacity abroad and support national governments in pursuing strategies that proactively address food price stability in order to decouple food systems from violent unrest. This brief offers proactive policy recommendations, including: – Improving our understanding of the relationship between food insecurity and political instability. This field is nascent, and a deeper comprehension of the linkages is important to build a policy platform. – Leveraging US knowledge to support improvements in strategic grain reserves in key regions. – Facilitating commodity hedging by importing governments. – Addressing export bans, which often have devastating impact on regional markets. – Encouraging the adoption of regional food balance sheets. – Helping foreign governments navigate the transition from general food subsidies to targeted, means-tested food assistance.

**Decline spills over, the U.S. is a major producer and exports a massive amount which creates vunerability**

Jeff **Horwich**, Interim host of Marketplace Morning Report and Rob Bailey, Royal Institute of International Affairs, “U.S. drought could have global impact on food prices,” **’12**, <http://www.marketplace.org/topics/world/us-drought-could-have-global-impact-food-prices>

Bailey: Well America is an **agricultural superpower** as well as a traditional global superpower, so it's the biggest producer of maize in the world, it's the biggest producer of soy beans in the world. So as soon as there's a decrease in U.S. agricultural production, that has **massive effects** **for the global economy**. These sorts of **price impacts could ripple across economies** across borders. Horwich: And geopolitically, let's just think back a few years when food prices start to rocket in some parts of the world, crazy **things can happen**. Bailey: Absolutely, if you think back to 2008 in Haiti the government actually fell as a result of riots connected to food prices. Fast forward a couple more years to 2011, the Arab Spring actually was sparked by initial protests in a number of countries **about the price of bread** because the price of wheat had gone up in response to export bans following a really bad harvest in Russia and Ukraine after a heat wave and wild fires there. Horwich: Are there any particular flash points that you are looking at this time around? Bailey: The situation in the Middle East remains much the same, there is still **huge political vulnerability to a spike in wheat prices**. The other thing that the U.S. is having a big impact on is soy bean prices. But if we see a very sharp increase soy bean prices, you can expect meat prices to rise and this could actually have implications for China, quite seriously.

### 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.**

#### They say we need to be developing cures to nip pandemics in the bud but that’s a paradox – private firms will only recoup money from investing in these cures if they can treat a large amount of people. Simply, there needs to BE a pandemic to get private investment in vaccines in the first place!

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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 expected volume of a given market may be small either because there are few potential buyers or because each buyer is expected to demand only a small quantity of product. Uncertainty over market volume can also affect expected profits, such as where there is uncertainty as to when or to what extent disease outbreaks will occur. **Few buyers for emerging infectious disease medicines** Small markets have long been known to lead to challenges in incentivizing private investment in drug development. In 1983, Congress recognized that small market size was delaying the development of drugs for certain rare (orphan), primarily noninfectious diseases such as Huntington’s disease, amyotrophic lateral sclerosis, muscular dystrophy, and Tourette’s syndrome.9 In response, it passed the Orphan Drug Act to provide tax incentives, research grants, and seven-year statutory exclusivity to stimulate research and development for drugs that treat any disease “occur[ing] so infrequently in the United States that there is no reasonable expectation that the cost of developing” a treatment will be recovered.10 The following year, the definition was expanded to also include diseases annually affecting fewer than 200,000 people in the United States, regardless of expected return on investment.11 The market for emerging infectious diseases is small because, by definition, emerging diseases initially affect few people. In 2013, the most recent year for which data are available, the Centers for Disease Control and Prevention (CDC) estimated that drug-resistant tuberculosis, Pseudomonas aeruginosa, and Salmonella typhi affected about 1042, 6700, and 3800 people, respectively, in the United States each year, while vancomycin-resistant Staphylococcus aureus affected approximately 2 people each year.12 These diseases therefore are only about 3% or less as prevalent as diseases defined as rare under the Orphan Drug Act. Although drug-resistant pathogens may affect small numbers of people at first, treatments are needed well in advance of contagion. The urgency derives not only from the unmet needs of current patients, but from the inability of the patent-based market to respond quickly enough to prevent substantial suffering or loss of life once prevalence increases. Product development **can take too long to help those** affected during the first waves of epidemics or pandemics,13 even after taking into account the various FDA expedited pathways that can be used in cases of urgent need.14 Even where experimental vaccines are already in development at the time of an outbreak, a lack of patient-ready prophylactics or treatments can be deadly. After an Ebola outbreak began in West Africa in 2014, 5837 people received an experimental vaccine that proved to be highly effective,15 but the **intervention came too** late for the 28,646 people who contracted the disease during the outbreak and the 11,323 people who died.16 Prior to 2014, the average annual number of cases of Ebola was 62 (deaths: 41), and the largest ever Ebola outbreak, in 2000, infected 425 people, of whom 224 died.17

#### 3 other key factors mean that the plan can’t increase innovation – uncertainty over demand, cures require few doses, and successful cures directly limit potential sales for businesses – all these coalesce into underinvestment in diseases

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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

