## 1NC

### Core CP

#### TEXT: The United States federal government should:

#### prohibit further expansions of the scope of its core antitrust laws

#### pass a statute which prohibits   anti-competitive business practices that artificially extend medical patents of drugs that share bioequivalence.

#### grant the Federal Trade Commission a primary responsibility for issuing regulations prohibiting anti-competitive business practices that artificially extend medical patents of drugs that share bioequivalence

#### provide *chevron* deference to the regulations prohibiting anti-competitive business practices that artificially extend medical patents of drugs that share bioequivalence under the new statute

#### It’s competitive---the CP doesn’t expand existing antitrust laws, bans the aff, and establishes a new law that regulates anticompetitive conducts

#### That solves the aff---the plan relies on the core antitrust law’s common law framework to regulate “new” anticompetitive practices, which necessarily requires judicial overreach

Sitaraman 18 (Ganesh Sitaraman is Professor of Law at Vanderbilt Law School and the author of The Crisis of the Middle-Class Constitution, “Don't trust the courts to fight monopolies. They are a barrier to progress,” 10-26, <https://www.theguardian.com/commentisfree/2018/oct/26/antitrust-monopolies-courts-concentration>, y2k)

America has a concentration problem. Across the political spectrum – from progressives like Joe Stiglitz to centrists at Brookings and conservatives at Breitbart – experts and commentators agree that antitrust needs to be a priority. But there has been significant debate on what to do: do we need more enforcement or new laws? Is the problem technical or ideological? This year, one thing has become clear: the courts are a barrier to making progress in fighting the new age of monopoly power – and reform will have to involve taking antitrust away from the courts.

Some background will be helpful. Antitrust policymaking differs from virtually every other area of policymaking. In other areas of policymaking, Congress passes laws commanding government agencies to regulate different areas. The EPA regulates pollution in air and water. The National Highway Transportation Safety Administration ensures that cars and trucks are safe. The Consumer Products Safety Commission oversees children’s toys. Each agency is filled with experts in these fields, and they rely on this expertise in issuing regulations. They are also required to follow an extensive process to receive input from industry and from the general public. Courts do review regulations, but they grant significant deference to the agency’s expertise.

In antitrust law, the courts have become the primary expositors of antitrust policy

Antitrust isn’t like this. In antitrust law, the courts have become the primary expositors of antitrust policy. They interpret the main antitrust statutes in a “common law” fashion – in other words, judges have embraced the role of policymakers. This is a serious problem. First, in our constitutional system, judges are not supposed to be policymakers. They are supposed to interpret the laws and review regulations to ensure they are not outside the scope of the law. Second, the courts have no expertise in the economy. They don’t conduct studies or investigations, and certainly can’t keep up with our dynamic, fast-moving business sector. The courts thus make policy by relying on the parties in a case and on amicus briefs, and the result is an unbalanced set of intellectual inputs. Third, the courts are not politically accountable. The judicial process has limited public participation and oversight. Judges can’t be fired for coming up with the wrong decisions. And it is very difficult for Congress to fix an incorrect judicial decision. These are all virtues when judges are interpreting the constitution and the laws, but they are vices when judges become policymakers.

#### New statutory framework solves the aff---it doesn’t require expanding existing antitrust jurisprudence under core antitrust laws and allows for more direct regulations of anticompetitive practices

Paquette 17 (Jenny Paquette Associate Attorney at Narayan Travelstead PC. Kessler Topaz Meltzer & Check, LLP, Temple University - James E. Beasley School of Law, OLD IS NOT ALWAYS WISE: THE INAPPLICABILITY OF THE SHERMAN ACT IN THE AGE OF THE INTERNET, 89 Temp. L. Rev. Online 2, y2k)

II. DISCUSSION

The Sherman Act is outdated for purposes of attempting to regulate search engines. However, it is still applicable to industries that use business models [\*30] similar to those used at the time of its enactment. The Sherman Act is not a good fit for newer industries, but antitrust regulation is still needed for consumer protection. As such, a new statutory framework is needed.

To provide the necessary flexibility to handle new and evolving industries, an industry-specific framework should be enacted. Intellectual property law, which includes several doctrines tailored to fit particular needs but connected by one unifying purpose, provides an instructive framework on which Congress should model such a new statutory framework. A divided framework would allow for an individualized statutory framework and unique handling of Internet businesses. Under such a proposed new system, courts would have the flexibility to allow Google the freedom to act in a manner that benefits consumers. Additionally, such a new framework would allow courts to step in to halt Google's actions if they ever lead to anticompetitive harms that outweigh consumer benefits.

A. Competition is Good, But Chaos is Not: Why We Still Need Antitrust

Though the Sherman Act may not be a workable option for combatting anticompetitive actions in Internet companies, it is still applicable for traditional industries. Additionally, the general purpose of antitrust law is still applicable for all industries. Consumers are still consuming, so there is still a need for their protection as they do so. While antitrust generally is still needed, the Sherman Act as a specific framework is outdated.

The Act predates much of the current technology, and thus many of the related industries, that operate in the world today. When the Act was enacted in 1890, the United States was in the midst of a massive expansion of its industries, [\*31] which were primarily manufacturing, agriculture, and railroads. Since the Sherman Act's enactment, the advent of airplanes has drastically increased the globalization of commerce. Changes in communication technology have also altered the development of commerce as we increasingly rely on computers and the Internet. As the first home Internet connection came a century after the Sherman Act was enacted, it's impossible to fathom that the drafters imagined the state of commerce as it exists today.

Regardless of the possible legislative intent that existed at the time of its enactment, the Sherman Act has since been used as a consumer protection statute. Although commerce has evolved, many of the same concerns regarding consumer protection remain. Cartelization, price fixing, horizontal agreements, and other anticompetitive behaviors are still possible, and the Sherman Act is still competent to address these issues in traditional industries. Even some industries [\*32] relying on newer technology are suitable for analysis under the Sherman Act as the business models remain largely similar to those that existed in 1890.

Antitrust law must be changed in order for it to apply to nontraditional industries that use business models unsuitable for a Sherman Act analysis. This area of law cannot be abandoned altogether, as some scholars have suggested. Some of today's most profitable industries, such as Internet search engines, did not even exist in the most fledgling fashion when the Sherman Act was enacted. As the business models of some new industries are vastly different from what existed in 1890, the potential for consumer harms also differs. The scope of markets and what constitutes an "anticompetitive act" in such nontraditional industries can vary greatly from what is seen in traditional industries.

Attempting to apply an outdated statutory framework comes with a risk of inapplicability. The FTC's 2012 investigation of Google did not culminate in a lawsuit because the FTC found that Google only disadvantaged its competitors, [\*33] not competition. While this was the correct outcome, even if it were not, there was no appropriate alternative. Even if the FTC found that Google was acting in an anticompetitive manner, it is unlikely that a lawsuit against Google would have prevailed due to a lack of evidence of consumer harm. If a court found that Google was intentionally disadvantaging its rivals, it would be appropriate to hold Google liable under a traditional antitrust analysis. However, because Google was acting with the pro-consumer purpose to improve its search engine, such a holding would have been contrary to the goals of promoting consumer welfare.

Due to the multisided structure of a search business model, any action taken by Google potentially impacts users, advertisers, and Google's competitors simultaneously. As such, Google may help one of these groups while also harming another without incurring liability. Ignoring potential harms to competition renders an antitrust framework underinclusive and inapplicable to a goal of promoting competition. However, holding against Google for actions harming competitors would be overinclusive as it would thwart actions that benefit consumers. For antitrust to apply to search engines and other nontraditional industries, a more flexible antitrust framework is needed to avoid such issues of overinclusiveness and underinclusiveness.

B. Divide and Conquer: An Industry-Specific Approach to Antitrust

To create an antitrust system that is applicable to a vast array of businesses, it is necessary to create several doctrines that are able to evolve independently of one another. This will accommodate the great variations between industries. A multipart framework should be created for antitrust analysis of modern businesses. This framework should also permit the creation of additional categories as needed for unforeseen developments in technology.

Most businesses can be lumped into industry categories. Examples include energy (including oil and gas), industrial goods and services, consumer goods, [\*34] consumer services (such as media, food service, and travel), health care, financial services, information services, telecommunication services, and the Internet. An exact list of industries that should be considered in an antitrust framework is beyond the scope of this paper. However, it is necessary to consider a split that looks something like this to solve the shortcomings of a regime based on the Sherman Act. Congress should determine the appropriate industry list, since it is able to employ the assistance of various experts from different fields.

Perhaps the most suitable model for a new antitrust statutory framework can be found in intellectual property. Similar to antitrust, intellectual property necessarily seeks to strike a balance between consumer protection and incentives to promote a healthy marketplace. However, while intellectual property has a fairly uniform set of policy goals focused on encouraging investment and innovation, the various areas covered within it require different, though partially overlapping doctrines to achieve these objectives. As a result, intellectual property exists in the separate, but related, areas of patents, copyrights, and trademarks, as well as a few others. Each of these areas requires a different legal approach to best achieve the common goals of intellectual property. Each area has its own statutory framework that has been updated periodically to expand and keep pace with changes in technology and society.

[\*35] Patent law, while also part of intellectual property law as a whole, focuses on protecting inventions. It is based in the United States Patent Act (Patent Act). Congress enacted the first iteration of the Patent Act in 1790 under the power granted in Article I, Section 8 of the Constitution. Throughout the nineteenth and twentieth centuries, as the types of inventions being produced expanded and changed, patent law expanded accordingly. For example, patent law was expanded to include industrial designs in 1842, plants in 1930, and surgical procedures in the 1950s. The Supreme Court first held that computer software was patentable in its 1981 decision, Diamond v. Diehr. Over time, the courts have adjusted their interpretations of patent laws to allow or deny patents as needed to compensate for changes in technology and the needs of society.

Copyright law provides protection for "original forms of expression," and is governed by the United States Copyright Act (Copyright Act). Like the Patent Act, the Copyright Act has gone through several versions. Congress adopted the original Copyright Act in 1790. Since that time, there have been changes in copyright law which have altered the duration of protection afforded to authors, expanded the types of works covered, and improved the rights of copyright holders. For example, musical recordings and photographs, neither of which existed at the time the first Copyright Act was enacted, are both afforded protection under its current iteration. Computer software is also protected under the Copyright Act. As technology has evolved to allow for the creation of new types of work, copyright doctrine has expanded accordingly.

[\*36] Trademark law protects the symbols and words used to identify the source of goods and services. Trademark protection initially appeared in the United States as a common law development in the mid-nineteenth century. In 1946, Congress enacted the Lanham Act, which allows for federal statutory protection of trademarks and provides for remedies against infringement. In its early existence, trademark protection was only available for trademarks that included the name of the manufacturer. Over time, the protection has expanded to include a vast array of terms and product designs, and has even evolved to include protection against the trademark being diluted or tarnished.

Intellectual property law is most instructive to engineering a new antitrust framework because of the way its doctrines have adjusted in reaction to society. Through the nineteenth century, the economy in the United States evolved from one that was heavily dependent upon agriculture to one increasingly dependent upon industry. In the twentieth century, the economy again shifted with the emergence of information technology. As the economy has evolved, the need for intellectual property rights has evolved with it. As a result, the doctrines of intellectual property have remained useful and relevant in a way that antitrust has not.

Courts and lawmakers can increase the flexibility and efficacy of antitrust law by dividing it in a fashion similar to intellectual property. In applying the Sherman Act to evolving industries and society over time, the courts have necessarily jumped through analytical hurdles and created numerous exemptions. As such, an analysis under the Sherman Act requires a number of steps--and added steps mean added opportunities for error and oversight. Under a divided antitrust scheme, Congress could correct court errors through updated legislation for specific affected industries, similar to updates to the Patent and Copyright Acts. As it currently exists, correcting an error through legislation would require a complex analysis of how the full antitrust framework may be impacted.

[\*37] Dividing antitrust into more closely tailored frameworks for various industries may not fully eliminate the need for judicially created exemptions. However, it is likely that fewer exemptions would be needed, as the frameworks would be more closely tailored to fit each industry. As a result, antitrust would be simplified and the application of it would be more straightforward. More bright-line rules could be created, rather than the vague standards that exist under the Sherman Act. Any necessary exemptions could additionally be broad enough to apply throughout an industry without the risk of affecting future cases in other industries.

To emulate the split framework of intellectual property for use in antitrust, Congress should enact separate statutes for each industry category, similar to the Patent Act, Copyright Act, and Lanham Act. These statutes should include similar provisions to the Sherman Act, stating the general types of behaviors that are anticompetitive. Unlike the Sherman Act, the specific purpose of the statutes--consumer protection--should be made clear. Each statute should also be made more specific, including in its text behaviors by firms that are known in that industry to result in consumer harms. Over time, the statutes should be updated as necessary, which will ideally result in frameworks that work separately by industry, but still achieve a unified goal of consumer protection.

C. The Internet Industry and What it Might Look Like

To best address consumer harms that may result from the business models of online-only products, a separate antitrust approach should be used for the Internet. The Internet industry should include only businesses whose offered products or services are digital in nature, rather than tangible goods and services that can be purchased through online channels. An Internet industry would [\*38] necessarily need to include the variety of online offerings we are accustomed to today, as well as have room to accommodate rapid innovation. As such, an ideal statutory framework must accommodate various business models used for online products, which may harm consumers in different ways. To provide this flexibility, an Internet antitrust statute should include factors to be weighed by courts in determining whether a firm's pro-consumer actions outweigh potential harms.

To further accommodate various online business models, as well as the evolution of society toward a web-based center, the Internet industry should be further divided. An ideal statute should divide the Internet into market types, each of which raises its own unique concerns in how to define the relevant market, how competition may be thwarted, and how consumers may be impacted. For example, the business model of an information website that users mainly access to read content may be very different from a social media platform with the primary purpose of facilitating interactions between users.

Statutory provisions should be included for specific handling of search engines, social media, information websites, email and communication services, streaming media, and software. While all of these categories involve paid advertising as part of their business models, the advertising appears differently and interacts with consumers in various ways. The ways in which a consumer may be harmed by targeted advertising differs--depending on how that advertising is targeted, what information is involved in the behind-the-scenes processes that result in these ads being served up to the user, and the ways these ads may differently affect the competitors of the firm operating the service on which the ad appears. As such, a holding of liability against a firm for consumer harms in one area could erroneously thwart pro-consumer actions in another area, simply because both utilize paid advertising. By maintaining separate statutory provisions for each, such effects could be minimized.

[\*39] While each Internet subcategory presents its own concerns, many of these services are interconnected in ways that are unprecedented in any prior market. Companies like Google, Yahoo!, and Microsoft operate in more than one of these areas and offer services that link their product offerings together for ease of use by consumers utilizing more than one product. For example, Google offers Internet search, advertising, email services, a social media platform, YouTube, and even its own browser, Google Chrome. This unique situation can be best handled by viewing each of these products separately, while also balancing the effects each has on the others.

Aside from the interconnection of products that exist online, there are other concerns which affect the function of an antitrust framework and they vastly differ from what has been seen in traditional industries. As market definition, market stability, and the cross-elasticity of demand differ greatly from traditional industries, an analysis of market power should likewise look different. As the factors impacting a firm's ability to thwart competition and harm consumers do not exist in the same way online, the traditional analysis does not apply. If courts attempt to apply the Sherman Act to the search engine industry, they risk setting precedent that will make it less applicable to traditional industries, where it is still useful. Instead, an Internet antitrust statute should include each of these differences in guidelines for analyzing a firm's behavior to ensure each aspect is appropriately considered.

To include all of the above-mentioned concerns, I propose an Internet antitrust act similar to the following:

Section 1: Every contract, combination in the form of trust or otherwise, or conspiracy, in restraint of online trade or commerce among the several States, or with foreign nations, with a likely result of harm to consumers, shall be illegal.

[\*40] Section 2: (a) Any person or persons who shall (i) monopolize, (ii) attempt to monopolize, or (iii) combine or conspire with any other person or persons, to monopolize any part of the online trade or commerce among the several States, or with foreign nations, with a likely result of harm to consumers, shall be deemed guilty of a felony. (b) Such a violation shall require a finding that (i) the person or persons possess monopoly power in the relevant market, determined by their ability to control market activities; and (ii) the person or persons intentionally acted to acquire or maintain this power, as distinguished from growth or development as a consequence of a superior product, business acumen, or historic accident.

Section 3: This statute shall apply to all businesses providing products or services that exist solely online and in no tangible form.

Section 4: Whether a harm to consumers is a likely result of the actions of a person or persons shall be determined by weighing such potential harms against the potential benefits of such actions. This analysis should include, but should not be limited to, the following factors:

(a) whether the product in question is a search engine, social media platform, email or communication service, streaming media service, or software product;

(b) whether consumers pay for the use of the product or service;

(c) whether the person or persons gain revenue from advertising targeted to consumers as part of the product or service;

(d) any barriers to entry that exist or are lacking in the relevant market for the product or service;

(e) the relative ease or difficulty of consumers to switch to an alternative product or service and the time and monetary cost to the consumer of engaging in such a switch;

(f) the amount of time for which the person or persons has held, or is likely to hold, a market share of a sufficient size to control any market activity; and

(g) whether, and to what degree, the product or service in question is connected to another product or service controlled by the same person or persons.