Producer uncertainty over volume Although some infectious disease products are sufficiently rare to fall within the provisions of the Orphan Drug Act, rarity operates differently in the infectious disease context. Many of the non-infectious diseases that motivated the Orphan Drug Act are rare because the genetic defects that are believed to contribute to those diseases occur infrequently. Because genetic disorders generally persist throughout a person’s life and human genes are transmitted only through inheritance, the prevalence of these disorders is unlikely to change rapidly. By contrast, adaptive microbial mutations, horizontal transmissibility, and the ability of medicines or the immune system to rid the body of microorganisms can sometimes lead to sudden and dramatic changes in infectious disease prevalence. Recent outbreaks of influenza,18 Zika,19 cholera,20 and Ebola demonstrate the unusual volatility of many infectious diseases, including their potential to rapidly create large markets or shrink down into small ones. In extreme cases, global contagion can occur in a matter of months, as happened during the 1917 influenza pandemic,21 which infected an estimated 500 million people of whom 50 to 100 million died.22 On the other hand, development efforts may halt when outbreaks unexpectedly diminish or resolve. Less than two years after the World Health Organization declared Zika an international public health emergency, Sanofi announced it was discontinuing development of two Zika virus vaccines due to a decline of new infections and new limits on U.S. government funding.23 Businesses therefore face great uncertainty when estimating market size for certain infectious disease treatments. This uncertainty is compounded by the limited patent term, since producers must not only correctly predict that contagion will occur, but that it will occur within twenty years of patent filing.24 Cures and preventions require fewer doses than treatments The completeness with which modern-day antibiotics and other antimicrobials can eradicate the underlying cause of once-deadly infectious diseases is one of the great success stories of modern medicine, and contrasts with the chronic or incomplete treatments often available in other disease categories (antiviral medications taken chronically, such as HIV treatments, represent an exception). Yet from a business perspective, rapid therapeutic success limits sales potential, since fully recovered patients no longer need medicine. Drugs in other therapeutic categories that must be taken on an ongoing basis—such as statins for lowering cholesterol or insulin for managing blood sugar in diabetes— provide a much more favorable business model. Similarly, treatments that offer only partial or symptomatic relief, such as many cancer or psychiatric medications, mean that companies have greater opportunities to make small, serial improvements in efficacy and generate revenue from second-, third-, and later-generation products. Unlike the antimicrobial market, the number of people in need of vaccines can be much larger than the prevalence of the corresponding disease, since vaccines may be sold to all those potentially at risk. Vaccines for rare diseases may therefore not qualify under the Orphan Drug Act, which excludes vaccines that would be given to more than 200,000 persons per year, regardless of disease prevalence.25 Despite relatively high patient volume, however, the per-person unit demand for vaccines can be even more limited than it is for cures. Although repeated vaccinations are possible, the CDC adult immunization schedule does not include recommendations for boosters for most vaccines,26 and a patient may receive a given vaccine sequence only once in his or her lifetime. Most vaccine sequences do not exceed three doses,27 and some immunizations consist of a single injection per vaccine or even less: The three-vaccine combination of measles, mumps, and rubella, for example, is recommended as a two-dose sequence,28 or only 2/3 of an injection per vaccine. Positive externalities mean lower volume Products that prevent or resolve infection benefit not only the patients who are vaccinated or treated, but also those who are not consumers of these medical products but whose risk of acquiring the disease is nevertheless mitigated. These positive externalities, which are not present for non-infectious disease products, contribute to high public health value but also mean that some people may free-ride, knowingly or unknowingly, by relying on or benefiting from others who obtain treatment while declining or not needing to pay for the treatment themselves.29 Effective products undermine their own markets To the extent a medicine is effective in preventing further transmission—one of the key benefits that produces high public health value—it prevents growth in market demand. At the extreme, eradication of an infectious disease (as with smallpox in the 1970s) could cause a market for an antibiotic or other antimicrobial product to collapse, creating tremendous public health value but entirely eliminating sales potential. By contrast, if a cure were developed for a non-infectious disease, the potential market for that medicine would never fall below the incidence rate, that is, the number of people who are newly diagnosed with a disease during a give time period. In exceptional cases, a collapsed market might be buoyed if fear of terrorism or other disease resurgence prompts governments to hedge against unlikely risks. In 2011, for example, the U.S. government committed $433 million to obtain 1.7 million doses of a smallpox antiviral medication, which supplements its existing $1 billion stockpile of smallpox vaccine.30 Few diseases, however, are likely to prompt similar funding.31

#### Competition will not solve any of these issues – competition or monopoly won’t be able to make investments in anti-ineffective drugs profitable at best the plan will get companies to leave the market causing shortages

Alpern, Dunlop, and Stauffer 19 – Division of Infectious Diseases, Department of Medicine, HealthPartners, Minneapolis. Department of Emergency Medicine, Hennepin County Medical Center, Minneapolis, Minnesota. Division of Infectious Diseases, Department of Medicine, HealthPartners, Minneapolis, Minnesota.

Jonathan Alpern, Stephen Dunlop, and William Stauffer, April 11 2019, “Broken drug markets in infectious diseases: Opportunities outside the private sector?” PLOS, https://journals.plos.org/plosntds/article?id=10.1371/journal.pntd.0007190

While policies aimed at encouraging generic manufacturer competition or outlawing price gauging may be effective for keeping prices reasonable for high-volume drugs (i.e., EpiPen for anaphylaxis), these solutions will likely be ineffective for drugs in low demand in the US, including many important anti-infective drugs. Many of these drugs have characteristics that make the market in the US nonviable: off-patent, cheap to manufacture, very limited volume for potential sales, and frequently used for neglected infections that affect low-income populations.

Pharmaceutical companies that sell these drugs are faced with difficult choices: continue to sell at minimal profit (or a loss), withdraw from the market, raise prices, or sell the license to a third party. Current policy solutions and public attention has been directed at pharmaceutical companies cornering the market for an essential drug and charging “what the market will bear” [[4](https://journals.plos.org/plosntds/article?id=10.1371/journal.pntd.0007190#pntd.0007190.ref004)]. We are concerned that, in the case of well-intentioned drug price gouging legislation, there may be unintended consequences that threaten the availability of these important drugs. Forced to charge reasonable prices, companies may discontinue manufacturing of drugs with a small market share and limited, or no, profit potential. For drugs with a single manufacturer, this could lead to a drug’s withdrawal from the market all together.

Consider the monopolized antiparasitic drug market that has exhibited steep price increases recently [[5](https://journals.plos.org/plosntds/article?id=10.1371/journal.pntd.0007190#pntd.0007190.ref005)]. Prior to the popularity of this business model, few manufacturers were attracted to this space due to limited profitability, and drug discontinuation from the US market was common. Some of these withdrawn drugs remain commercially unavailable, such as quinacrine (giardia), niclosamide (tapeworm), and diethylcarbamazine (filarial diseases) [[6](https://journals.plos.org/plosntds/article?id=10.1371/journal.pntd.0007190#pntd.0007190.ref006)]. More recently, in December 2017, the sole manufacturer of intravenous quinidine gluconate discontinued manufacturing for reasons not related to safety or efficacy, with plans to continue product distribution only through March 1, 2019 [[7](https://journals.plos.org/plosntds/article?id=10.1371/journal.pntd.0007190#pntd.0007190.ref007)]. Quinidine is the only FDA-approved intravenous drug available for the treatment of severe malaria in the US. While the reasons for discontinuation have not been publically disclosed, limited profitability due to low demand in the US is likely the primary factor. Historically, its primary use in the US has been treating atrial and ventricular arrhythmias, not malaria, and use has decreased with the adoption of safer antiarrhythmic drugs. Since US providers and hospitals will no longer have access to parenteral quinidine, parenteral artesunate will need to be acquired from the Centers for Disease Control (CDC). Although artesunate is considered first-line therapy for severe falciparum malaria, the drug is not currently FDA approved in the US and is available solely through the CDC as an investigational new drug (IND). Access to artesunate requires obtaining permission from the CDC, shipment from one of quarantine station repositories, obtaining emergent approval from an Institutional Review Board and patient consent, resulting in delays in administration. The FDA approval of artesunate would be a welcome development, ensuring improved access to treatment for a disease that can be fatal in hours. However, with quinidine now unavailable—even in the best circumstances—there will be delays in therapy for patients with severe malaria infection until there is an FDA approved drug available in the U.S that is standard of care for treatment of severe malaria.

The fragility of high-value but low-volume drugs is perhaps best exemplified by the arsenal of drugs for multidrug-resistant tuberculosis (MDR-TB). Of the first- and second-line drugs indicated for the treatment of MDR-TB (n = 12), over one-half have two or fewer manufacturers, and five of these drugs are produced by only one manufacturer ([Table 1](https://journals.plos.org/plosntds/article?id=10.1371/journal.pntd.0007190#pntd-0007190-t001)). While these drugs are at risk for exploitative pricing strategies—as occurred briefly with Seromycin (cycloserine)—the lack of generic competition in this space and the small market suggests that drug discontinuation and withdrawal from the market is another risk.

When important drugs are withdrawn from the US market for reasons other than safety or efficacy, there are limited mechanisms to ensure they remain available to patients that need them. The CDC drug service currently stocks 12 biologic agents and drugs considered essential for public health that are not available through commercial avenues [[9](https://journals.plos.org/plosntds/article?id=10.1371/journal.pntd.0007190#pntd.0007190.ref009)]. Many of these drugs are obtained through foreign sources and lack FDA approval, requiring the CDC to sponsor an IND in order to legally distribute them in the US. Although the CDC formulary is an important resource for individual patients, relying on this drug service as a “safety net” for essential drugs—if more are withdrawn—is tenuous. Multiple barriers exist, including the lack of a mechanism for drug distribution (currently done on an individual patient basis) and timeliness for severe diseases such as malaria.

Meanwhile, for-profit pharmaceutical companies remain unreliable sources for drugs that are essential to human health but have limited profit-generating potential. For drugs with these characteristics, the market is broken because companies either corner the market and charge “what the market will bear,” or sell the drug at a reasonable price, which limits profitability. In the latter example, withdrawal from the market becomes a risk, as occurred with intravenous quinidine. Therefore, relying on the free market for a rational solution seems futile and other policy solutions are needed.