In addition to the above text, such a statute should likely include sections specifying appropriate criminal penalties and civil sanctions. However, such considerations are beyond the scope of this paper and best left to the legislature.

[\*41] D. An Analysis of Google

Under the proposed new framework, a court should analyze Google and other search engines with consumer interests in mind. As David Balto states in the opening line of his article in support of Google, "[i]t's about the consumer, stupid." To best protect consumers, antitrust regulation should tread carefully in the area of search. An application of antitrust law that would force Google to cease functioning as it currently does could have massive detrimental effects on the everyday lives of most Americans. While competition is necessary to incentivize continued innovation, ceasing any actions of Google to help its competitors may be unwise.

Focusing on Google's search engine, the relevant consumer for an antitrust analysis should be the end user. The relevant market should include not only competing search engines, but all search services that are publicly available at no cost to the consumer, excluding only specialty paid search services. This market should be viewed as a two-sided market with advertising. Advertising should include all online ads that are targeted to the user's preferences or information, including display ads on webpages and search ads tied to query terms. Additionally, users may access websites through other channels, such as clicking links in emails or typing a URL directly into the navigation bar of their browser. Such channels should be considered when discussing the relevant market and a search engine's share in it.

In applying the above-proposed statutory framework, an analysis of Google's search engine would weigh in favor of greater latitude to maximize the [\*42] potential benefits to consumers than a Sherman Act analysis would allow. In considering factors (b) and (c) of Section 4 of the proposed statute, users do not pay for the use of Google search and Google's revenue is gained through targeted advertising. Thus, potential harms to consumers would likely stem from manipulation of search results to favor these paid ads. The barriers to entry for competition are very low in search engines, which weighs against a finding that consumer harms are likely under factor (d). Likewise, under factor (e), the relative ease and lack of cost for users to switch to an alternative search engine or access information in another way weighs against a finding of likely consumer harms. As Google is unlikely to maintain a strong enough market share to control market activity over an extended time, factor (f) also weighs against antitrust liability under the proposed framework.

Factor (g), whether the product or service in question is connected to another product or service, is more complex. The balancing concern for this factor is whether such connections serve to benefit the consumer, or if the connections create a barrier against competitors from entering the market. Google offers all of the services listed in Section 4(a), which work together to provide integrated services to consumers. This list does not address Google's vertical search services, which include shopping, Google Maps, local results, flight planning, and will certainly include a host of new services in the near future. This also excludes the many areas in which Google is currently investing time and money, such as augmented reality and driverless cars. As long as an investigation into these services shows they potentially benefit consumers more than they potentially harm competition, this factor should also weigh in favor of Google.

Google, to date, has provided users with benefits that far outweigh any potential harms. Search engines generally create the enormous social benefit of connecting content providers with users in a mutually beneficial manner. [\*43] However, as a result of having such power, search engines do have the potential to inflict massive harm on both sides of this relationship. Thus, antitrust policy should carefully consider allowing the necessary freedoms to maximize these benefits while still exercising sufficient control when harms are recognized. So long as other search engines are staying in business against Google to maintain some form of competition, there is no reason for regulators or courts to hinder Google's freedom to innovate. Under the proposed statutory framework, if Google's actions begin to harm competition more than they benefit consumers, such actions could be stopped. In short, so long as Google is not blatantly acting with the intention to harm competition or consumers, it should be left to innovate as best it can.

III. CONCLUSION

The Sherman Act, over its long history, has served America's consumers well. If treated properly, it may continue to do so well into the future. If it is allowed to be picked apart, piece by piece by stretched precedents and exceptions, it will eventually fall apart. In an ever-changing technological landscape, we cannot afford to let the legal frameworks protecting us go stale. However, we must treat innovation and technology with the same respect, rather than suffocating it with outdated law.

#### Common law-oriented antitrust undermines *stare decisis*---collapses business confidence and rule of law

Tracer 13 (Daniel M. Tracer, Attorney, United States Department of Justice, Antitrust Division, Stare Decisis in Antitrust: Continuity, Economics, and the Common Law Statute, 12 DEPAUL Bus. & COMM. L.J. 1 (2013), y2k)

B. Stare Decisis's Diminished Role in Antitrust

In the wake of recent antitrust case law,3' scholars now take for granted the fact that stare decisis plays a diminished role in the area of antitrust.32 In particular, the Supreme Court has understood the Sherman Act to implement a common law approach whereby antitrust law can adapt and change course as needed.33 Scholars thus assume that stare decisis is simply not as big of an obstacle to change in the antitrust context as it is in other legal contexts. 34 For instance, it is understood that antitrust precedent may not survive as long and that antitrust legal tests may frequently change.35 Indeed, because of the widespread belief that antitrust's legal doctrine can and will be overruled and repealed as appropriate, scholars frequently attempt to predict which formerly binding rules of law will be abandoned next and which, if any, have staying power.36 To be sure, the diminished function of stare decisis in antitrust is a welcome development in the eyes of some. Those who subscribe to this understanding primarily highlight the flexibility that results from a weaker version stare decisis.37 Accordingly, antitrust law is thought to benefit from the Court's ability to more easily abandon precedent that no longer fits with contemporary economic views and the Court's ability to keep the antitrust laws up-to-date with economic thinking. In other words, this trend marks a triumph of economic reality over legalistic formality in the antitrust realm. Of course, one serious consequence of a weaker version of stare decisis is that the antitrust practitioner must also be an economist. 38 Thus stated, this view of stare decisis would hardly surprise students of the Chicago School and its understanding of antitrust law as nothing more than a branch of applied microeconomics. 39 In contrast, a somewhat more dominant view of stare decisis takes a negative attitude of such a state of affairs. As an initial matter, scholars have criticized the predominance of economic theory over traditional legal reasoning in antitrust law due to a concern that judges may lack the proper expertise to fully base their decision on economic analysis. This concern goes beyond a judge's possible lack of formal economic training, taking into account the institutional impediments of a court in deciding economic matters and the lack of consensus among economic scholars themselves on the costs and benefits of various business practices. 40 Moreover, to the extent that the Court's antitrust decisions are in tension with stare decisis, the Court's tendency to overrule antitrust precedent goes against the Court's function to interpret law rather than promulgate policy. 41 The consequences of failing to abide by stare decisis, especially in economic matters, include the following: the inability of businesspeople to confidently transact under the assumption of settled law,4 2 diminished public confidence in the Court,43 and a lack of fairness or evenhandedness in the way justice is administered, which tends to undermine the concept of the rule of law. 4 4 In other words, many of the benefits associated with stare decisis may be lacking in antitrust law. One final perspective that has gained traction in recent years is the notion that weaker stare decisis in the field of antitrust flows-or ought to flow-from the regulatory nature of the antitrust laws.4 5 Under this view, it is assumed that regulatory agencies, as opposed to courts, tend to change the rules and doctrines they apply very quickly, often reflecting shifting policies and priorities of incoming executive administrations as well as the technical expertise of the agency involved.46 Thus, if one assumes there is some carryover in the way that courts and the Antitrust Division of the Department of Justice (DOJ) and the Federal Trade Commission (FTC) are involved in the interpretation and enforcement of the antitrust laws, it may be somewhat less surprising that stare decisis should play a less pronounced role. 4 7

#### Global rule of law solves extinction

Feldman 8 (Noah, Professor of Law – Harvard University School of Law, "When Judges Make Foreign Policy", New York Times, 9-28, Lexis)

Why We Need More Law, More Than Ever

So what do we need the Constitution to do for us now? The answer, I think, is that the Constitution must be read to help us remember that while the war on terror continues, we are also still in the midst of a period of rapid globalization. An enduring lesson of the Bush years is the extreme difficulty and cost of doing things by ourselves. We need to build and rebuild alliances — and law has historically been one of our best tools for doing so. In our present precarious situation, it would be a terrible mistake to abandon our historic position of leadership in the global spread of the rule of law.

Our leadership matters for reasons both universal and national. Seen from the perspective of the world, the fragmentation of power after the cold war creates new dangers of disorder that need to be mitigated by the sense of regularity and predictability that only the rule of law can provide. Terrorists need to be deterred. Failed states need to be brought under the umbrella of international organizations so they can govern themselves. And economic interdependence demands coordination, so that the collapse of one does not become the collapse of all.

From a national perspective, our interest is less in the inherent value of advancing individual rights than in claiming that our allies are obligated to help us by virtue of legal commitments they have made. The Bush administration’s lawyers often insisted that law was a tool of the weak, and that therefore as a strong nation we had no need to engage it. But this notion of “lawfare” as a threat to the United States is based on a misunderstanding of the very essence of how law operates.

Law comes into being and is sustained not because the weak demand it but because it is a tool of the powerful — as it has been for the United States since World War II at least. The reason those with power prefer law to brute force is that it regularizes and legitimates the exercise of authority. It is easier and cheaper to get the compliance of weaker people or states by promising them rules and a fair hearing than by threatening them constantly with force. After all, if those wielding power really objected to the rule of law, they could abolish it, the way dictators and juntas have often done the world over.

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### AT PIC

#### The United States federal government should adopt a remedial regulation prohibiting anti-competitive business practices that artificially extend medical patents of drugs that share bioequivalence

#### Solves by punishing the existence of an anticompetitive market.

-CP agrees that refusals to deal/high rates are only problematic insofar as they arise from market power. It places the onus on the licensor to prove that competition exists/they are being fair and reasonable.

-there’s even more incentive to abide by obligations under SSOs otherwise you’re subject to this regulation that gives you shitty rates for your license

-the counterplan still allows for ‘innovation’ --- it doesn’t purport to establish a market rate --- it encourages the establishment of a market rate by threatening the regulation as the punitive fallback.

Kristelia A. Garcia 16, Associate Professor, University of Colorado Law School, “Facilitating Competition by Remedial Regulation,” Berkeley Technology Law Journal, Vol. 31:1, 2016, pages 183-258.

V. FACILITATING COMPETITION THROUGH REGULATION

There is a third option for checking anticompetitive behavior, maintaining competition, encouraging innovation, preventing technological lock-in, and ensuring payment to artists: regulation. The conventional view of regulation is as a system that works against competition; one that thwarts new entry and protects incumbents.23 8 Indeed, the Telecommunications Act of 1996-intended to mark the deregulation of the telecommunications industry-proclaims as its purpose: "To promote competition and reduce regulation in order to secure lower prices and higher quality services for American telecommunications consumers and encourage the rapid deployment of new telecommunications technologies." 239 The goal of this Part is to challenge the conventional view and to present regulation as potentially procompetitive.

Conventional thinking about how to approach the competition problem, or bargaining breakdown, in content generally falls into two divergent points of view: There are those who would reduce dependence upon (or in some cases do away with altogether) the current statutory licensing regime in favor of private ordering and/or other, preferable mechanisms such as fair use, patent pools, and collectives; 2 40 and those who favor compulsory licensing over private deal making for avoiding bottlenecks and for more robust information exchange. 241 The former view ignores the important role compulsory licenses play in ensuring access to content; the latter ignores the potential informational value derived from private rate setting. Both of these perspectives ignore the competitive market.

This Article departs from both of these perspectives, proposing instead a new model for maintaining competition in the licensing of intellectual property rights. This proposal calls for adherence to a mandatory, compulsory license by default, but embraces private ordering where (and only when) real competition can be shown to exist between rival content licensors. This proposal, referred to herein as the "remedial regulation model," utilizes existing mechanisms-specifically, statutory licenses, a collective administrator, and existing regulatory authorities-to correct anticompetitive behavior at minimal cost.

The current competition policy for the licensing of intellectual property assumes robust competition, and so allows for private ordering in the shadow of the statutory license. For example, § 114 of the Copyright Act allows copyright owners to either use the statutory license, or to negotiate their own royalty rates and license terms for the public performance of sound recordings.24 2 As a result, conventional antitrust mechanisms-like ASCAP's consent decree-are wholly ineffective against anticompetitive behavior perpetrated by individuals, who can merely opt-out.

The remedial regulation model updates copyright's competition policy by reversing this assumption. Instead, it assumes monopolistic (or oligopolistic) market power, thereby converting the existing, circumventable statutory licenses into mandatory, compulsory licenses under which parties may petition for permission to deal privately. Requiring only minimal statutory amendment and utilizing existing regulatory agencies and collectives, the remedial regulation model offers licensors and licensees a compromise: Continued access to content for all at a predictable rate and the flexibility to negotiate private terms, so long as industry consolidation has not reached a point so as to call into question the arms-length nature of any such transactions. This proposal builds, in part, on the existing literature on penalty defaults and altering rules. After a brief review of default theory, this Part will show its application in the regulatory context and will detail a remedial regulatory solution to copyright's competition problem.

A. PENALTY DEFAULTS, ALTERING RULES & COMPETITION

1. Default Theory

A "penalty default" is an undesirable fall back option designed to penalize those who, through failure to do or to not do some thing (be it negotiate, or share information); do not otherwise negotiate around it. The concept of "penalty default rules" was first introduced by Professors Ian Ayres and Robert Gertner,2 4 who described them as unpalatable fallback options in contract law that kick in unless the parties negotiate their own terms. Such rules, they argue, induce more knowledgeable parties to "reveal information by contracting around the default penalty." 2 44 Prior work has extended this concept to licensing and demonstrates that "penalty default licenses encourage[] more efficient deal making among otherwise unequal parties by motivating them to circumvent an inefficient statutory license in favor of private ordering. "245

In other words, penalty defaults are a mechanism by which regulators can encourage or discourage a certain behavior without regulating that behavior directly. This is particularly useful where the behavior sought to be modified is not easily regulated, such as to encourage retirement savings, organ donation, and to curb pollution.2 46 The next section argues that penalty defaults might also prove especially useful for regulating behavior that is not readily ameliorated by existing legal regimes, such as the anticompetitive behavior of the individual music publishing companies whose tacit collusion and parallel pricing activities are not checked by antitrust.

Altering rules establish the "necessary and sufficient conditions for altering default legal consequences.1"247 "Impeding" altering rules aim to "deter opt-out by artificially increasing its difficulty." 248 This is effectively what remedial regulation does: By requiring a showing of sufficient competition before private ordering is permitted, the statutory license is made "quasi-mandatory" or sticky.24 9

2. Application to Regulation In the regulatory context, the remedial concept behind impeding altering rules works to penalize an undesirable behavior in hopes of encouraging a different behavior. Here, it does so by mandating compliance with a statutory rate-thereby foreclosing private ordering with all of its potential benefits-unless and until sufficient competition can be shown in the relevant marketplace.

There is precedent for this approach. In wholesale electricity, for example, the Federal Energy Regulatory Commission (FERC) sets the applicable rates for energy transmission. A utility company is allowed to charge a "market-based tariff only if [the company] demonstrates that it lacks or has adequately mitigated market power, lacks the capacity to erect other barriers to entry, and has avoided giving preferences to its affiliates."250

Varying in procedure, but similar in spirit, are patent pools, or the pooling of patents between two or more companies. Patent pooling is generally acceptable, even favored, unless "(1) excluded firms cannot effectively compete in the relevant market for the good incorporating the licensed technologies and (2) the pool participants collectively possess market power in the relevant market." 25 1 Where these conditions exist, the DOJ or the FTC will review the licensing arrangement for anticompetitive effect before determining whether the parties will be allowed to engage in the pooling activity. In both of these examples, a competitive marketplace is not assumed, but must first be shown.

B. REMEDIAL REGULATION

In lieu of antitrust, this Article advocates utilizing remedial regulation-or, regulation that discourages industry consolidation-in order to open the market and maintain competition. This model assumes a baseline that tends toward oligopoly, natural or otherwise, and so allows for private ordering only where sufficient competition can first be shown. Otherwise, regulation operates to ensure ongoing access to the relevant input(s) for all prospective consumers or licensees able and willing to meet the statutory requirements and to pay the statutory rate. Because this regulation does not necessarily represent a market rate-nor, indeed, as high a rate as private ordering might obtain-this Article labels it "remedial." It punishes the lack of a competitive marketplace.

If a company wants to engage in private ordering to obtain a higher rate or better terms, it must first petition to show the existence of sufficient competition in the relevant market. While such "remedial regulation" cannot create a robust competitive market where none exists, it can prevent a few powerful firms from unilaterally controlling the price for an input, or from barring new entry to the market altogether to the detriment of both consumers and innovators in the space. As is the case with other highly regulated industries, the underlying assumption here is that the government has a greater responsibility for checking anticompetitive behavior in the music licensing space owing to its role in the granting of exclusive property rights via copyright.