## 1NR

### PIC Per Se

#### We have a more precise understanding – Prohibit means to forbid a given practice – that’s distinct from restrictions

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.

#### Dictionary definitions are clear that a prohibition is a sweeping proclamation, and does not take into account specific circumstances

Sweet 03 – Judge, United States District Court, New York Southern

Robert W. Sweet, Am. Nat'l Fire Ins. Co. v. Mirasco, Inc., 249 F. Supp. 2d 303, United States District Court for the Southern District of New York, March 2003, LexisNexis

In any case, even if the word "embargo" does not stretch so far, there is no doubt that the restriction against the importation of all IBP goods constitutes a "prohibition" under Clause D. HN15 "Prohibition" is defined by Black's Law Dictionary to be "a law or order that forbids a certain action." Black's Law Dictionary 1228 (7th ed. 1999). The dictionary definition is similar: "a declaration or injunction forbidding some action." Webster's New International Dictionary, Unabridged 1978 (2d ed. 1944). The common understanding of the word "prohibition" has similar connotations, with one exception. As Mirasco points out, any governmental action -- including the rejection on which insurance coverage is based -- could potentially be deemed a prohibition under the definitions above as a declaration forbidding the entry of goods. Therefore, a prohibition must be qualitatively different from a rejection. That difference is that the prohibition occurs prior to the government's dealing with the specific cargo at issue and is of a more sweeping nature than the simple administrative function performed by customs officials determining whether or not goods should be permitted into the country. Decree # 6 is such a prohibition, in that it was a law or declaration -- issued prior to, separate from and broader than the Egyptian authorities' administrative determination of whether the M/V Spero cargo should be permitted entry -- that forbids the importation of IBP products.

#### Any alternate interpretiation would actually be a regulation which is NOT mandated by the plan

Feldman 86 – Member of Procopio's Native American Law practice

Glenn M. Feldman, On Appeal from the United States Court of Appeals for the Ninth Circuit, California v. Cabazon Band of Mission Indians, 1986 U.S. S. Ct. Briefs LEXIS 1221, Supreme Court of the United States, 1986, LexisNexis

In arguing that California's bingo laws are prohibitory rat ther than regulatory, the appeallants have simply misunderstood the fundamental distinction between "prohibition" and "regulation" of conduct. As succinctly put by the Supreme Court of Washington more than 50 years ago, after noting that the prohibition and regulation of the sale of liquor are entirely different things: "To prohibit the liquor traffic implies the putting a stop to its sale as a beverage, to end it fully, completely, and indefinitely." In contrast, regulation "implies that the sale of intoxicating liquor shall go on within the bounds of certain prescribed rules, restrictions, and limitations." Ajax v. Gregory, 32 P.2d 560, 563 (Wash. 1934). Because regulation of conduct involves prescribing limitations, regulation, by definition, necessarily involves some degree of prohibition. Blumenthal v. City of Cheyenne, 186 P.2d 556, 566 (Wyo. 1947). The two concepts, however, are analytically distinct. Therefore, when courts have been faced with statutory schemes similar to California's bingo laws, they have consistently held them to be regulatory and not prohibitory.

#### Court consensus

Hadley 1909 – Judge

Hiram E. Hadley, McPherson v. State, 174 Ind. 60, Supreme Court of Indiana, December 1909, LexisNexis

In the majority opinion it is conceded "that there is a marked difference" between unqualified prohibition of the sale of intoxicating liquors and the regulation of such sale. It is said in the opinion that "to regulate, restrict and control the sale implies that the sale shall go on within the bounds of certain prescribed rules, restrictions or limitations." Citing Sweet v. City of Wabash (1872), 41 Ind. 7; Duckwall v. City of New Albany (1865), 25 Ind. 283; Loeb v. City of Attica (1882), 82 Ind. 175, 42 Am. Rep. 494.

"Prohibition," states the majority opinion, "as applied to the liquor traffic, implies putting a stop to its sale as a beverage; to end it fully, completely and indefinitely. So, if the purpose of the act in question is to authorize the exercise of unqualified prohibitory power, as usually understood by the term, the act is void because its subject is not expressed in the title." The court might properly have further said [\*\*\*45] that if the act under its provisions is not one to regulate the sale of intoxicating liquors it is void, for the reason that it does not meet or respond to the subject as expressed in its title.

#### The term “prohibitions” is unambiguously applicable to bans.

Espa 17 – Senior Assistant Professor of International Economic Law at the Università della Svizzera italiana (USI), Senior Research Fellow at the World Trade Institute (WTI), Adjunct Professor at the Law Faculty of the Università Cattolica del Sacro Cuore

Ilaria Espa, “Climate, energy and trade in EU–China relations: synergy or conflict?,” China-EU Law Journal, Vol. 6, June 2017, https://link.springer.com/article/10.1007/s12689-017-0076-0

7 The term ‘prohibitions’ unambiguously applies to measures that impede exports outright (i.e. export bans). Hence, it has not created interpretative problems. Ibid., p. 170.