As with the wholesale electricity example, remedial regulation places the burden of proving a competitive marketplace on the party seeking to get out from under the statutory regime. This resets the baseline assumption and brings competition policy in line with positive market conditions, while at the same time establishing a "safe harbor" that allows for private ordering (and its concomitant advantages) when, and only when, sufficient competition can be shown. The next section outlines one possible path toward implementation of remedial regulation in the music licensing context.

### States

#### TEXT: The attorney generals of 50 states and relevant territories, through the National Association of Attorneys General’s Multistate Antitrust Task Force, should prohibit anti-competitive business practices that artificially extend medical patents of drugs that share bioequivalence. The 50 states and relevant territories should pass a statute which increases prohibition on anti-competitive business practices that artificially extend medical patents of drugs that share bioequivalence

#### A multistate AG antitrust enforcement over state antitrust statutes solves the aff---causes federal follow-on

Artega 19 (Juan A. Arteaga is an experienced antitrust attorney and a former Deputy Assistant Attorney General for the U.S. Department of Justice’s Antitrust Division, The Role of US State Antitrust Enforcement, Global Competition Review, 11-19, <https://www.lexology.com/library/detail.aspx%3Fg%3Dd423301d-f4d1-4550-a99c-1880869e67e7+&cd=11&hl=en&ct=clnk&gl=us>, y2k)

In the United States, competition laws have been implemented and enforced through a dual system where the state and federal governments play distinct, yet complementary, roles in regulating the competitive process. While the Department of Justice (DOJ) Antitrust Division and Federal Trade Commission (FTC) are widely viewed as the stewards of US antitrust laws, state attorneys general have long played an important, albeit varying, role within the United States’ antitrust enforcement regime. This has been especially true during the past 30 years because state attorneys general have become much more effective at coordinating their antitrust enforcement efforts to ensure that they have a meaningful seat at the table in any actions brought jointly with their federal counterparts or are able to bring their own actions when the DOJ and FTC decide not to do so.

Prior to the enactment of the first federal antitrust law – the Sherman Act – in 1890, state antitrust enforcement was quite robust in the United States because at least 26 states had already enacted some form of antitrust prohibition. In addition, state enforcers had often used general corporation law and common law restraint of trade principles to regulate anticompetitive business practices and transactions. This well-established state antitrust enforcement infrastructure – coupled with the fact that the Antitrust Division and FTC had only recently been created – permitted state attorneys general to continue playing a leading enforcement role for the first 30 years after the Sherman Act’s passage. Indeed, state attorneys general successfully prosecuted a number of the most consequential antitrust enforcement actions during this period.

In the early 1920s, however, state antitrust enforcers began playing a less prominent role because ‘the national dimension of the most important trusts, . . . as well as their ability to restructure in order to evade problematic state laws’, made clear that the federal government needed to step forward in order to adequately protect consumers and the competitive process. As a result, the DOJ and FTC – whose national jurisdiction and greater resources enabled them to tackle the most pressing competition issues of the time – displaced state attorneys general as the primary source of government antitrust enforcement within the United States. This largely remained true until the mid-1970s when Congress, in response to the DOJ and FTC’s perceived inactivity, passed two laws that expanded the authority of state attorneys general to enforce the federal antitrust laws and provided them with financial resources to do so.

In 1976, Congress passed the Hart-Scott-Rodino Antitrust Improvement Act, which, among other things, authorised state attorneys general to bring *parens patriae* suits (i.e., legal actions brought on behalf of natural persons residing within their states) seeking monetary (treble damages) and injunctive relief for Sherman Act violations. Congress also passed the Crime Control Act of 1976, which, among other things, provided state attorneys general with tens of millions in federal grants as ‘seed money’ for the creation of antitrust bureaus within their offices. These laws had their intended effect of reinvigorating state antitrust enforcement.

During the 1980s, for example, state attorneys general once again emerged as vigorous antitrust enforcers, especially with respect to the prosecution of resale price maintenance practices and other vertical restraints. The rise in the level and prominence of state antitrust enforcement during this period was largely due to a perceived enforcement void at the federal level, where the DOJ and FTC had mostly limited their focus to ‘prohibiting cartels and large horizontal mergers’. No longer content with ceding antitrust enforcement to federal enforcers, state attorneys general expanded their antitrust dockets from prosecuting purely ‘local matters, such as bid-rigging on state contracts’, to actively investigating and litigating matters with multistate and national implications. To help ensure that they had a larger seat at the antitrust enforcement table, state attorneys general also increased the coordination of their enforcement efforts and competition advocacy through organisations such as the National Association of Attorneys General (NAAG), which created a Multistate Antitrust Task Force and issued state Vertical Restraints and Horizontal Merger Guidelines during this period.

Since the reawakening of state antitrust enforcement nearly 30 years ago, state attorneys general have continued to play an important role in the enforcement of both state and federal antitrust laws. During periods of lax federal antitrust enforcement, state attorneys general have often ramped up their enforcement activity in order to protect consumers from anticompetitive transactions and business practices. During periods of vigorous federal antitrust enforcement, they have often served as strong partners for the DOJ and FTC by, among other things, offering valuable insights about competitive dynamics in local markets, assisting with obtaining information from key market participants (including state governmental entities that are direct purchasers of goods and services), and helping develop and implement litigation strategies for cases being tried before federal judges presiding in their states.

Since January 2017, state attorneys general have increasingly played a leading and independent antitrust enforcement role. State antitrust enforcers have significantly increased their enforcement activity and willingness to act separately from their federal counterparts because many of them believe that there has been ‘under-enforcement’ by the DOJ and FTC. State antitrust enforcers have also been able to enhance their influence over key competition policy issues and the antitrust enforcement agenda within the United States because there appears to have been a significant decline in the coordination and relationship between the DOJ and FTC.

In once again flexing their enforcement muscle, state attorneys general have shown a willingness to publicly disagree with the DOJ and FTC on both policy and enforcement decisions, and have also sought to pressure their federal counterparts into more aggressively policing certain industries. Recent examples of the increased independence and assertiveness of state antitrust enforcers include:

In their joint investigation into the T-Mobile/Sprint merger, nearly 20 state attorneys general have sued to block the transaction even though the DOJ, along with seven state attorneys general, have approved the deal after securing certain structural and behavioural remedies. After the DOJ announced its proposed settlement with the companies, the Attorney General for New York, who has been leading the states’ challenge to the merger, issued a press release dismissing the adequacy of the remedies negotiated by the DOJ: ‘The promises made by [the divestiture buyer] and [the merging companies] in this deal are the kinds of promises only robust competition can guarantee. We have serious concerns that cobbling together this new fourth mobile [phone] player, with the government picking winners and losers, will not address the merger’s harm to consumers, workers, and innovation.’

The DOJ, FTC and several state attorneys general have been actively investigating and prosecuting ‘no-poach’ agreements (i.e., where competitors for employees agree not to recruit or hire each other’s employees)in recent years. However, the DOJ and state attorneys general have taken directly opposing positions in private litigation challenging the legality of ‘no-poach’ clauses in corporate franchise agreements. The DOJ has argued that courts should review these clauses under the rule of reason whereas various state attorneys general have argued that these clauses should be deemed per se unlawful.

None of the more than 20 state attorney general offices that actively investigated the AT&T/Time Warner merger joined the DOJ’s unsuccessful challenge to the transaction despite the DOJ’s concerted effort to secure their support. In fact, nine state attorneys general filed an amicus brief opposing the DOJ’s appeal of the trial court’s decision.

After the FTC declined to seek any Colorado-related remedies in connection with Optum’s acquisition of DaVita Medical Group, the Attorney General for Colorado required the merging companies to lift the exclusivity provisions in contracts with certain healthcare providers and to extend their existing contracts with certain health insurers. In announcing this settlement, the Colorado Attorney General stated: ‘I recognize that this case marks an important step in state antitrust enforcement . . . . I am committed to protecting all Coloradans from anticompetitive consolidation and practices, and will do so whether or not the federal government acts to protect Coloradans.’

After voicing displeasure with federal antitrust enforcement in the technology sector, numerous state attorneys general launched their independent investigations into ‘Big Tech’ companies even though the DOJ and FTC have ongoing investigations into these companies.

Given that companies will increasingly have to engage with state attorneys general in a meaningful manner with respect to antitrust matters, this chapter discusses key issues related to state antitrust enforcement in the United States. Specifically, this chapter discusses:

the federal and state antitrust laws under which state enforcers operate;

the processes through which state enforcers coordinate with each other and their federal counterparts;

the opportunity for coordination and conflict between state enforcers and private counsel during litigation;

strategic and practical considerations when engaging with state attorneys general; and

certain noteworthy enforcement actions that state enforcers have recently prosecuted.

Statutory regime governing US state antitrust enforcement

Civil enforcement of federal antitrust laws

Enforcement actions on behalf of state governmental entities

Under the federal antitrust laws, state attorneys general have the express authority to bring civil actions on behalf of their state, municipalities, and governmental entities for harm suffered when directly purchasing goods or services. In bringing such actions, state attorneys general can seek monetary (treble damages) and injunctive relief, as well as their costs and reasonable attorney’s fees.

In actions seeking monetary relief, state attorneys general typically allege that the state plaintiffs were forced to pay higher prices by an unlawful horizontal conspiracy, such as a price-fixing or bid-rigging scheme, and seek to recover the overcharges. In some cases, state attorneys general have sought to recover damages arising out of anticompetitive unilateral conduct, such as overcharges paid by state governmental entities due to a defendant’s actual or attempted monopolisation of a specific market.

In seeking injunctive relief, state attorneys general often argue that such relief is proper because the business practice or transaction in question – in addition to harming the state plaintiffs – has or will cause injury to the state’s general economy. While general harm to a state’s economy can serve as a basis for injunctive relief, state attorneys cannot base their request for damages on such harm.

Parens patriae enforcement actions

A well-settled principle in the United States’ legal system is that ‘the States have a quasi sovereign interest in protecting their citizens from ongoing economic harm’. Consequently, the federal antitrust laws expressly authorise state attorneys general to file parens patriae actions in federal court that seek to redress the harm suffered by their citizens due to federal antitrust violations. In providing state attorneys general with parens patriae authority, the federal antitrust laws permit state antitrust enforcers to seek monetary (treble damages) and injunctive relief, as well as their costs and reasonable attorney’s fees. State attorneys general have been empowered to seek such broad and substantial relief on behalf of their citizens to allow them ‘to deter further economic harm and to obtain relief for the injury inflicted on their economies and their citizens’.

In exercising their parens patriae authority, state attorneys general have often sought to protect their citizens and state economies from the harm caused by anticompetitive business practices. For example, in the e-Books Litigation, 33 state attorneys general alleged that Apple, Inc and various book publishers unlawfully conspired to fix the prices of electronic books, which resulted in their citizens paying higher prices and harm to their states’ general economies. Ultimately, these state attorneys general, working alongside private class counsel, secured settlements from the defendants that provided nearly US$600 million in direct refunds to their citizens. In a pending lawsuit brought against various manufacturers of generic pharmaceuticals, 44 state attorneys general have alleged that the defendants unlawfully conspired to fix the prices for numerous generic drugs, which forced their states and citizens to pay billions of dollars in overcharges, as well as significantly harmed their states’ general economies.

State attorneys general have also invoked their parens patriae authority to protect their citizens and state economies from the harm caused by anticompetitive transactions. For instance, in their pending challenge to T-Mobile’s proposed acquisition of Sprint, nearly 20 state attorneys general have alleged that the transaction will result in their residents paying higher prices for lower quality mobile phone services as well as harm to their states’ general economies. Likewise, the state attorneys general that joined the DOJ’s successful challenges to the proposed Anthem/Cigna and Aetna/Humana mergers alleged that these mergers would have harmed their citizens and the general economies of their states by reducing the number of large health insurance providers from five to three.

There are, however, important limitations on the parens patriae authority conferred to state attorneys general under the federal antitrust laws. For instance, the monetary relief sought by state attorneys general must: (1) arise out of a Sherman Act violation; (2) have been incurred by natural persons residing in their states (i.e., the losses suffered by business organisations cannot be included in the alleged damages); (3) exclude harm suffered by indirect purchasers of the goods and/or services in question; (4) avoid the risk of multiple recoveries by excluding amounts previously awarded for the same injuries; and (5) arise out of actual financial losses rather than general harm to their state’s economy. Moreover, state attorneys general must provide their residents with adequate notice of the lawsuit and a meaningful opportunity to opt out of the litigation.

In seeking to prove the monetary harm suffered by their citizens, state attorneys general can employ many of the same methods utilised by private plaintiffs. In price-fixing cases, for example, state attorneys general can prove the claimed aggregate damages by utilising ‘statistical or sampling methods’, ‘comput[ing[ [the] illegal overcharges’, or relying on any other methodology deemed ‘reasonable’ by the court. In addition, a number of state antitrust laws authorise their state attorney general to hire private lawyers to handle parens patriae actions, which the state attorneys general challenging the T-Mobile/Sprint merger have done.

Civil enforcement of state antitrust laws

Most states have enacted state antitrust laws that are comparable to Sections 1 and 2 of the Sherman Act. In addition, some states have passed antitrust laws that are similar to Sections 3 and 7 of the Clayton Act and the Robinson-Patman Act. These state antitrust laws typically contain provisions expressly requiring that ‘they be construed in conformity with comparable [f]ederal antitrust statutes’.

State antitrust statutes typically provide state attorneys general with broad authority to investigate possible violations, including the power to ‘issue civil investigative demands compelling oral testimony, the production of documents, and responses to written interrogatories to individuals and corporations’. Like the federal antitrust laws, most state antitrust laws authorise state attorneys general to file civil lawsuits on behalf of their states and state governmental entities whenever a violation has caused them to suffer harm in their capacity as direct purchasers of goods or services, as well as parens patriae actions on behalf of their citizens.

### Enforce Squo

#### The United States federal government should increase anti-trust enforcement against product hopping.

### Con Con

The United States, through a limited constitutional convention called for by at least thirty-four of the States and ratified by at least thirty-eight of the States, should prohibit anti-competitive business practices that artificially extend medical patents of drugs that share bioequivalence

#### It solves, causes follow on, and avoids politics.

Cooper ’21 [Charlie; 2021; President of Get Money Out Maryland and Retired Human Services Administrator; Get Money Out Maryland, “A Convention of States is Wise and Safe,” <https://www.getmoneyoutmd.org/peoples_convention>]

When Congress fails to represent the people who elected them, the U.S. Constitution provides a path for the people to propose a Constitutional amendment through the states. Article V lays out two equal alternatives:

"The Congress, whenever two thirds of both Houses shall deem it necessary, shall propose Amendments to this Constitution, or, on the Application of the Legislatures of two thirds of the several States, shall call a Convention for proposing Amendments, which, in either Case, shall be valid to all Intents and Purposes, as Part of this Constitution, when ratified by the Legislatures of three fourths of the several States..."

Thus there are only two ways to amend the U.S. Constitution:

* A proposal passed by two-thirds of each chamber of Congress, then ratified by three-quarters of the states
* A proposal passed by a convention called by two-thirds of the states, then ratified by three-quarters of the states

As former U.S. Supreme Court Justice Antonin Scalia said about this second option: "[When] the Congress is simply unwilling to give attention to many issues which it knows the people are concerned with—and which issues involve restrictions upon the federal government’s own power—I think the founders foresaw that and they provided this method in order to enable a convention to remedy that.”

In a 2016 report, the Congressional Research Service noted that an Article V Convention “was included [in the Constitution] to provide the people, through applications by their state legislatures, with the means to call a convention having the authority to consider and propose changes to the Constitution, particularly if Congress proved incapable of, or unwilling to, initiate amendments on its own."

All 27 Amendments to the Constitution were passed using the first of the two methods: Congress proposed an amendment, then two-thirds of state legislatures ratified it. So why is a convention of states necessary to obtain a 28th Amendment? As George Mason argued when he proposed the convention language: It is necessary when Congress itself is the problem.

The 17th Amendment is the best example of a convention campaign working effectively to add an amendment to the U.S. Constitution. The 17th Amendment, which allows for the popular election of U.S. Senators, came about in reaction to Senators being appointed by state legislatures until the early 1900s. That process was widely recognized as corrupt due to the disproportionate influence of wealthy individuals and special interests. In fact, the Senate became so corrupt that individual senators took nicknames such as the "Coal Senator," the "Bank Senator," and the "Oil Senator."

Citizens responded to this overt venality by using every tool of democracy available including petitions, local legislation, ballot referendums, educational campaigns, resolutions calling on Congress to propose a Constitutional amendment, and finally, after all else failed, applying for an Article V Convention to propose an amendment.

When that movement was just one state shy of the two-thirds needed to force a convention on this topic, Congress reacted by proposing an amendment requiring the direct election of U.S. Senators for the states to ratify—resulting in the 17th Amendment to the U.S. Constitution. The Congressional Research Service has called this technique the "prodding effect." It worked then, and it could work today.

Arguments Against an Article V Convention

Both left- and right-leaning groups—Common Cause and the John Birch Society among them—have argued vehemently against the use of Article V Conventions. They say correctly that such a convention has never been used to amend the Constitution. Never having held an Article V Convention, however, is hardly a reason to avoid one, since the framers provided this Constitutional alternative in anticipation of a time when Congress fails to represent the people. Opponents also fear the prospect of a "runaway" convention, where any topic could be proposed, possibly threatening the process for ratifying amendments or the Constitution itself. See authoritative answers to these arguments below.

Experts Respond

The Constitution’s framers foresaw a time—when Congress itself is the problem—for citizens to have the Constitutional authority to pursue an amendment through the states. That time is now: Supreme Court rulings in Citizens United and other cases have created no-holds-barred politics in which Big Money steamrolls the democratic process. A Congress that is the result of this increasingly lawless system can hardly be expected to propose an amendment to dismantle that system without an extraordinary level of public pressure. A citizens’ drive toward a convention of states under Article V would apply such pressure.

Government and legal agencies have responded to critics opposing a convention of states:

* Criticism: Individual delegates could bring up matters unrelated to those the convention was originally called to address.

Response #1: For a convention to stray from its original topic, delegates would have to propose topics that were not included in the original resolution approved by their state legislatures. Nine states to date have made it a felony for any delegate to a state-called convention to call for or vote on any topic that was not part of the original convention topic.

Response #2: The Justice Department concluded in 1987 that Article V Conventions can be called "for limited purposes, and that a variety of practical means to enforce such limitations are available." In addition, "Congress may decline to designate the mode of ratification for those proposed amendments that it determines are outside the scope of the subject matter limitation and therefore beyond the authority of the convention to propose."

### Drug Prices CP

#### The United States federal government should

#### establish drug regulatory boards to assess and lower pharmaceutical prices

#### substantially increaser R&D funding for pharmaceutrical research

#### Solves the case – this is what Europe Does

### 1NC – FDA

#### The United States federal government should substantially increase it usage and enforcement of suitability petitions

#### Anti-trust worse than regulation

Arti K. Rai and Barak D. Richman 18. 5-22-18. Arti Rai, Elvin R. Latty Professor of Law and co-Director of The Center for Innovation Policy at Duke Law. Barak D. Richman, JD, PhD, is the Katherine T. Bartlett Professor of Law and Business Administration at Duke University. “A Preferable Path For Thwarting Pharmaceutical Product Hopping” <https://www.healthaffairs.org/do/10.1377/hblog20180522.408497/full/>

The recently announced White House blueprint to curb the high cost of pharmaceuticals addresses a policy problem that both ranks near the top of consumers’ health care concerns, and is a leading reason why US healthcare spending is the highest among OECD nations. Many critics attribute significant blame to pharmaceutical companies that engage in what is euphemistically called “life cycle management,” in which pharmaceutical firms manipulate U.S. Food and Drug Administration (FDA) processes and patent laws to extend their market exclusivity beyond an appropriate term. The FDA has held hearings seeking to restore generic drug competition, in which Commissioner Scott Gottlieb decried those who are “gaming our system,” and the agency continues to develop action s that combat strategies seeking to deter generic entry. One common strategy by firms that produce brand-name pharmaceuticals is called “product hopping.” A firm engages in product hopping when it moves its customers from one branded drug to another, very similar drug with a longer patent life, thus extending its market exclusivity by many years. The most common tool to combat product hops has been to sue branded firms under the antitrust laws, and many commentators view antitrust law as the best, or perhaps only, mechanism for addressing product hopping. However, antitrust actions have had mixed success. We contend that the FDA could implement a superior and more precisely tailored fix—**a “suitability petition”—that avoids the cost, delay, and imprecision of antitrust enforcement.** To our knowledge, this fix has not yet been suggested in the literature. **Product Hopping And Antitrust** In a typical product hop, a branded manufacturer faces patent expiry and generic challenge on one version of its branded drug (“Drug 1”). In response, it makes a small change to Drug 1, secures patents on that new formulation (“Drug 2”), and then discontinues Drug 1. Because this conduct channels physicians towards Drug 2, firms that produce a generic alternative of Drug 1 find that physicians have stopped writing prescriptions for Drug 1, even in branded form. Moreover, because the slight change means that the FDA does not currently consider Drug 2 “therapeutically equivalent” to Drug 1, state-level drug substitution laws that allow pharmacists to substitute generic drugs for therapeutically equivalent branded drugs prevent substitution of the generic version of Drug 1 for Drug 2 prescriptions. In short, patients must pay monopoly prices for a branded Drug 2 because there is no generic alternative, and the market for Drug 1 evaporates just as a generic becomes available. A prominent instance of product hopping featured a branded Alzheimer’s treatment produced by Actavis. In that case, Actavis sought to replace its twice-daily dosage of the memantine molecule (Namenda IR) with an extended release, once-daily version (Namenda XR). Namenda XR was covered by multiple patents that lasted over a decade longer than the patents over Namenda IR. Although the FDA had approved Namenda XR in 2010, Actavis chose not to introduce it into the U.S. market until 2013. Then, in late 2014, nine months before patents on IR expired in July 2015, Actavis sought to remove Namenda IR from the market. The New York State Attorney General sued Actavis under the antitrust laws, claiming that the product hop was an illegal extension of monopoly power. The Court of Appeals for the Second Circuit agreed, ruling that Actavis had to keep Namenda IR on the market for 30 days after the introduction of the generic. Although Actavis engaged in unquestionably problematic conduct, antitrust lawsuits are not reliable countermeasures against this kind of “evergreening” strategy. **Antitrust suits are expensive and time-consuming, and any remedy they provide typically emerges many years after the fact** (though the Namenda case represents an exception). The U.S. Supreme Court has also warned that, when antitrust operates against the backdrop of a complex regulatory regime, **it often produces inconsistent and mistaken rulings** since it relies on “dozens of different courts with different nonexpert judges and different nonexpert juries.” Policymakers and health policy experts should be wary of **asking courts** **to determine that a manufacturer must keep a particular product design on the market.**

**PO---1NC**

The fifty states and relevant territories should enact a public option.

**Public option solves costs and disease**

**Gudiksen et al 21** “Who Can Rein in Health Care Prices? State and Federal Efforts to Address Health Care Provider Consolidation” KATHERINE L. GUDIKSEN - MS, PhD, is a senior health policy researcher for The Source on Healthcare Price and Competition, ALEXANDRA D. MONTAGUE - JD, is a health policy researcher at The Source for Healthcare Price and Competition, JAIME S. KING - JD, PhD, is the John and Marylyn Mayo Chair in Health Law and a professor of law at the University of Auckland Faculty of Law; senior affiliate scholar of the UCSF/UC Hastings Consortium on Science, Law and Health Policy; and executive editor of The Source for Healthcare Price and Competition, JUNE 24, 2021, https://www.milbank.org/publications/who-can-rein-in-health-care-prices-state-and-federal-efforts-to-address-health-care-provider-consolidation/

Injecting Competition by Offering a Public Option

In addition to protecting markets through better merger review and oversight of anticompetitive conduct, lawmakers are also considering increasing competition in health care markets by creating a public option. A public option is a health insurance plan offered by a government agency that competes with private health insurance companies.57 **By offering a public option, the government can drive down the cost of both premiums and health services, but only if it limits provider rates or other costs to apply competitive pressure**.58

With the federal public option facing what has been called “the biggest health care fight since Obamacare,”59 and without the votes in the Senate to overcome a filibuster, states may find it easier to create a public option plan than the federal government would. While the federal government has fewer legal constraints than state governments face when designing a public option, such as budget neutrality and waiver requirements, states have taken the lead in designing and prototyping public option plans.58 Specifically, Washington started selling a public option plan on its Health Benefit Exchange on January 1, 2021,60 and other states, including Colorado61 and Nevada,62 appear poised to follow Washington’s example.

While the initial premiums for Washington’s public option plan were higher than its proponents hoped,63 Washington may now experiment with lower provider rate caps or additional cost controls.58 The states that choose to offer public option plans may help refine provider caps and network requirements to ensure that public option plans can control costs and provide adequate networks. Lawmakers in the forerunner states recognize that they cannot wait for the federal government to implement new laws and policies and are forging ahead with public options designed to fulfill state goals like covering the remaining uninsured.

### Court PTX

#### The court will avoid abortion ban now due to the perceived fear of court reform

Scher 4-20 (Bill Scher is the host of the history podcast "When America Worked" and the co-host of bipartisan online show and podcast "The DMZ", Should Biden Pack the Supreme Court? <https://washingtonmonthly.com/2021/04/20/should-biden-pack-the-supreme-court/>, y2k)

After four congressional Democrats introduced a bill expanding the Supreme Court, Senate Minority Leader Mitch McConnell accused Democrats of trying to pressure the current Justices. “It’s not just about whether this insane bill becomes law. Part of the point here are the threats themselves,” said the Kentucky Republican who always evinces a tender concern for the sanctity of the Court. “The left wants a sword dangling over the Justices when they weigh the facts in every case.”

Well, yeah.

I agree with McConnell that packing the Court would be insane. Allowing one party to determine control of the Supreme Court whenever it controlled the White House and Senate would destroy the legitimacy of the entire judiciary, if not the underpinning of our constitutional government. Threatening to pack the Court, however, is perfectly sane, and may already be working. Count me in.

Prior ideologically driven attempts to either pack the Court or strip powers from the Court never became law. But they appear to have influenced Court behavior. As my colleague Daniel Block explained last fall, “In the mid-1950s, the liberal Warren Court backed away from protecting victims of McCarthyism because a popular Senate bill threatened to strip the Court’s powers. Throughout the 1970s and 1980s, conservative politicians flooded Congress with legislation to stop the Court from ruling on racial integration. The justices retreated from enforcing busing regulations.”

Franklin D. Roosevelt’s 1937 court-packing scheme came in response to rulings that shut down New Deal programs and curtailed federal government power. FDR’s bill was rejected by Congress—even though Democrats controlled 71 of 96 seats in the Senate. But after its introduction the Court began to uphold New Deal laws. Historians continue to debate whether FDR lost the battle but won the war. Understanding what happened then is instructive for determining how far Democrats should go today.

In the June 1936 Tipaldo case, decided on a 5-4 vote, the Supreme Court struck down a women’s minimum wage law in New York State. The decision was part of a long line of rulings based on the principle that employers and employees have the “freedom” to forge contracts, and any “[l]egislative abridgement of that freedom can only be justified by the existence of exceptional circumstances.”

Roosevelt announced his plan to expand the Court on Feb. 5, 1937. Fifty-two days after FDR’s move, the Supreme Court ruled in the Parrish case that Washington State’s minimum wage for women was constitutional. As the law was very similar to the one struck down nine months before, the ruling amounted to a complete reversal. Between the two cases, Justice Owen Roberts moved from the conservative to liberal position, a move that became known as the “switch in time that saved nine.”

Parrish was followed in April with the Court’s upholding of FDR’s National Labor Relations Act. Then in May, Social Security was also deemed constitutional. Even though in July the Senate sent the court-expansion bill back to committee, to be filleted, the Court was no longer an obstacle to the New Deal.

That chronology of events suggests FDR’s bill moved the Court. Roosevelt himself championed that narrative in an introduction to a volume of his public papers: “The Court began to interpret the Constitution instead of torturing it. It was still the same Court, with the same justices. No new appointments had been made. And yet, beginning shortly after the message of February 5, 1937, what a change!”

But FDR left out two key data points. One (most likely unbeknownst to FDR) is that Roberts executed his switch in December 1936—before FDR’s message. In a 1945 memo, Roberts explained that the December vote wasn’t immediately made public because one Justice was ill. The Court could have deadlocked 4-4 and still have upheld Washington State’s minimum wage law, because it would have left in place a lower court ruling, but the Justices knew their absent colleague would also support the law and they wanted a majority 5-4 vote.

We can say that FDR’s announcement did not pressure Roberts to switch, since the switch came first. What remains a source of scholarly debate is whether speculation in the press about a forthcoming court-packing plan, in the immediate aftermath of FDR’s landslide 1936 re-election win, nevertheless pressured Roberts to switch. If not, was there already evidence of doctrinal evolution by Roberts, and other Justices, in the midst of Depression and modernization, which culminated with the springtime 1937 liberal rulings? (For a deep dive into this debate, read this series of essays in the October 2005 edition of the American Historical Review.)

Roberts himself gives conflicting evidence. On one hand, he insisted in his 1945 memo (published posthumously 10 years later) that in the two minimum wage cases, he didn’t switch at all. He just wasn’t asked in Tipaldo, the first case, to overrule the 1923 Adkins opinion—which struck down a law passed by Congress establishing a minimum wage for Washington, D.C. But the second case, Parrish, did confront Adkins directly, and then Roberts made his view known. He admitted he could have taken the “proper course” and written his own concurring opinion for Tipaldo plainly stating his view, and neglected to give a reason why he didn’t.

FDR biographer Kenneth S. Davis, in FDR, Into the Storm 1937-1940, found Roberts’ belated explanation “disingenuous” and “desperately contrived … made solely for the purpose of protecting the Court against a probable attempt to drastically limit its powers.” And, as Block noted, Roberts acknowledged in congressional testimony that he was “fully conscious” of how the “court-packing plan” put “tremendous strain and threat to the existing Court.” Roberts didn’t say he switched because of that strain, but those dots seem very connected.

The other data point FDR left out of his narrative is the political damage he suffered as a result of his bill’s decisive rejection by the Senate. Many FDR allies in the chamber urged him to stand down after the switch, but he greedily persisted and paid a steep price.

In Roosevelt’s Purge, the historian Susan Dunn explained how the defeat emboldened the conservative anti-New Deal wing of the Democratic Party, mere months after Roosevelt’s historic 24-point election victory in 1936: “Gleefully, they banded together to sabotage the rest of the New Deal, voting down Roosevelt’s progressive tax measures, abolishing the graduated tax on capital gains, killing his proposal for seven regional agencies patterned after the TVA, tearing apart his executive reorganization plan and burying in committee his Fair Labor Standards Act.” Davis sharply concluded, “his sadly mistaken court-packing effort effectively ended the New Deal as a reforming, transforming social force[.]” FDR can’t cheerily claim he won the war for the Court, if in the process he lost the war for his agenda.

How should Democrats apply the FDR lessons? As the chess adage goes, “the threat is stronger than the execution.”

We can’t cleanly separate and sort out what factors influenced Roberts, but we do know that FDR’s announcement wasn’t one of them, because it was after the fact. Moreover, FDR’s proposal was immediately unpopular: 47 percent in favor, 53 percent opposed in an early March 1937 Gallup poll. After the “switch” became public, support further declined. Despite FDR’s electoral mandate, his attempted power grab depleted his strength. But beforehand, the landslide election and speculation over court-packing was likely helping to move the Court his way. If FDR hadn’t announced a specific proposal, he probably would have gotten the same results from the Supreme Court, without shattering his congressional coalition.

Today’s congressional Democratic leadership has kept their distance from the court-packing bill. Leaning on the President’s new blue ribbon commission exploring non-specific judicial reforms, House Speaker Nancy Pelosi said she has “no plans to bring [the bill] to the floor.” This is wise. FDR couldn’t move public opinion in favor of the bill, and he won his election by 20 more points than Biden. While there are far fewer conservative Democrats today than in 1937, a move to a floor vote could well have split the Democrats and harmed the rest of their agenda.

But McConnell is correct that the threat still looms—which is a good thing. What if the Supreme Court moved in a radical right-wing direction now that it has a 6-3 conservative majority? What kind of backlash would materialize? Could it lead to big Democratic gains in the upcoming elections and give Biden a greater mandate to pack the Court than FDR had? The conservative Justices can’t know for sure, and they may not want to test the proposition with a slew of provocative rulings.

John Roberts has shown for almost a decade that he’s happy to lead the march in a conservative direction, but not too quickly, avoiding some incendiary cases and defusing others—most notably, preserving Obamacare in 2012. This could explain why the Court has kept punting on the Mississippi 15-week abortion ban case. If the Court’s conservatives are ready to overturn Roe v. Wade, right now they would take the case. If they want to avoid needless divisiveness and protect their legitimacy, they will leave it alone.

So long as the latter strategy appears to be in effect, that strongly suggests the conservative Justices see the dangling sword. Biden, Pelosi and Schumer are wise to keep it sheathed, and keep them guessing.

#### Plan allows Roberts to moderate the court’s conservative credentials and builds credibility---that relieves pressure on the court

Masters 20 (Brooke Masters, FT’s Chief Business Commentator and an Associate Editor, US Supreme Court adjusts to new tilt to the right, 12-10, <https://www.ft.com/content/16489a50-e828-4cc6-8d0d-a261c1f1f9d8>, y2k)

The US Supreme Court is having adjustment problems. The addition of three conservative appointees by President Donald Trump in four years has disturbed the balance and possibly destroyed the comity of America’s highest court. The arrival of Amy Coney Barrett in October, replacing the late Ruth Bader Ginsburg, gives the court a 6-3 conservative majority after decades of a 5-4 split or control by a moderate block.