#### A prohibition implies the entire destruction of the subject-matter in question---that’s distinct from regulation that allow for continuance.

Ellison 1905 – Judge, Missouri Supreme Court

George Robb Ellison, State ex rel. Sheffel v. McCammon, 111 Mo. App. 626, Court of Appeals of Missouri, Kansas City, April 1905, LexisNexis

Under power conferred on cities of the fourth class "to regulate and to license" dramshops, there is no authority to wholly prohibit or suppress. Where [\*\*\*10] there is mere power in a municipality to regulate in a State with a general policy of conducting licensed saloons, authority to prohibit is excluded. "The difference between regulation and prohibition is clear and well marked. The former contemplates the continuance of the subject-matter in existence or in activity; the latter implies its entire destruction or cessation." Black on Intox. Liq., section 227; 17 Amer. & Eng. Ency. Law (2 Ed.), pp. 285, 286; 1 Dillon on Munic. Corp. (3 Ed.), section 357, note 2, section 363 and notes; Berry v. Cramer, 58 N.J.L. 278, 33 A. 201; Steffy v. Monroe City, 135 Ind. 466, 35 N.E. 121; Champer v. Greencastle, 138 Ind. 339, 35 N.E. 14; Ex parte Hinkle, 104 Mo. App. 104, 78 S.W. 317.

#### Affirmatives that allow the conduct they affect to continue to a certain extent or which subject that conduct to certain conditions are imposing restrictions, not prohibitions.

Groves 97 – Solicitor with Pritchard Englefield, the City law firm, specialising in intellectual property law

Peter Groves, Sourcebook on Intellectual Property Law, Google Books

Then I come to the word ‘restrict’. A person though not prohibited is restricted from using something if he is permitted to use it to a certain extent or subject to certain conditions but otherwise obliged not to use it, but I do not think that a person is properly said to be restricted from using something by a condition the effect of which is to offer him some inducement not to use it, or in some other way to influence his choice. To my mind, the more natural meaning here is restriction of the licensee’s right to use the article and I am fortified in that opinion by two considerations.

### Access

#### 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.

#### 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.

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#### Their ev concededs – it’s about narcotics generally

Grinberg ’19 [Alexander Grinberg, U.S. Army officer, “Is Mexico a Failing State?” Strategy Bridge, Reeal Celar Defense, 2—7—19, <https://www.realcleardefense.com/articles/2019/02/07/is_mexico_a_failing_state_114170.html>, accessed 5-15-20]

Mexico is a fragile state, and without action, faces the risk of becoming a failing, or worse, a failed state. The Organisation for Economic Cooperation and Development defines a fragile state as one that is “unable or unwilling to perform the functions necessary for poverty reduction, the promotion of development, protection of the population and the observance of human rights.” In 2009, U.S. Joint Forces Command released a statement expressing concerns over Mexico, highlighting the potential even then for a total collapse. At the time, then-President Felipe Calderón responded to the report, stating it was entirely false; allegedly, he even wanted President Obama to release a statement to that effect.

In August 2018, the State Department released a do-not-travel warning for five of the thirty-two Mexican states. Many other states are still considered dangerous, and the U.S. State Department has advised American tourists caution if not total reconsideration. The warning indicates a lack of stability and control on the government’s part in the region. The Mexican government is in a prolonged state of civil war with various cartels, and the state is losing. Rampant corruption from the local to federal level breaks down the fundamental principal-agent relationship between the government and its population, encouraging locals to turn to militias for protection. The militias are, in part, a result of widespread corruption as well as the Mexican military’s deterioration. Mexico’s military faces large numbers of desertions, while measures to provide security for its population continue to fail. The United States should continue to treat Mexico as a welcome economic partner but accept that Mexico is a fragile state, and thus a serious security risk.

The drug war in Mexico is escalating, and it is creating a spillover effect in the United States. In the United States, the majority of the concern from the Mexican drug war focuses on its impact on the opioid epidemic, a growing topic in both countries. According to the U.S. Centers for Disease Control, the total economic burden for opioid misuse, often leading to heroin abuse, is $78.5 billion a year. CNN reported that from 2002 to 2016 the number of heroin users increased from 404,000 to 948,000, a 135% increase. The opioid epidemic is part of the drug war in Mexico, where violence spills over. Demand in the United States for narcotics profit drug trafficking organizations and money is then laundered back to the cartels

who use these funds to purchase weapons in order to take more territory or assert control in Mexico.