A court that has been reliably pro-business for years will stay that way at a time when incoming president Joe Biden is expected to favour stricter regulation and labour rights. The court also appears poised to invalidate or sharply narrow social reforms and government programmes that are popular with the majority of Americans, including abortion rights, gay marriage and Obamacare.

Some of the justices cannot wait. Samuel Alito, long one of the most conservative, recently complained in a speech that the court’s landmark 2015 gay rights decision in Obergefell vs Hodges had made traditional views unacceptable. “You can’t say marriage is a union between one man and one woman,” he said. “Until very recently, that’s what the vast majority of Americans thought. Now it’s considered bigotry.”

The significance of Ms Barrett’s arrival was underscored last month when the court blocked New York’s Covid-19 related restrictions on public religious services, saying they violated the freedom to worship. Before Ginsburg’s death, the court had upheld similar rules in California and Nevada, holding that they were necessary to control the pandemic and did not treat religious gatherings differently from secular ones.

The New York ruling was also notable for its many sharply worded opinions. Trump appointee Neil Gorsuch declared bitterly it was “past time” to strike down such restrictions, writing: “Even if the constitution has taken a holiday during this pandemic, it cannot become a sabbatical.”

The question now is not whether the court will move to the right, but how far. History shows that even though the justices are required to base their decisions on the constitution and legal precedent, popular opinion plays a role. After all, the court has no enforcement mechanism — it de­pends on the rest of government and the respect accorded to its rulings.

In the past, when Supreme Court rulings departed too far from public consensus, it has ended up adjusting. The best known instance is often described as the “switch in time that saved nine”.

In the 1935-36 terms, the justices capped a 40-year period of conservative rulings by striking down several New Deal statutes by 5-4 votes, drawing public opprobrium and a threat from then president Franklin Roosevelt to pack the court with additional liberals. While the bill was still pending, Owen Roberts changed sides — “switched” — and voted to uphold a Washington state minimum wage bill and continued to support regulation of business.

But liberals have seen the court shy away from confrontation as well. In 1954, in Brown vs Board of Education, the court invalidated segregated schools but put off immediate implementation, saying in Brown II a year later that states and school boards merely needed to act with “all deliberate speed”.

Chief Justice John Roberts has already shown he is deeply concerned with maintaining the Supreme Court’s institutional strength. For years, he has sometimes provided the liberals with a fifth vote on questions where he felt the court’s credibility could be at stake, including a 2012 ruling that turned back the first major challenge to the Affordable Care Act (ACA) that established Obamacare, and on cases regarding abortion rights and young immigrants last spring.

Supreme Court watchers observe that its history can place a powerful weight on members

Early signs suggest he is still playing a similar role, even though Ginsburg’s death has shifted the balance on the court. At a time when the ACA is more popular than ever, he was openly sceptical in oral arguments of a new claim that Congress wanted the entire act to fail when it voted to change one part of it. In the New York Covid-19 religious services case, he defended his liberal colleagues from Justice Gorsuch’s criticism, saying “they simply view the matter differently after careful study”.

But Ms Barrett’s arrival means the chief justice can no longer make the difference on his own: he must bring along at least one conservative colleague to make a majority. In a landmark LGBT+ case last year, that extra conservative was Mr Gorsuch, and at the ACA hearing Brett Kavanaugh sounded sympathetic to Mr Roberts’ efforts to limit the reach of the case. But on the New York Covid-19 restrictions, the conservative bloc held.

After the ACA, the biggest early tests are likely to be in social policy cases involving gun rights and abortion. There already were five votes for pro-business decisions, so Ms Barrett’s arrival is unlikely to change the outcome of financial and regulatory cases.

On guns, the court has not taken up a recent case, but four justices previously supported an expansive approach to the second amendment right to bear arms. Ms Barrett expressed similar views as an appeals court judge. On abortion rights, the conservative bloc has criticised Roe vs Wade, the 1973 decision that proclaimed a constitutional right to have an abortion. Ms Barrett has signed public letters opposing abortion, and on the appeals court she dissented when other judges declined to rehear an Indiana case where tough abortion restrictions had been blocked.

Still, Supreme Court watchers know the institution’s history can place a powerful weight on its members. With the balance tilted to the political right, and an incoming administration committed to changes on climate and labour, the left will hope one or more of the justices will surprise.

The question remains: which could it be?

#### That provides a breathing room for conservative rulings

Bazelon 15 (Emily Bazelon is a staff writer for the magazine and the Truman Capote Fellow at Yale Law School, Marriage of Convenience, 2-1, New York Times, l/n, y2k)

More significant, if the court is seen as transcending partisan politics, Roberts will probably have more chances, over time, to accomplish what appears to be his primary long-term goal: to move the court in a more conservative direction on a range of issues. In particular, Roberts's brand of conservatism has manifested itself in two main areas. The first is in decisions that are sympathetic to corporations. A 2013 study found that he had been more likely to side with businesses than any justice in the previous 65 years, except for Samuel Alito. The second is in decisions that are antagonistic toward the idea of taking race into account in shaping law or policy. Roberts has voted repeatedly against affirmative action, writing last year that it was not hard to conclude that racial preferences may ''do more harm than good.'

When Roberts was nominated to be chief justice 10 years ago by President George W. Bush, he exuded calm neutrality at his confirmation hearing, comparing judges to umpires who call balls and strikes. At the end of his first term, he emphasized the importance of the court's ''credibility and legitimacy as an institution,'' in an interview with the George Washington University law professor Jeffrey Rosen.

But in 2010, Roberts supplied the fifth vote for the court's remarkably unpopular ruling in Citizens United. By striking limits that Congress set on campaign spending by corporations, the court was perceived as favoring the interests of the wealthy. The court's approval rating fell 10 percentage points, to barely break even, from 61 percent.

Since then, the court has fared better with the public when it pairs conservative decisions with progressive ones. And same-sex marriage is part of that equation. In 2013, the term ended with a splashy ruling in which five justices -- Roberts not among them -- struck down part of the Defense of Marriage Act, which restricted federal benefits for spouses to male-female couples. This decision came one day after the court gutted a central component of the Voting Rights Act, in a 5-to-4 decision written by Roberts.

#### Abortion ban collapses reproductive rights---extinction

Paul Ehrlich 18, President, Center for Conservation Biology, Bing Professor of Population Studies, Stanford University, 3/24/18, quoted by Sputnik News, “Overconsumption, Inequity 'Lower Chances of Avoiding Global Collapse' – Scholar,” https://sputniknews.com/analysis/201803241062865525-overconsumption-inequity-global-collapse/

The collapse of civilization in the next few decades is imminent, and it could be triggered by a variety of factors, Paul Ehrlich told Sputnik. "It could be caused by a nuclear war, droughts and floods leading to mass starvation, a bursting of the debt bubble, political unrest from refugee flows or increasing economic inequity, trade wars, terrorism or synergizing combinations of these and other factors," the researcher said. The main reasons behind all these negative predictions are, according to the scientist, overpopulation and overconsumption. He is confident that these two factors will drive our civilization over the edge. "The basic problem is the wrecking of human life-support systems by growth in aggregate consumption — and that is a product of growth in population size and growth in per capita consumption. Various forms of inequity — gender, racial, religious could contribute by making it less likely that people will provide the cooperation required to give the chance of avoiding a collapse," the analyst argued. In Ehrlich's view, the situation has significantly worsened since he released a corresponding warning in his book "The Population Bomb" 50 years ago. "The population has doubled in size, climate disruption is now much more thoroughly understood and is already causing problems, there soon will be more weight of plastics in the oceans than fish; hormone-mimicking synthetic chemicals are now toxifying earth from pole to pole and are the likely cause of plunging sperm counts around the world; almost half of wildlife has been exterminated in the greatest mass extinction episode in the last 66 million years," the analyst said. According to him, the chances of a global nuclear war wiping out civilization are now also "higher than at any time during the Cold War except for the Cuban missile crisis." Although, there have been numerous warnings about the way humans are threatening life on earth, governments and the international community have so far failed to reduce this threat, and Ehrlich believes that there are several reasons for this. Among them are "the lack of education in basic science, especially among economists and politicians, who think economic growth is the cure for everything rather than what it is — the basic disease," the analyst said, adding that a key role is also being played by such negative traits if a human character as "greed, stupidity and arrogance." Answering the question about which measures he considers essential to change the situation for the better, the scientist said that, among other things, it's important to "supply everyone with modern contraception and backup abortion," "give women equal rights and opportunities with men," "end racial and religious discrimination so that all people are free to help solve the human dilemmas" and "redistribute wealth."

### FTC

#### COVID-related enforcement is key to effective recovery---it’s a key priority

OECD 20 (The Role of Competition Policy in Promoting Economic Recovery – Note by the United States, 12-2, <https://www.ftc.gov/system/files/attachments/us-submissions-oecd-2010-present-other-international-competition-fora/economic_recovery_us.pdf>, y2k)

1. The Antitrust Division of the Department of Justice (DOJ) and the U.S. Federal Trade Commission (FTC) (collectively the Agencies) offer this joint submission in response to the Competition Committee’s review of the role of competition policy in promoting economic recovery. In this paper, we highlight some key steps that the Agencies have taken to respond to the present COVID-19 crisis in the United States and to help promote a rapid and sustained economic recovery.

2. The U.S. antitrust agencies have undertaken initiatives in several categories to help spur recovery from the COVID-19 crisis, including stepped-up criminal enforcement, policy guidance to health and emergency-related government agencies, and expedited review of private sector cooperative efforts. The Agencies strongly believe that competition policy has an important role to play in the COVID-19 recovery process and intend to continue to engage in partnership with domestic and international counterparts to ensure the protection of competition and consumers.

2. Deterrence of Cartel Activity, Price Gouging, and Other Harmful Activity

3. Deterrence of unlawful commercial activities has long been a key mission of the Agencies, rendered even more critical by the social and economic disruptions caused by the COVID-19 crisis.1 While most Americans have acted to help their neighbors and communities during the past year, crisis-related disruption increases the risk that some individuals will make unlawful windfall profits at the expense of public safety and the health and welfare of their fellow citizens.2

4. While hoarding and exploitation are not themselves antitrust violations, such behaviors are often accompanied by criminal antitrust collusion, price fixing, and bid rigging, and other attempts to take advantage of the public. As with other natural disasters, the COVID-19 crisis increases the risk that individuals and organizations will engage in these unlawful commercial activities, necessitating increased vigilance by the Agencies.

2.1. COVID-19 Hoarding and Price Gouging Task Force

5. To coordinate enforcement efforts, the Attorney General in March 2020 announced the creation of the COVID-19 Hoarding and Price Gouging Task Force.3 The Task Force is charged with developing effective enforcement measures and best practices, and coordinating nationwide investigation and prosecution of illicit activities. Because health care products and markets are central in responding to the health care crisis and eventually to economic resilience and recovery, the Task Force focuses on protecting the availability of those products designated essential by the Department of Health and Human Services (HHS) under Section 102 of the Defense Production Act. The DOJ consults with HHS during this process, including advising on the antitrust implications of COVID-19 for affected markets and products.

6. The Task Force is currently being led by a coordinating U.S. Attorney, with assistance as needed from the Antitrust Division’s Criminal Program. Each United States Attorney’s Office, as well as other relevant Department components, is directed to designate an experienced attorney to serve as a member of the Task Force. The Antitrust Division’s role in the Task Force involves investigating allegations of criminal antitrust harms, such as price fixing and bid rigging, and responding to citizen complaints about collusive or anticompetitive disaster-related behavior.

2.2. Procurement Collusion Strike Force

7. The DOJ is also stepping up efforts to combat crisis-related disruption through the newly-created Procurement Collusion Strike Force (PCSF). COVID-19 recovery will require substantial investment by national, state, and local authorities, with $3.48 trillion appropriated to date.4 The size and pace of such efforts unfortunately create opportunities for fraud and collusion affecting government procurement and grant-making. Through the creation of the PCSF, DOJ is dedicating significant resources to help identify and prevent these unlawful activities.5

8. The PCSF is an interagency partnership dedicated to protecting taxpayer-funded projects from antitrust violations and related crimes at the federal, state, and local levels. Under the umbrella of the PCSF, prosecutors from the Antitrust Division’s five criminal offices and 13 U.S. Attorneys’ Offices have partnered with agents from the FBI and four federal Offices of Inspector General, including the U.S. Postal Service and Department of Defense, to conduct outreach and training for procurement officials and government contractors on antitrust risks in the procurement process.

9. Since its creation in 2019, over 50 federal, state, and local government agencies have already sought training and assistance from the PCSF, as well as opportunities to work with the PCSF on investigations. So far, the PCSF has led over a dozen interactive virtual training programs for approximately 2,000 criminal investigators, data scientists, and procurement officials.6 Over a third of the Antitrust Division’s current investigations relate to public procurement, and the PCSF marks an important effort to marshal enforcement resources to tackle these cases. Several grand jury investigations already have been opened as a direct result of the work of the PCSF. In addition to playing a meaningful role in COVID-19 economic recovery, the PCSF will continue to be an important resource for detecting fraud and collusion in government procurement for years to come.

2.3. Protecting Competition in Labor Markets

10. The DOJ and FTC are working to protect competition in labor markets, which have been subject to significant dislocation due to the economic impact of COVID-19. In April 2020, the Agencies issued a statement warning that antitrust enforcers are closely monitoring improper employer coordination that may disadvantage workers.7 The statement affirmed that antitrust laws with respect to hiring and employment remain fully in effect despite the crisis, and stated that “COVID-19 does not provide a reason to tolerate anticompetitive conduct that harms workers, including doctors, nurses, first responders, and those who work in grocery stores, pharmacies, and warehouses, among other essential service providers on the front lines of addressing the crisis.”8

11. Given the special impact of COVID-19 on medical staffing and employment, the Agencies are focused on preventing employers, including health care staffing companies and recruiters, from engaging in collusion or other anticompetitive conduct in labor markets, such as agreements to lower wages or to reduce salaries or hours worked. This announced focus continues the Agencies’ policy of devoting resources to preventing labor malpractice in critical industries, especially health care. As one example, the DOJ in April 2020 reached a significant resolution in the criminal investigation of Florida Cancer Specialists (FCS) for entering into a market allocation agreement that gave FCS a monopoly for services in a densely populated part of southwest Florida. As part of the deferred prosecution agreement reached in that case, the Division obtained a $100 million fine – the statutory maximum – and FCS agreed to waive certain non-compete provisions for current and former employees, including physicians and other healthcare professionals.9 In another important matter, early this year, the FTC investigated, and the parties abandoned a proposed tie-up between two providers of nursing staff. The proposed merger had likely anticompetitive effects in multiple localities across the country on markets both for nursing services and for private duty nursing care.10

2.4. Consumer Protection

12. The FTC has worked aggressively to address consumer protection issues arising from the COVID-19 pandemic. Since late March, as the coronavirus emerged, the FTC has received nearly 225,000 consumer complaints relating to COVID-19, including concerns about fraud related to the government’s economic impact payments.11 In addition, the FTC has been monitoring the marketplace for unsubstantiated health claims, illegal robocalls, privacy and data security concerns, online shopping fraud, and a variety of other scams related to the economic fallout from the COVID-19 pandemic.

13. Acting on this market information, the FTC has pursued a rigorous warning letter program and filed law enforcement actions for injunctive and other relief in federal courts.12 In the health claims area, for example, the FTC and the Food and Drug Administration (FDA) have, to date, issued over 90 joint warning letters to marketers regarding claims that their products will treat, cure, or prevent COVID-19.13 The FTC on its own has issued more than 225 additional warning letters to marketers.14 The letters warn recipients that their conduct is likely to be unlawful, that they could face serious legal consequences if they do not immediately stop, and require a response to the FTC within 48 hours. In nearly every instance, companies that have received FTC warning letters have taken quick steps to correct or eliminate their problematic claims. The FTC also has issued warning letters, in conjunction with the Small Business Administration, to companies making potentially misleading claims about federal loans or other temporary small business relief.15

14. The FTC has also filed court actions involving COVID-19 health claims, distribution claims, and government stimulus check claims.16 For example, the FTC filed four lawsuits in federal district courts against online merchandisers for failing to deliver on promises that they could quickly ship products like face masks, sanitizer, and other personal protective equipment (PPE) related to the coronavirus pandemic.17

15. Finally, the FTC has launched numerous consumer education campaigns, including a website on COVID-19 scams and a resource page that contains brochures, graphics, and videos in multiple languages.18

3. Guidance and Cooperation to Peer Agencies as Part of a Coordinated, GovernmentWide Response Effort

16. The FTC and DOJ also have shared their competition expertise with other international and federal agencies in order to facilitate COVID-19 response and recovery while preserving competitive markets. Among other efforts, the Agencies have been working closely with the Federal Emergency Management Agency (FEMA) to develop a Voluntary Agreement governing cooperation among industry participants seeking to respond to the pandemic.19 The purpose of the Agreement is to maximize the effectiveness of the manufacture and distribution of critical healthcare resources nationwide to respond to the pandemic. Organized under the authority granted by the Defense Production Act, participants to the Agreement receive antitrust immunity for actions taken to carry out the Agreement. Before the Agreement can become effective, however, the Attorney General must find that the purposes of the Agreement may not be achieved through a voluntary agreement having less anticompetitive effects. These efforts also have helped inform the Agencies’ responses to business review letters seeking approval for cooperation in the production of critical health care products, as discussed below.

3.1. International Advocacy

17. U.S. enforcers also have been leveraging our existing bilateral relationships and ties to multilateral organizations, such as the International Competition Network (ICN) and the Organisation for Economic Co-operation and Development (OECD), to increase communication and cooperation.

18. In the immediate aftermath of the declaration of a state of national emergency in the United States, the Agencies played a key role in facilitating communication and cooperation among international enforcers by collecting and sharing on a regular basis rapidly developing information on how COVID-19 has impacted competition law enforcement efforts around the world. After DOJ successfully developed a regular internal process for collecting and disseminating this information, the ICN integrated this project into its ongoing work streams. In early April, as the economic impact of COVID-19 and possible enforcement challenges began to emerge, the ICN Steering Group issued a statement on key considerations related to competition law enforcement during and after the COVID-19 pandemic.20 The Agencies contributed with the FTC serving as a lead drafter of the statement recognizing the importance of competition to economies in crisis and urging agencies to remain vigilant regarding anti-competitive conduct. The statement also calls for transparency of operational and policy changes during the crisis and advocates for competition as a guiding principle for economic recovery efforts in the aftermath of the pandemic.

19. Since spring 2020, the Agencies have participated in several virtual events hosted by the ICN, the OECD, and the United Nations Conference on Trade and Development on international cooperation, investigations and competition law policy in the wake of COVID-19.21 In September 2020, the U.S. Agencies hosted the ICN 2020 Virtual Conference, which brought together enforcers from around the world to discuss antitrust developments, including how to address enforcement and policy challenges raised by COVID-19.

3.2. Doctrinal Responses

20. While procedural aspects of the Agencies’ work have changed as a result of COVID-19, the Agencies’ view of key U.S. antitrust standards has not changed. The Agencies have reiterated that the antitrust laws are flexible enough to account for changing market conditions, even during uncertain times.22

21. In particular, the Agencies continue to take the view that the failing firm defense is “narrow in scope,” and should be invoked selectively.23 The Agencies have continued to reiterate in speeches and publications that they will not relax the stringent conditions that define a genuinely “failing” firm and continue to apply the test set out in the U.S. Horizontal Merger Guidelines24 and reflected in our long-standing practice, and that they will require the same level of substantiation as was required before the COVID pandemic.25 As such, while it is possible that more firms may fail as a result of an economic crisis such as COVID-19, the view of the United States is that economic dislocation, on its own, does not provide a compelling reason why the assets of failing firms should be purchased by close competitors.

3.3. Competition Advocacy

22. The Agencies are continuing to advocate for changes to regulations that may impede competition, which may cause even greater harm in the context of the COVID-19 crisis. For example, the Agencies have submitted multiple letters to state legislatures in recent years expressing their concerns over “certificate of need” laws26 and other restrictions on the availability of health care resources.27 Given the extraordinary disruptions created by COVID-19, the United States views protecting the free functioning of health care markets as even more urgent, and the Agencies plan to continue our advocacy to remove regulatory impediments to competition in the health care sector.

23. Directly relating to the COVID-19 public health emergency, FTC staff submitted a comment to the Centers for Medicare & Medicaid Services (CMS) on its Interim Final Rule with Comment Period (IFC).28 The FTC comment supported the IFC’s provisions that reduce or eliminate restrictive Medicare payment requirements for telehealth and other communication technology-based services during the public health emergency. FTC staff noted that if telehealth practitioners’ entry is limited or reimbursement requirements are overly restrictive, consumers’ access to care and choice of practitioner might be unnecessarily restricted, especially in areas where there is a shortage of healthcare professionals. The IFC’s rule would reduce restrictions on Medicare reimbursement for telehealth services. This is especially important, not only to enhance the use of telehealth to care for Medicare beneficiaries, but also to encourage private payers to expand the use of telehealth. Reducing or eliminating restrictions on reimbursement of telehealth services could potentially enhance competition, improve access and quality, and decrease health care costs in both the public and private sectors. By connecting widely separated providers and patients, telehealth can alleviate primary care and specialty shortages.

24. The FTC continues to advocate against states issuing certificates of public advantage (COPA). For example, in September 2020 FTC staff submitted a public comment opposing issuance of a COPA to the Texas Health and Human Services Commission. FTC staff expressed concern that the proposed merger at issue would lead to significantly less competition for healthcare services in Midwest Texas.29

25. The FTC and its staff have also analyzed potential competitive concerns associated with professional regulations in the health care sector, including licensure and scope of practice.30 For example, FTC staff sent advocacy letters to the Texas Attorney General and the Texas Medical Board relating to regulations that could harm competition by impeding access to surgical and other health care services provided by certified registered nurse anesthetists.31 FTC staff recommended that Texas maintain only CRNA supervision requirements that advance patient protection and avoid adopting regulations that impede CRNA practice.

26. DOJ hosted a virtual joint workshop with the USPTO in July 2020 that included debate on the role of innovation and public-private collaboration in responding to the COVID-19 pandemic.32 The workshop, entitled “Promoting Innovation in the Life Science Sector and Supporting Pro-Competitive Collaborations: The Role of Intellectual Property,” comprised 10 sessions over two days. Panelists included leading figures from industry, government agencies, prominent research labs, the non-profit sector, academia, and the broader legal and economic community. Members of the public were also able to submit questions throughout the event.

4. Facilitation of Cooperative Public and Private-Sector Efforts to Resolve the Crisis

27. The Agencies are working together to bolster the recovery by providing guidance relating to recovery-related collaborations on an expedited basis.33 In a joint statement in April, the Agencies emphasized the potential importance of pro-competitive collaborations between private firms to bring essential goods and services to communities in need. In addition to providing high-level collaboration guidelines consistent with previous DOJ and FTC policies, the statement contained guidance specific to COVID-related business activities, including reaffirming that the Agencies will account for exigent circumstances in evaluating collaborative efforts to address the spread of COVID-19, and that medical providers’ development of suggested practice parameters to assist in clinical decisionmaking will not be challenged, absent extraordinary circumstances.34

28. The Agencies also announced an expedited business review letter program, under which all COVID-19-related requests will receive responses within seven calendar days of the Agencies receiving all necessary information. This expedited process for COVIDrelated business review letters is an outgrowth of the Agencies’ role in advising other executive branch agencies on facilitating COVID-related cooperation within the antitrust laws, and each of the letters issued through the expedited process in 2020 addresses proposed conduct that is critical to COVID-19 response. Since March 2020, DOJ has issued the following four expedited business review letters:

1. A letter approving a collaboration by McKesson Corporation, Owens & Minor Inc., Cardinal Health Inc., Medline Industries Inc., and Henry Schein Inc to expedite and increase manufacturing for the distribution of personal protective equipment (PPE) and coronavirus-treatment-related medication in a way unlikely to lessen competition;35

2. A letter approving a collaboration by AmerisourceBergen with FEMA, HHS, and other government entities to “identify global supply opportunities, ensure product, quality, and facilitate product distribution of medications and other healthcare supplies to treat COVID-19 patients;”36

3. A letter approving a collaboration by Eli Lilly and Company, AbCellera Biologics, Amgen, AstraZeneca, Genentech, and GSK to “exchange limited information about the manufacture of monoclonal antibodies that may be developed to treat COVID19” in order to optimize COVID-19 vaccine production as part of Operation Warp Speed;37 and

4. A letter approving a collaboration by the National Pork Producers Council (NPPC) and the U.S. Department of Agriculture (USDA) “to address certain hardships facing hog farmers as a result of the COVID-19 pandemic.”38 29. The Agencies also pledged to expedite the processing of filings under the National Cooperative Research and Production Act, which provides flexible treatment of certain standards development organizations and joint ventures under the antitrust laws.

5. Revised Rules Regarding Merger Enforcement

30. The Agencies have adapted to changing work conditions and reallocated resources to maintain continuity of core operations and enforcement efforts. COVID-19 initially necessitated temporary changes to ensure the continuation of expeditious and thorough merger review.39 Changes made by both Agencies include (1) extending standard timing agreement provisions so that the post-compliance period runs for sixty to ninety days (instead of thirty days) for pending or proposed transactions that may be subject to a Second Request, (2) requiring all merger filings with the FTC and DOJ to be submitted via the FTC’s electronic filing system, and (3) committing to conducting all meetings and depositions by phone or video conference when possible, absent extenuating circumstances.40 For the initial period of only two weeks at the start of the COVID crisis, the Agencies also suspended the granting of early termination, which can shorten the waiting period for non-problematic mergers. The option of early termination was resumed in March, and timing of grants of early termination has returned to pre-pandemic levels.41

31. Notably, COVID-19 did not sideline other important efforts to improve the Agencies’ enforcement programs. Among other efforts, in June 2020, the Agencies for the first time issued joint Vertical Merger Guidelines.42 In September, the Division also issued a modernized Merger Remedies Manual. As an update to the 2004 edition, the new manual provides “greater transparency and predictability regarding the Division’s approach to remedying a proposed merger’s competitive harm,” including an emphasis on structural remedies and a renewed focus on enforcing consent decree obligations. The Division also has continued to follow through on its September 2018 commitment to modernize banking merger review, with the goal of expedited and efficient resolution for uncomplicated merger matters.43 Economic downturns, as often occur in the wake of disasters such as the COVID-19 crisis, may impact merger activity, which is why continuing to improve the Agencies’ approach to reviewing and remedying potentially anticompetitive mergers remains a priority.

#### Plan causes a trade-off and devastates antitrust agency effectiveness

Sacher & Yun 19 (Seth B. Sacher, Economist, & John M. Yun, Antonin Scalia Law School, George Mason University, TWELVE FALLACIES OF THE "NEO-ANTITRUST" MOVEMENT, 26 Geo. Mason L. Rev. 1491, y2k)

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

Most of those that have worked within, or before, the antitrust agencies, despite their inevitable disagreement with certain actions or policies, are generally very impressed with the high degree of skill, professionalism, and dedication exhibited by the career staff. 131As will be discussed more fully in the [\*1515] context of Fallacy XI below, many proponents of neo-antitrust do not accept the proposition that the antitrust agencies and their staffs function relatively well, in spite of the views of many (on all sides of the political spectrum) who have had experience working within or before the antitrust agencies. Regardless of how neo-antitrust proponents view the agencies, many of their proposals run a serious risk of adversely affecting competition agency performance.

There are a number of objective reasons to expect antitrust agencies to function relatively well. First, antitrust agencies tend to be small relative to many other regulatory agencies and bureaucracies in general. 132Second, their staffs tend to be highly trained professionals, consisting primarily of lawyers and Ph.D. economists. 133Third, they have a well-defined objective (i.e., the consumer welfare standard or some similar standard based on economic reasoning, such as the total welfare standard). 134Finally, although antitrust is considered a form of regulation, it is distinct from other forms of regulation in that it does not involve a continuing relationship between the regulated firms and the regulator. As a goal, antitrust seeks to enable markets to more nearly achieve certain social objectives on their own. 135

First, advocates of neo-antitrust would like to see the responsibilities of the antitrust agencies expanded in a number of ways. This includes more aggressively enforcing existing antitrust laws, as well as the consideration of issues beyond those currently within that purview. 136Further, many of their proposals, such as requiring data sharing, monitoring markets to prevent tipping, or approving platforms' algorithm changes, 137 will require significantly more active market supervision than is currently the case. While many [\*1516] proponents of modern antitrust would agree that the antitrust agencies are underfunded, 138 there is certainly a point at which expanding the antitrust agencies will have "bureaucratic" diseconomies of scale. Fully following the recommendations of neo-antitrust advocates could very well require many antitrust agencies to expand beyond some critical point, which will inevitably lead to significantly larger bureaucracies and associated inefficiencies.

Second, many of the above proposals would require not only more staff, but also staff with differing expertise from that held by most agency lawyers and economists. For example, monitoring data sharing is far from straightforward, as it is frequently unclear where data begins and technology ends. Similarly, considerations of income inequality or environmental questions may involve tradeoffs beyond the expertise of mere law or economics, such as technology, ethics, or even psychology. While staff of the antitrust agencies will frequently contact market participants and other experts with specialized knowledge on an as-needed basis, it is unknown how well such expertise would function within the long-term framing of antitrust, which has been a legal and economic domain since its inception.

#### Failed COVID recovery triggers multiple hotspots

Wright 20 (Robin Wright, a contributing writer and columnist @ The New Yorker, The Coronavirus Pandemic Is Now a Threat to National Security, 10-7, https://www.newyorker.com/news/our-columnists/america-the-infected-and-vulnerable, y2k)

The broader danger is the world’s perception now of America as inept and vulnerable, Doug Lute, a retired lieutenant general who was the director of operations for the Joint Chiefs and a deputy national-security adviser to Presidents George W. Bush and Barack Obama, told me. “There are two things that would drive our competitors—the general sense of incompetence by the executive branch and a reading that we are totally self-absorbed internally,” he said. “There’s an overlapping of the pandemic, the protests, and now the election that amplifies that image. In broad terms, those conditions internally will be viewed by external competitors as opportunities.” America faces threats from a spectrum of overseas adversaries, the retired Marine General John Allen, who is now the president of the Brookings Institution, told me. “I’m deeply concerned that there will be foreign actors, all the way from jihadists to state actors, that try to take advantage of a level of duress that we haven’t seen for a long time. It has not been lost on our adversaries, or those who would seek to gain ground, that the United States has consciously chosen to withdraw.” The sense of “sheer confusion” surrounding American politics in 2020 compounds the temptation of foreign actors to make moves, either for their own gains or to diminish America, Allen said. The most obvious perils are from the big powers, which may calculate that the White House will not counter their moves elsewhere in the world during such domestic turbulence, especially on the eve of an election, former military and Pentagon officials told me. From Russia, President Vladimir Putin could dig deeper into Ukraine, meddle in unstable Belarus, or test the strength of the Baltic states to resist. From China, President Xi Jinping could further threaten Taiwan, exert its claim to islands in the South China Sea by deploying equipment or personnel, or take more draconian actions in Hong Kong. Both countries have moved steadily to deepen their presence and influence across Asia and deep into the Middle East—with its access to the Mediterranean

and the West. For Moscow and Beijing, overt challenges would be a big bet, especially with an erratic and sometimes reckless President (currently on steroids) in the White House. Yet both countries will also understand that the American public has little appetite for more trauma, the military and security officials said. “I’m sure that foreign adversaries’ intelligence services have their collection systems turned up high so that they understand exactly how disruptive this pandemic is on our national-security structure,” the former C.I.A. director John Brennan said on CNN this week. North Korea and Iran may also try to exploit the moment, although both have fewer capabilities than Russia or China. Tehran is still smarting from the U.S. assassination, in January, of General Qassem Suleimani, the head of its élite Quds Force, a wing of the Revolutionary Guards, which supports several militias that have attacked U.S. troops in Iraq and Lebanon. “I suspect Iran is not done seeking revenge for the killing of Suleimani,” Lute told me. Tehran’s strength is in the proxy forces it arms, aids, and often directs across the Middle East, particularly Lebanon, Iraq, and Yemen. Since Suleimani’s death, attacks by the Popular Mobilization Forces on U.S. troops and the American Embassy in Iraq have steadily escalated; the P.M.F., backed and sometimes directed by Iran, is the umbrella for some sixty predominantly Shiite militias that operate in separate brigades. Last month, the campaign sparked a diplomatic crisis when Secretary of State Mike Pompeo warned the Iraqi government that the United States would close its Embassy in Baghdad—one of the largest American diplomatic facilities in the world—if the government did not prevent the militias from firing on the U.S. compound and American troops based elsewhere in Iraq. “Our global deterrence at the high end—nuclear and conventional deterrence in Europe, Asia, and the Gulf—will not be tested,” Lute said. “But there may be challenges at lower levels through cyber or by proxies.”