#### Mexico will never collapse

Neil Couch, Brigadier, British Army, “Mexico in Danger of Becoming a Collapsed State. Reality or Exaggeration?” Defence Studies, 13:2, 152-191, ‘13

The evidence indicates that the Pentagon’s **apocalyptic horizon-gazing was** exaggeration. The **conjecture** may have arisen from a failure to understand the nature of the ‘war’, to paraphrase Clausewitz. The US’s inclination to classify it as an insurgency, George Bush’s judgement on the threat from failed states and assessments of Mexico’s poor progress all add up to make the Pentagon’s prognosis **understandable**, but nonetheless flawed. However, if Mexico is not failing, it certainly is not winning in its drug war. The flow of arms, drugs and money in and out of the country continues undiminished and the number of deaths each year continues to rise. What is surprising, therefore, is the extent to which the country **confounds** the **predictions** of theories **that indicate looming weakness.** The inability to provide security throughout the country and to control its borders should be expected to undermine the rule of law and thus state legitimacy, as should the corruption that causes lack of confidence in key institutions such as the police and judiciary. The scholarly work that this paper has referenced indicates that organised crime and corruption pose challenges to Mexico’s legitimacy, rule of law and institutions similar to those described in the theory of state failure. Crime and corruption threaten its economy. The media are not unfettered. The police forces may not be ‘paralysed’, but are distrusted and ineffective. The military is one of few, if not the only, institutions that retains its integrity, despite being unable to ‘secure the population from violence and fear’ across the ‘whole of its domain’. Mexico’s borders are not fully controlled. Drug barons, though not warlords, act as alternative suppliers of services, such as protection and community projects. The legal system and judicial framework are not structured to deliver justice equitably. The economy is underperforming, as is the delivery of public goods and services. However, Clausewitz, Garzon and Rotberg explain why **these are not existential threats.** The aim of the gangs is to **make money** and they use violence and corruption only to shape the environment in order to do so. **They have no political agenda**. Their violence is not ‘politics by other means’ nor is it directed at the regime in order to gain greater autonomy, political power or concessions. The majority of the violence is internecine, **between gang members**; security forces are engaged only when they interfere with the narco-traffickers’ business. In fact, it is possible the gangs would not want the state to fail. They rely on protection from compromised elements of the state and on the infrastructure and services that enable them to continue their business and which allow them to enjoy their profits. **The error**, therefore**, lies in confusing the motives of drug gangs with** those of terrorists and **insurgents**.

### Econ

#### This isn’t a one off, consensus of studies

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Ameet Sarpatwari, Jonathan DiBello, Marie Zakarian, Mehdi Najafzadeh, Aaron S. Kesselheim, July 20 2019, “Competition and price among brand-name drugs in the same class: A systematic review of the evidence,” Plos Medicine, https://journals.plos.org/plosmedicine/article?id=10.1371/journal.pmed.1002872#sec012

The studies in our review **did not find a price-lowering effect** of new drug entry on intraclass brand-name products. Examining the H2 blocker market from 1977 to 1993—when no generics were present—Berndt and colleagues found that the average price per patient-day of the first-in-class drug cimetidine (Tagamet) fell from about $1 to $0.80 before facing competition [[17](https://journals.plos.org/plosmedicine/article?id=10.1371/journal.pmed.1002872#pmed.1002872.ref017)]. Introduction of ranitidine (Zantac) at $1.25 per patient-day in 1983, however, did not depress the price of cimetidine further. Instead, prices of both drugs increased over time, with a faster rate of increase observed for cimetidine. This upward trajectory persisted with market entry of famotidine (Pepcid) in 1986 and nizatidine (Axid) in 1988. By the end of the study period, the average price per patient-day of cimetidine had increased 44% to $1.44, while the average price per patient-day of ranitidine had increased 13% to $1.41.

Studying the anti-infective market from 1984 to 1990, Wiggins and **Maness failed to detect an association between a drug’s price and the number of existing “related” products** [[19](https://journals.plos.org/plosmedicine/article?id=10.1371/journal.pmed.1002872#pmed.1002872.ref019)]. The nonsignificant effect was far smaller than that observed for “brand-generic” competition, which occurs when interchangeable generic versions of brand-name drugs made by different manufacturers emerge after market exclusivity expires. However, the investigators did not focus on the impact of new drug entry, and their category of related products may have included generic and brand-name versions of intraclass competitors.

Bokhari and Fournier assessed the market for attention deficit/hyperactivity disorder stimulants between 1993 and 2003 [[20](https://journals.plos.org/plosmedicine/article?id=10.1371/journal.pmed.1002872#pmed.1002872.ref020)]. Despite the introduction of 8 new brand-name drugs over this period, the average retail price of only 1 of the 7 brand-name drugs available at the start of the study period decreased. Complicating the interpretation of the analysis, however, the market also featured generic versions of 2 drugs within the class (immediate- and extended-release methylphenidate and pemoline) at study initiation.

Covering the period 1993 to 2013, Hartung and colleagues evaluated drugs for multiple sclerosis [[21](https://journals.plos.org/plosmedicine/article?id=10.1371/journal.pmed.1002872#pmed.1002872.ref021)]. The annual treatment price of the first-generation agents interferon-β-1b (Betaseron), interferon-β-1a (Avonex), and glatiramer (Copaxone) increased from $8,292–$11,532 (initial range) to $59,158–$61,529 (ending range) over this time notwithstanding the market entry of interferon-β-1a (Rebif) in 2002, natalizumab (Tysabri) in 2004, interferon-β-1b (Extavia) in 2009, fingolimod (Gilenya) in 2010, teriflunomide (Aubagio) in 2012, and dimethyl fumarate (Tecfidera) in 2013. Following the introduction of interferon-β-1a (Rebif) and the reintroduction of natalizumab in 2006 (after its withdrawal for safety concerns).