#### These all go nuclear

David Kampf 20, senior PhD fellow at the Center for Strategic Studies at The Fletcher School, “How COVID-19 Could Increase the Risk of War,” World Politics Review, 6-16-2020, https://www.worldpoliticsreview.com/articles/28843/how-covid-19-could-increase-the-risk-of-war

It’s hard to see the U.S. reluctance to lead as anything other than a sign of its inevitable, if slow, decline. The country’s institutionalized inequalities and systemic racism have been laid bare in recent months, and it no longer looks like a beacon for others to follow. The global balance of power is changing. China is both keen to assert a greater leadership role within traditionally Western-led institutions and to challenge the existing regional order in Asia. Between a rising China, revanchist Russia and new global actors, including non-state groups, we may be heading toward an increasingly multipolar or nonpolar world, which could prove destabilizing in its own right.

Finally, the pacifying effect of nuclear weapons could be waning. While vast nuclear arsenals once compelled the United States and the Soviet Union to reach arms control agreements, old treaties are expiring and new talks are breaking down. Mistrust is growing, and the chance of an unwanted U.S.-Russia nuclear confrontation is arguably as high as it has been since the Cuban missile crisis.

The theory of nuclear peace may no longer hold if more countries are tempted to obtain their own nuclear deterrent. Trump’s decision to abandon the Iran nuclear deal, for one thing, has only increased the chance that Tehran will acquire nuclear weapons. It’s almost easy to forget that, just a few short months ago, the United States and Iran were one miscalculation or dumb mistake away from waging all-out war. And despite Trump’s efforts to negotiate nuclear disarmament with Kim Jong Un’s regime in Pyongyang, it is wishful thinking to believe North Korea will give up its nuclear weapons. At this point, negotiators can only realistically try to ensure that North Korea’s nuclear menace doesn’t get even more potent.

In other words, by turning inward, the United States is choosing to leave other countries to fend for themselves. The end result may be a less stable world with more nuclear actors.

If only one of these theories for peace were worsening, concerns would be easier to dismiss. But together, they are unsettling. While the world is not yet on the brink of World War III and no two countries are destined for war, the odds of avoiding future conflicts don’t look good.

The pandemic is already degrading democracies, harming economies and curtailing international cooperation, and it also seems to be fostering internal instability within states. Rachel Brown, Heather Hurlburt and Alexandra Stark argue that the coronavirus could in fact sow more civil conflict. If this proves accurate, the increase in civil wars is likely to lead to more external meddling, and these next proxy wars could soon precipitate all-out international conflicts if outsiders aren’t careful. With the usual deterrents to conflict declining around the world, major wars

### Adv 1

#### Integration between pharma and biotech is accelerating, unlocking innovation.

Cancherini ’21 [Laura; April 30; Consultant in McKinsey’s Brussels office; McKinsey, “What’s ahead for biotech: Another wave or low tide?” https://www.mckinsey.com/industries/pharmaceuticals-and-medical-products/our-insights/whats-ahead-for-biotech-another-wave-or-low-tide]

Fundamentals continue strong

When we asked executives and investors why the biotech sector had stayed so resilient during the worst economic crisis in decades, they cited innovation as the main reason. The number of assets transitioning to clinical phases is still rising, and further waves of innovation are on the horizon, driven by the convergence of biological and technological advances.

In the present day, many biotechs, along with the wider pharmaceutical industry, are taking steps to address the COVID-19 pandemic. Together, biotechs and pharma companies have [more than 250 vaccine candidates in their pipelines](https://www.mckinsey.com/industries/pharmaceuticals-and-medical-products/our-insights/on-pins-and-needles-will-covid-19-vaccines-save-the-world), along with a similar number of therapeutics. What’s more, the crisis has shone a spotlight on pharma as the public seeks to understand the roadblocks involved in delivering a vaccine at speed and the measures needed to maintain safety and efficacy standards. To that extent, the world has been living through a time of mass education in science research and development.

Biotech has also benefited from its innate financial resilience. Healthcare as a whole is less dependent on economic cycles than most other industries. Biotech is an innovator, actively identifying and addressing patients’ unmet needs. In addition, biotechs’ top-line revenues have been less affected by lockdowns than is the case in most other industries.

Another factor acting in the sector’s favor is that larger pharmaceutical companies still rely on biotechs as a source of innovation. With the [top dozen pharma companies](https://www.mckinsey.com/business-functions/m-and-a/our-insights/a-new-prescription-for-m-and-a-in-pharma) having more than $170 billion in excess reserves that could be available for spending on M&A, the prospects for further financing and deal making look promising.

For these and other reasons, many investors regard biotech as a safe haven. One interviewee felt it had benefited from a halo effect during the pandemic.

More innovation on the horizon

The investors and executives we interviewed agreed that biotech innovation continues to increase in quality and quantity despite the macroeconomic environment. Evidence can be seen in the accelerating pace of assets transitioning across the development lifecycle. When we tracked the number of assets transitioning to Phase I, Phase II, and Phase III clinical trials, we found that Phase I and Phase II assets have transitioned 50 percent faster since 2018 than between 2013 and 2018, whereas Phase III assets have maintained much the same pace. There could be many reasons for this, but it is worth noting that biotechs with Phase I and Phase II assets as their lead assets have accounted for more than half of biotech IPOs. Having an early IPO gives a biotech earlier access to capital and leaves it with more scope to concentrate on science.

Looking forward, the combination of advances in biological science and accelerating developments in technology and artificial intelligence has the potential to take innovation to a new level. A [recent report](https://www.mckinsey.com/industries/pharmaceuticals-and-medical-products/our-insights/the-bio-revolution-innovations-transforming-economies-societies-and-our-lives) from the McKinsey Global Institute analyzed the profound economic and social impact of biological innovation and found that biomolecules, biosystems, biomachines, and biocomputing could collectively produce up to 60 percent of the physical inputs to the global economy. The applications of this “Bio Revolution” range from agriculture (such as the production of nonanimal meat) to energy and materials, and from consumer goods (such as multi-omics tailored diets) to a multitude of health applications.

#### Antitrust law is a battering ram for innovation and chills patent stability.

Mosoff et al. ’19 [Adam, Kristen Osenga, Randall Rader, Mark Schultz, and Saurabh Vishnubhakat; January 28; Professor of Law at George Mason University; Regulatory Transparency Project, “How Antitrust Overreach is Threatening Healthcare Innovation,” <https://regproject.org/paper/how-antitrust-overreach-is-threatening-healthcare-innovation/>]

II. The FTC’s Heavy-Handed Meddling Upsets the Delicate Balance Between Branded and Generic Drug Companies, Hindering Innovation and Harming Consumers

Since the late 1990s, the FTC has devoted substantial resources to combating what it views as anticompetitive behavior on the part of drug companies in the healthcare market. The FTC has interposed its scrutiny even where the FDA has approved drugs and when the branded and generic companies have decided a legal fight is no longer worth having. The FTC’s meddling restricts behavior that is lawful under the Federal Food, Drug, and Cosmetic Act (FDCA). The FTC’s meddling also usurps the regime Congress carefully crafted for resolving patent disputes between branded and generic drug companies.

The FTC has devised a series of novel theories to justify treating lawful behavior as anticompetitive and worthy of enforcement action and legislative changes. These theories have been adopted—and adapted—by state antitrust enforcers as well as private antitrust plaintiffs. The FTC has conducted industry-wide investigations and prepared massive reports on supposed anticompetitive conduct to recommend legislative changes despite neither the branded nor generic drug industry seeking such changes. These changes to the law would restrict or punish patent owners and even patent challengers. The FTC has, on its own initiative, made the already volatile world of drug development more uncertain and more hostile, ultimately resulting in less innovation and fewer choices for consumers in the short term (e.g., generic options) and long term (e.g., new drugs).

The FTC’s aggression extends to the courtroom. For nearly two decades, the FTC and other antitrust plaintiffs have attacked patent settlements reached by branded and generic drug companies. As explained above, the regulatory scheme for new drugs gives rise to an unusual type of patent litigation in which the generic drug company—the defendant—is not at risk of money damages for infringement because litigation generally occurs before the generic drug has obtained FDA approval and enters the market. Because of this unusual arrangement, where each side had to yield something of value to the other at the settlement table, a patent owner occasionally pays a settlement to the defendant (rather than forgiveness of damages, which is typically not an option) in exchange for the defendant agreeing to slightly delay the launch of its generic drug. Other considerations, such as the generic company agreeing to source materials from the branded company or other business or research partnerships, are not uncommon.

Beginning in the 1990s, the FTC took the position that such settlements were a categorically illegal restraint of trade. Courts did not agree, as modern antitrust jurisprudence recognizes that declaring something categorically illegal in the absence of more facts and details is dubious. Courts generally concluded that a settlement within the scope of the patent—where the defendant agreed to remain off the market no more than already required by the patent but perhaps longer than a successful court challenge—did not itself violate the antitrust laws. Yet the FTC persisted in arguing its position to the Supreme Court. In the 2013 Actavis case, the Supreme Court declined the FTC’s invitation to find reverse payment settlements categorically anticompetitive, ruling instead that these settlements must be evaluated under antitrust law’s “rule of reason,”, which is a detailed look at all the relevant facts and circumstances of the individual case.7 Still undeterred in the wake of Actavis, the FTC continues to argue that a variety of patent settlements are anticompetitive and accuse district courts of misinterpreting Actavis.

The FTC’s basic position is that antitrust scrutiny is triggered when the patent owner offers anything of value beyond the litigation expenses that settlement would save. Any patent owner who tries to entice a generic competitor to settle by offering anything more than litigation costs is treated suspiciously by the FTC. Even if the settlement is a complex corporate transaction that involves manufacturing and promotion deals or other products—where both parties might benefit beyond merely the ending of a lawsuit—the FTC’s basic position is to presume an antitrust violation.

Not surprisingly, the FTC’s overzealous actions against drug makers make it very difficult to settle pharmaceutical patent litigation without branded and generic drug companies both expecting an antitrust case, which may itself end up effectively revisiting the patent issues the parties sought to move beyond by settling. Companies still try to craft agreements that eliminate the risk that both face in litigation while ensuring that generic market entry occurs well before patent expiry, but no matter the terms, the FTC stands ready to argue that the companies should not have settled. In the end, these parties seem to want patent litigation cases to continue to final judgment, even when this is not in the interest of the branded companies, generic drug companies, consumers or the federal court system.

The FTC has also started to interfere with the ordinary cycle of incremental innovation in the drug industry. Incremental drug innovation is both commonplace and can be medically important. New dosage forms and routes of administration can make life-sustaining drugs easier to administer to new populations. New formulations, such as extended release formulations, can simplify dosing, thus increasing patient compliance.

In recent years, however, the FTC has targeted these patents. The chief complaint advanced by the FTC is that incremental innovations are trivial advances and do not deserve patent protection. Where the branded company replaces an older version of its product with the patented new version, the FTC accuses the branded company of “product hopping” to force the market to move to new drugs. The problem with this argument is threefold. First, these innovations have satisfied the requirements of the Patent Act. Second, if they are indeed trivial, the patents will likely be held invalid in federal court when challenged by generic competitors.  Third, if the branded company’s new product does not provide better outcomes, insurers are unlikely to cover the product and will instead require a patient to use the generic version of the branded company’s first product. The FTC’s actions are thus a solution in search of a problem.

Conclusion

The FTC’s goals may be well-intentioned, but its intrusion into domains that other, more exper

t agencies already oversee and comprehensively regulate is troubling. By substituting its own agenda for the business judgment of sophisticated parties in the marketplace, the FTC has overreached its proper role and begun to disrupt the cycle of investment, product development, recoupment, further incremental advancement, and risk management that drives the creation of new drugs that save lives and promote greater public health.

**Natural pandemics won’t cause human extinction**

Sebastian **Farquhar** 1/23/**17**, director at Oxford's Global Priorities Project, Owen Cotton-Barratt, a Lecturer in Mathematics at St Hugh’s College, Oxford, John Halstead, Stefan Schubert, Haydn Belfield, Andrew Snyder-Beattie, "Existential Risk Diplomacy and Governance", GLOBAL PRIORITIES PROJECT 2017, https://www.fhi.ox.ac.uk/wp-content/uploads/Existential-Risks-2017-01-23.pdf

1.1.3 Engineered pandemics For most of human history, natural pandemics have posed the greatest risk of mass global fatalities.37 However, there are some reasons to believe that **natural pandemics are very unlikely to cause human extinction**. Analysis of the International Union for Conservation of Nature (IUCN) red list database has shown that of the 833 recorded plant and animal species extinctions known to have occurred since 1500, less than 4% (31 species) were ascribed to infectious disease.38 None of the mammals and amphibians on this list were globally dispersed, and other factors aside from infectious disease also contributed to their extinction. It therefore seems that our own species, which is very **numerous**, globally **dispersed**, and capable of a **rational response** to problems, **is very unlikely to be killed off by a natural pandemic**. One underlying explanation for this is that highly lethal pathogens can kill their hosts before they have a chance to spread, so **there is a selective pressure for pathogens not to be highly lethal**. Therefore, pathogens are likely to co-evolve with their hosts rather than kill all possible hosts.39

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

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

**A**nti**b**iotic-**r**esistant infections kill at least 700,000 people worldwide a year right now, according to an exhaustive report commissioned by the UK in 2014, and without any substantial medical breakthroughs or policy changes that slow down resistance, they may claim some **10 million deaths annually by 2050** — eclipsing cancer in general as a leading cause. These deaths largely **won’t** come from pan-resistant infections, just tougher ones. A preventable death there, a preventable death here. Leaving that aside, antibiotics, along with proper sanitation and nutrition, gird our entire way of living. Most every invasive surgery, pregnancy, organ transplant and chemotherapy session we go through will become riskier. Other diseases like HIV, malaria or influenza will become deadlier, since bacteria often exploit the opening in our immune system they leave behind. And already precarious populations like those living with cystic fibrosis, prisoners, and the poor will lose years off their lives. For all the warranted gloom, though, Farewell does think there are reasons to be hopeful. “I don’t think we are doing enough, but the scientific community along with many governmental and private foundations are **very actively involved** in finding not only new antibiotics, but new solutions to this problem,” she said. There’s been a noticeable change in attitude and increased urgency surrounding antibiotic resistance, she said, one that she hadn’t seen even five years ago, let alone twenty. Until recently, that attitude change could be seen from places as high up as the U.S. federal government. In 2014, former President Obama issued an executive order aimed at addressing antibiotic resistance, the first real acknowledgement of the problem from an administration, devoting funding and outlining a national action for combatting resistance. Through its federal agencies, the administration pushed to reduce antibiotic use on farms and encouraged doctors to stop using them in excess. “There has been a lot of work done the last couple of years, much of it spurned by [Obama’s] National Action Plan,” said Dr. David Hyun, a senior officer for Pew Charitable Trusts’ Antibiotic Resistance Project. The CDC, in particular, has used its funding to open up regional labs that allow them to better detect and respond to antibiotic-resistant outbreaks like the Nevada case, he said. They ultimately hope to create an expansive surveillance system that can easily keep track of resistance rates on a national, state and regional level. A parallel system also exists for monitoring resistance in the food chain, shepherded by the CDC and the U.S. Department of Agriculture. In fact, it was this sort of cooperation between national and local health agencies that enabled Nevada doctors to stop the worst from happening, said Dr. Lei Chen. The swift identification of a possible CRE strain by the hospital, coupled with the woman’s medical history, led to a precautionary quarantine, while also prompting Chen’s public health department and eventually the CDC into action. And it may help **prevent future cases from spilling into the public**. According to Chen, the CDC has allocated funding this year to all of Nevada’s state public health departments so they can better detect CRE and other dangerous resistant strains. Under the Trump administration, there’s no telling how these small victories will hold up or whether they will advance. All references to antibiotics once found on the Whitehouse.gov site have been removed, including a link to the Obama administration’s national action plan, and the fact that they’re already tried to bar USDA scientists from discussing their work with the public while stripping funding from other public health agencies isn’t encouraging. **Even with the best public policy**, however, there’s no clear light at the end of the tunnel.

Antibiotic resistance has gradually been worsening, even within the last 15 to 20 years, when superbugs like methicillin-resistant Staphylococcus aureus (MRSA) first became widely known, said Hyun. The effort needed to develop new drugs has been in short supply, hamstrung by pharmaceutical companies’ inability to recoup the costs of bringing new antibiotics to market. That’s because, unlike the latest heart medication, any new antibiotics will have to be treated like the last drops of water during a drought, used as little as possible — the exact opposite way to make money off a new product. Yet, much like climate change, the financial toll of not doing anything will total in the trillions years down the road. And it already numbers in the billions now, according to the CDC. Of course, we need bacteria to survive. And most need or pay no mind to us in return. Even pan-resistant bacteria don’t really mean harm. Some have been found in perfectly healthy people, a fact that’ll either comfort you or keep you awake at night, only causing problems when our immune system wavers. There’s **no army of sentient E. coli that will rise up and someday overthrow the human race**. But barring the calvary showing up, a new fear of ours will learn to settle in, almost unnoticed. It’ll creep in when we pick our heads up from a nasty fall that scrapes our skin open or breaks our bones; when we wave goodbye to our loved ones before they enter an operating room, or when we cradle our newborns into a world teeming with the living infinitesimal, wishing there was still a way to shield them from it as our parents once could for us. A fear of naked vulnerability. **The antibiotic apocalypse will be gentle**, if it fully arrives, but it won’t be any less devastating to the human spirit.