Gordon and colleagues assessed 24 injectable cancer drugs approved between 1996 and 2012 [[24](https://journals.plos.org/plosmedicine/article?id=10.1371/journal.pmed.1002872#pmed.1002872.ref024)]. The mean annual i**ncrease in the monthly cost of these drugs was 3.7%**, more than double the mean annual health-inflation rate (1.2%). Only 1 drug, ziv-aflibercept (Zaltrap), experienced a price decline. In multivariate modeling, the **introduction of new brand-name competitors was not associated with price changes** of existing drugs on the market.

Finally, San-Juan-Rodriguez and colleagues evaluated the price changes of TNF inhibitors between 2006 and 2016 [[22](https://journals.plos.org/plosmedicine/article?id=10.1371/journal.pmed.1002872#pmed.1002872.ref022)]. The investigators found that the mean annual cost of the 3 TNF inhibitors approved prior to 2009—adalimumab (Humira), etanercept (Enbrel), and infliximab (Remicade)—increased 144% between April 2009 and December 2016 despite the market entry of 3 new TNF inhibitors: golimumab (Aria), certolizumab pegol (Cimzia), and intravenous golimumab (Simponi Aria). An interrupted time-series analysis revealed that this increase was over 4-fold greater than what would have been expected if the new products were not introduced and secular trends had continued. Although the gross cost of the treatments under Medicare Part D experienced a similar trajectory, the annual out-of-pocket costs by patients in the program remained relatively stable.

#### Even if they reduce prices the gains won’t be passed onto consumers – pharmacies and insurance will charge the same!

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Marty Schladen, May 28 2021, “Eleven generic versions of an HIV drug rush onto the market… and list prices go up,” Ohio Capital Journal, https://ohiocapitaljournal.com/2021/05/28/even-with-11-generic-competitors-prices-for-one-drug-remain-a-lot-higher-than-they-need-to-be/

The health care system is supposed to incentivize the development of wonder drugs and then apply market forces to squeeze prices to a minimum. But a new report shows how at least for one drug, incentivizing is working a lot better than price-squeezing.

At least when insurance is involved.

For example, [Blueberry Pharmacy](https://blueberrypharmacy.com/) in the Pittsburgh area opted out of the traditional insurance system. It can offer versions of a new generic for $25 a month, while programs connected with middlemen and insurance companies are offering it for $75 in the best instance and often for more than $1,000.

The example illustrates how prices of most generic drugs are wildly inflated in a bewildering system of insurers and the middlemen they use to handle the transactions, Blueberry owner Kyle McCormick said.

And, he added, they do so when prices for the vast majority of generics are so low that the expense doesn’t need to be insured against the way you would against having to buy a new car or house or to get a heart transplant.

“Most generic medications are less than a bottle of Tylenol,” McCormick said. “We don’t need to pay for insurance to cover a bottle of Tylenol.”

Here’s how the system’s supposed to work: Drugmakers are granted patents so they have exclusive rights to sell new medicines and charge high prices for a period. That way they can recoup their research costs and turn a profit.

The profits the high prices bring give drugmakers a reason to go looking for the next new drug. And the next.

The way the system’s supposed to work, as patents expire, so does the drugmaker’s exclusive right to produce it. Other manufacturers can swoop in with their own generic versions and ruthlessly undercut one another until the price of the drug is as cheap as possible while still being profitable for a company to make.

But the great majority of those paying for generic Truvada are unlikely to see anything close to those minimum prices even though its patent expired in late 2020 and 11 generic versions subsequently swarmed into the marketplace, [46brooklyn Research](https://www.46brooklyn.com/), a nonprofit drug analysis firm, wrote in a [report](https://www.46brooklyn.com/news/2020/25/generic-truvada-launch)that was published Tuesday.

It analyzed [Truvada](https://www.truvada.com/what-is-truvada/understanding-truvada), an antiviral drug that greatly reduces the risk of contracting Human Immunodeficiency Virus — which causes AIDS — and can slow the progress of the disease in those who have contracted it when combined with other medications.

There was keen interest in producing generic versions of brand-name Truvada, with eight companies bringing products to market on the last two days of March alone. Increased competition cut the cost for pharmacies to buy generic Truvada by 90% off of the $1,800 for the brand-name version of the drug, the report said.

That might seem like the invisible hand of the market doing its stuff.

“However, this announcement, while welcomed, may miss a key point: Will patients actually see these generic savings at the pharmacy counter?” the analysis asked, suggesting that middlemen involved with insurers would ensure they won’t.

There is a tangled web of reasons why most customers at the drug counter won’t see that 90% price drop, according to the report’s authors.

One is that pharmacists working with insurers don’t see it as in their interest to pass the discount along.

Insurance companies that provide prescription benefits hire pharmacy benefit managers to administer them. The middlemen contract with networks of pharmacies, negotiate with drugmakers, decide which drugs are covered and determine how much to reimburse pharmacies for the drugs they dispense.

The pharmacy benefit managers, or PBMs, have enormous leverage over the other players in the drug supply chain. Three — CVS Caremark, OptumRx and Express Scripts — control more than 70% of the market, Ohio Attorney General Dave Yost said recently in a [lawsuit](https://ohiocapitaljournal.com/2021/04/12/conflicting-corporate-claims-at-the-heart-of-ohios-blockbuster-medicaid-suit/).

That means that if drugmakers and pharmacies want access to PBMs’ millions of clients, or “covered lives,” they have to do business with those three companies.

Insurers, too, want access to the bargaining power of the big three PBMs, although each now belongs to a corporation that also owns a big insurer. CVS owns Aetna. OptumRx is owned by UnitedHealth. And Express Scripts is owned by Cigna.

The PBMs typically reimburse pharmacies based on the lesser of two, seemingly arbitrary numbers: the “usual and customary” charge — or “cash” price — determined by the pharmacy and the “maximum allowable cost” determined by the PBM.

Ohio community pharmacists have for years been saying that the big PBMs use a non-transparent set of cost lists to cut reimbursements to the bone, in some instances [not even covering their cost](https://www.dispatch.com/news/20180312/cvs-accused-of-using-medicaid-rolls-in-ohio-to-push-out-competition) to dispense a drug. Those low reimbursements give pharmacies an incentive to keep cash prices high in non-insured transactions so they can make up for low PBM reimbursements, the 46brooklyn report said.

So if you go to pharmacies that rely on business with insurers and PBMs and ask for the cash price of generic Truvada, it’s likely to be much, much more than the $25 or so it would cost on the open market, the report said.

What your insurance company and government programs like Medicare and Medicaid are paying is likely to be a lot higher, too.

PBM reimbursement data are confidential, but one window onto how much more might be seen through the aggregator [GoodRx](https://www.goodrx.com/" \t "_blank). It groups patients not using insurance to cover their drugs and contracts with the PBMs to get pharmacies in their networks to discount their “cash” prices.

When 46brooklyn shopped GoodRx on May 17, the lowest retail pharmacy price it could find for generic Truvada was $112 — more than four times what it would cost a pharmacy working outside the insurance-PBM system to buy and dispense.

For mail order, the lowest price on GoodRx was $75. That’s about three times the price that Blueberry Pharmacy, which opted completely out of the insurance-PBM system, can sell it for.

The big PBMs have set up their own, GoodRx-like networks and their prices were almost as high as brand-name Truvada: $1,606 for OptumRx’s Optum Perks and $1,105 for Express Scripts’ Inside Rx, the report said.

And Amazon, that great disruptor that’s supposed to be reintroducing market forces to drug pricing? It’s charging $1,566 — or 8,000% — of what Blueberry’s McCormick says he can sell the drug for.

Greg Lopes is a spokesman for the Pharmaceutical Care Management Association, an industry group that represents PBMs. He said the group’s members save consumers money on generics as well as more-expensive brand-name and specialty drugs.

“America’s pharmacy benefit managers, PBMs, have a long history of supporting generic drugs to lower prescription drug costs for patients,” Lopes said in an email. “The key to lowering prescription drug costs is through enhanced competition among brand-name drugs from generic and biosimilar medications.”

However, the 46brooklyn analysis described another way American system of pricing drugs drives costs to consumers up instead of down.

When PBMs negotiate with manufacturers for discounts on generic drugs, they ask for a big cut off of the “average wholesale price” set by the manufacturer.

These can be discounts in excess of 80%, so that gives manufacturers an incentive to set an inflated average wholesale price. That way, the manufacturer will get 20% of a bigger number.

In the case of generic Truvada, the average wholesale price the 11 manufacturers came up with was indeed inflated. At $2,100, it was more than 15% higher than the cost of brand-name Truvada before the patent expired — and 84 times as much as Blueberry Pharmacy can sell it for.

So much for generic competition bringing down list prices.

“There’s some rent-seeking going on,” McCormick said. “There’s no way you can use insurance and not see prices go up.”

If, as the 46brooklyn report asserts, “cash” and wholesale prices for generics in the insurance-PBM system are artificially and wildly inflated, those prices might seem to be just that: artificial. But with most insured Americans now on [high-deductible plans](https://www.valuepenguin.com/enrollment-changes-to-high-definition-health-insurance-plans#:~:text=Fifty%2Done%20percent%20of%20the,over%20the%20past%20five%20years.)and for [33 million more](https://www.cdc.gov/nchs/fastats/health-insurance.htm) without any insurance, that inflation can mean much higher generic costs at the pharmacy counter.

As with Pittsburgh’s Blueberry, Columbus-area pharmacist Nate Hux decided to take a big step out of that system, opening [Freedom Pharmacy](https://www.facebook.com/freedom.pharmacy.oh/) in December. He’s still operating his Pickerington Pharmacy under the PBM-insurance system the same way the vast majority of American pharmacies do.

But he decided that for most generic medications, that system just doesn’t make sense.

“People have been brainwashed for so long to believe that these (insurance) cards bring value, but they really don’t,” he said. “They only make the rich richer and keep everybody else poor.”