### Adv 2

**Peak oil turns healthcare.**

**Pennock et al. 15**. Michael Pennock MASc is a population health epidemiologist based in Victoria, British Columbia. Formerly the Research Director of the Population Health Research Unit at Dalhousie University, Mike is currently working with the BC Ministry of Health where he is responsible for the Population Health Surveillance and Epidemiology program. Blake Poland, PhD is Associate Professor at the Dalla Lana School of Public Health, University of Toronto. His research has focused on the settings approach to health, the health of marginalised groups, and the sociology of tobacco control. Dr Trevor Hancock is a Professor of Public Health at the University of Victoria. 2015. “Resource Depletion, Peak Oil, and Public Health: Planning for a Slow Growth Future.” Geographies of Health and Development, edited by Isaac N. Luginaah and Rachel Bezner Kerr, Ashgate.

The Club of Rome Revisited In 1968 an international think-tank of industrialists, scientists and politicians called the Club of Rome asked a group at the MIT to model the effects of major global trends on the health of the planet. The MIT group built a world computer model to investigate five major trends of global concern – accelerating industrialisation, rapid population growth, widespread malnutrition, depletion of nonrenewable resources, and a deteriorating environment. The results were published in the 1972 book entitled Limits to Growth (Meadows et al. 1972). Three general conclusions arose from the projections: 1. If the present growth trends in world population, industrialisation, pollution, food production, and resource depletion continue unchanged, the **limits to growth on this planet will be reached sometime within the next 100 years**. The most probable result will be a **sudden and uncontrollable decline in both population and industrial capacity.** 2. It is possible to alter these growth trends and to establish a condition of **ecological and economic stability** that is **sustainable far into the future**. The state of global equilibrium could be designed so that the basic material needs of each person on earth are satisfied and each person has an equal opportunity to realise his or her individual human potential. 3. If the world’s people decide to strive for this second outcome rather than the first, **the sooner they begin working** to attain it, **the greater will be their chances of success** (Meadows et al. 1972). In 1992, the modellers published an **update** of their original projections and found the trends **relatively unchanged** (Meadows 2004). They stated that they would re-write the three basic conclusions as follows: 1. Human use of many essential resources and generation of many kinds of pollutants have already surpassed rates that are physically sustainable. Without significant reductions in material and energy flows, there will be in the coming decades an uncontrolled decline in per capita food output, energy use, and industrial production. Resource Depletion, Peak Oil, and Public Health 179 2. This decline is not inevitable. To avoid it two changes are necessary. The first is a comprehensive revision of policies and practices that perpetuate growth in material consumption and in population. The second is a rapid, drastic increase in the efficiency with which materials and energy are used. 3. A sustainable society is still technically and economically possible. It could be much more desirable than a society that tries to solve its problems by constant expansion. The transition to a sustainable society requires a careful balance between long-term and short-term goals and an emphasis on sufficiency, equity, and quality of life rather than on quantity of output. It requires more than productivity and more than technology; it also requires maturity, compassion, and wisdom. In 2008 Graham Turner at the Commonwealth Scientific and Industrial Research Organisation in Australia published a paper called ‘A Comparison of `The Limits to Growth` with Thirty Years of Reality’ (Turner 2008). It examined the extent to which the trends of the past 30 years were consistent with the Limits to Growth forecasts and concluded that changes in industrial production, food production and pollution are all in line with the book’s predictions of economic and societal collapse by the middle of the twenty-first century. In summary, the original forecasts produced by the MIT group which predicted a substantial collapse of the global ecosystem and economy during the mid-century period appear to be on track 30 years after they were generated. One of the key trends included in the MIT/Club of Rome analysis involved a sharp tightening of global energy supplies and this is the topic of the remainder of this chapter. Peak oil is a compelling and imminent example of a resource depletion issue that has profound environmental, economic and social implications. Although some effects will be potentially positive, many will be negative. As we argue below, the likely effects will include a reversal of historic post-industrial trends in globalisation, economic growth, travel, and availability and cost of both staples and luxury goods, a worsening of income inequalities, and negative impacts upon the social determinants of health. Although many of the scenarios which are sketched around peak oil are described by some in almost ‘doomsday’ overtones, a successful adaptation to the new reality of scarce and expensive oil could create a future which is also consistent with many of the characteristics of a healthy community: cleaner air, healthier lifestyles, improved food security, greater conviviality/ social capital and, possibly, improved economic security. The chapter will conclude with a brief discussion of the role that public health can play in facilitating a successful adaptation to this new world of resource scarcity. What is Peak Oil? The term ‘peak oil’ refers to the expectation that global oil production will reach a maximum or ‘peak’ at some point and then decline in subsequent years. This is not about the ‘end of oil’ but rather the point at which it cannot be extracted any faster. This usually happens when roughly half of the available reserve has been exploited, necessitating additional measures (e.g. injection of high pressure steam) to continue expected extraction rates. Since most of the largest oil fields in current production have already peaked, and they decline at a documented rate of 4–12 per cent (a rate that may increase over time) (Hook et al. 2009; UKERC 2009), this has necessitated chasing after more remote (and 180 Geographies of Health and Development expensive) sources (deep water, oil sands etc.). This cost issue is often expressed in terms of the amount of energy (expressed in barrels of oil) that is required to extract each barrel of oil, also known as ‘energy return on investment’ (EROI). Mature Saudi oil fields had an EROI of 1:100 for most of their pre-peak years. As the surface levels of those sources were extracted, the energy requirements increased to extract deeper reserves. By 1999 world production averaged out at 35 barrels produced for each barrel invested and the numbers continued to fall as new sources such as the tar sands produce only two to four barrels and shale production average five barrels for each barrel invested (Murphy and Hall 2010). The majority of new oil discoveries are in deep sea locations and the estimated cost of developing those sites is between $60 and $85 a barrel, compared to $20 for Saudi Arabian oil (Murphy and Hall 2011). History of Peak Oil In the mid-1950s, an American geologist named M. King H Hubbert developed a model which predicted that production from US oil fields would peak in the early 1970s (Bridges 2010; Hubbert 1956). Although his projections were widely rejected by his colleagues in the petroleum industry, his projection turned out to be remarkably accurate. This midway point became known as Hubbert’s Peak. Discussion about when the global Hubberts Peak would occur have been numerous and passionate. The estimated dates, from various sources are presented in Table 11.1 (Based on Frumkin, Hess and Vindigni, 2009, with more recent sources added). The more recent estimates seem to cluster around 2015–2020 or out to 2030, although some suggest there will be no peak. Fatih Birol, the Chief Economist of the International Energy Agency, stated in an April 2011 interview on the Australia Broadcasting Corporation that the IEA believed that world oil production had peaked in 2006: On the one hand we have this pressure on the demand side, but when we look at the production side the prospects are a little bleak. We think that the crude oil production has already peaked in 2006, but we expect oil to come from the natural gas liquids, the type of liquid we have through the production of gas, and also a bit from the oil sands. But in any case it will be very challenging to see an increase in the production to meet the growth in the demand, and as a result of that one of the major conclusions we have from our recent work in the energy outlook is that the age of cheap oil is over. We all have to prepare ourselves, as governments, as industry, or as a private car driver, for higher oil prices. (Birol 2011) The concept, reality, and timing of peak oil have been hotly debated since Hubbard’s first formulation, and understandably so given the centrality of cheap oil to the global economy and the ramifications that the end of cheap oil would have on globalisation. Accurate projections of remaining supplies are complicated by uncertainties in estimating the size of reserves, economic and political pressures to over-estimate the size of known reserves (e.g. OPEC production quotas are tied to reserve size, as are oil company share values), and the sheer complexity of the field. Moreover, production rates depend not only on underlying geology but also drilling techniques, production quotas, and political developments (insurgency, local unrest, sanctions). More recently, it has been suggested that new developments in ‘fracking’ for shale oil has altered the picture significantly, with some claims being made that peak oil is postponed indefinitely or that the US will soon emerge as a global energy superpower and net exporter (Ungar 2012; McClanahan 2012; Cohen 2013). On the other hand, detailed analysis of existing fracking wells reveal high annual depletion rates- with observed rates between 33 per cent (Biermann 2012) and 52 per cent (Hughes 2012) – well above the 4–10 per cent reported for conventional oil fields, such that growth in production can only be achieved with exponential increases in drilling rates (Whipple 2012). With these more recent developments in mind, then, we make two crucial observations. On balance, it seems that most analysts accept that there will be a peak to oil production, and that it will come in the next 10–15 years. But that may not be – indeed probably is not – the key issue. There are two other aspects of the argument that are more important than deciding when/if peak oil will arrive. • First, peak oil is not so much a peaking of supply or production as it is the end of the era of **cheap** oil. Since globalisation requires not just oil but cheap oil, the ramifications are significant, **regardless of when peak production** (which will only be evident in hindsight) occurs. The development of deepwater, arctic and tar sands sources despite a weak economy suggests **the end of cheap oil is upon us**, as many of these new sources are only economical at **$80+/barrel**. The implications for the global economy are profound. • Second, as McKibben (2012) and others have made clear, even if there was no peak oil, we are fast approaching – and may already be past – the peak of oil production (and fossil fuel production more generally) that the **planet can tolerate**. It has been estimated that we cannot burn more than another 565 gigatons of carbon dioxide if we are to stay below the 2°C of warming that is the target upper limit for global warming, but it is also estimated that the fossil fuel corporations now have 2,795 gigatons in their reserves, or five times the allowable upper limit (Carbon Tracker Initiative 2012). And they have no intention of leaving it unburned. Put simply, we’re beyond the era of cheap or limitless oil and other fossil fuels, because even if oil, coal and gas were limitless, we need peak oil, because we can no longer afford (environmentally) to exploit remaining known reserves. However, as Hopkins (2008) points out in The Transition Handbook, although we might ‘need’ peak oil, the likelihood is that without a clear societal commitment and plan to transition to a low-carbon future, the response to peak oil is likely to be to chase whatever alternative fossil fuel reserves we can get – and many of these, like coal, are going to exacerbate climate change. Thus so-called ‘solutions’ to peak oil can **exacerbate climate change** and so the response must be a coordinated one on both fronts, one that deals with the economic, political, social, and distributive impacts of a fossil-fuel-constrained future alongside the **ecological impacts of the damage we’ve already wrought** – and will continue to wreak, because it will take us decades of continued fossil fuel use to make the transition. The Health-related Implications of Rising World Oil Prices The debate about the actual date of the global Hubbert’s Peak, although interesting, is less important than the implications for energy prices. Regardless of when the actual peak takes place, it is expected that prices will rise and, in the short term, become more volatile as the peak is approached and continue to rise thereafter. As reflected in the figure below, world oil prices have behaved in recent years in a way that is consistent with the peak oil theory. Prices rose dramatically after 2005 as a result of increased costs of production coupled with the impact of increasing demand from China and India. They reached a peak of $140 a barrel at the start of the current recession, and it has been suggested that these prices were the underlying cause of the recession (Rubin 2009). Further, it is suggested that in this close relationship between energy prices and economic performance, the spare capacity required to fuel a global economic ‘recovery’ no longer exists, and that globalisation (itself highly dependent on cheap oil) is in question (ibid.). It’s unlikely that we can continue to fill Dollar Stores and Walmarts in North America with items produced in China when shipping costs outweigh the actual dollar value of the items themselves. The effects of these rising prices are expected to be **widespread and profound** given the widespread use of petroleum as both an energy source and an input into the many products of the petrochemical industry, such as plastics and fertilisers. **Widespread inflation is anticipated**, particularly in food prices, heating, transportation, fertilisers and all plastic products. Some industries, such as tourism and airlines will be particularly **hard hit** and some analysts, such as former CIBC world markets chief analyst Jeff Rubin have argued that the world economy will be in danger of entering a long period of stagflation (ongoing recession accompanied by high levels of inflation) (Rubin 2009). Not all of the consequences will be negative. An era of high energy prices could decrease the quantity of CO2 produced into the atmosphere as individuals are forced to reduce their consumption. In essence, Peak Oil will accomplish the goals of a carbon tax by decreasing the supply of energy (and thus increasing its price) to the point where individuals are forced to conserve. Rubin (2009) has argued that rising energy prices will bring an end to globalisation by dramatically increasing the transportation costs of bringing goods to market, but that this will also boost local production. However, none of this is a foregone conclusion. It’s just as possible that rising oil prices will press more coal into production, not only for electricity production, but also in terms of large-scale coal ‘gasification’ projects, and/or make oil extraction from tar sands or through fracking more economical. The potential for a catastrophic increase in Greenhouse Gas emissions from coal at a time when we are already perilously close to major climatic tipping points, should not be underestimated. In recent years the implications of increasing energy prices on health has received increased attention from within the public health community. In March 2008, the US Figure 11.1 Crude Oil Prices 1861–2011 (2011 US Dollars) Source: BP Statistical Review of World Energy June 1012; http://www.bp.com/statisticalreview. 184 Geographies of Health and Development Centers for Disease Control and the Johns Hopkin School of Public Health sponsored a symposium on the subject, and three prominent public health journals in the UK and the US have devoted special issues to the topic (Public Health 2008, Public Health Reports Jan–Feb 2008; and the American Journal of Public Health September 2011). The Canadian public health community has been slower to respond. No articles on the topic have appeared in the Canadian Journal of Public Health, although a number of Canadian health researchers have been addressing peak oil in other venues (Poland and Dooris 2010; Spady and Gagnon 2010; Hancock 2011; Poland et al. 2011) and Canadians were early prominent voices on these issues outside of the health sector (e.g. Homer-Dixon 2006; Rubin 2009). The remainder of this chapter will discuss some of the implications of peak oil that have been identified for the health care system and for population health. We conclude that the most profound effects will be on income equity and the social determinants of health and that will require meaningful mitigation through effective social policies. We highlight potential roles that the public health sector can play in facilitating an effective adaptation to this particular expression of resource scarcity in fossil fuels. As such, these discussions can illuminate the potential role of the sector in facilitating successful transitions to a future of slower growth and diminished supplies of a variety of natural resources. Peak Oil and Environmentally Responsible Health Care As large-scale consumers of fossil-fuel energy for uses such as heating, transportation and electrical equipment, lighting etc., **health care providers** will experience the inflationary impact of peak oil. The sector is also a major consumer of **plastics**, as the majority of modern anti-septic practices have come to rely on disposable plastic materials, including tubing, syringes and gloves. In addition, many medications are developed from **petroleumbased products**, including aspirin, many antihistamines, antibiotics, antineoplastics, and psychoactive drugs. Petroleum-based products are also used for **tablet binders** and **pillcoatings**. Hospitals are **substantial users of energy**. A Natural Resources Canada study in 2003 concluded that Canadian hospitals consumed as much energy as 450,000 households (Natural Resources Canada 2003). The **upward pressure on health care costs** which will result from escalating energy prices will occur at a time when governments are facing other revenue and expenditure challenges which are associated with the cost increases and an economy in decline. Based on past performance in the US, Hess, Bednarz, Bae and Pierce (2011), estimated that a 1 per cent increase in monthly fuel oil prices would result in a 0.03 per cent increase in monthly medical care prices with an 8 month time lag. Thus a **doubling in fuel prices would result in a 3 per cent increase in medical costs**.

**Economic decline increases cooperation.**

Christina L. **Davis &** Krzysztof J. **Pelc 17**, Christina L. Davis is a Professor of Politics and International Affairs at Princeton; Krzysztof J. Pelc is an Associate Professor of Political Science at McGill University, “Cooperation in Hard Times: Self-restraint of Trade Protection,” Journal of Conflict Resolution, 61(2): 398-429

Conclusion Political economy theory would lead us to expect rising trade protection during hard times. Yet **empirical evidence** on this count has been mixed. Some studies find a correlation between poor macroeconomic conditions and protection, but the worst recession since the Great Depression has generated surprisingly moderate levels of protection. We explain this apparent contradiction. Our statistical findings show that under conditions of pervasive economic crisis at the international level, states exercise more **restraint** than they would when facing crisis alone. These results throw light on behavior not only during the crisis, but throughout the WTO period, from 1995 to the present. One concern may be that the restraint we observe during widespread crises is actually the result of a decrease in aggregate demand and that domestic pressure for import relief is lessened by the decline of world trade. By **controlling** for **product-level imports**, we show that the restraint on remedy use is not a byproduct of declining imports. We **also** take into account the ability of some countries to **manipulate their currency** and demonstrate that the relationship between crisis and trade protection **holds** independent of exchange rate policies. Government decisions to impose costs on their trade partners by taking advantage of their legal right to use flexibility measures are driven not only by the domestic situation but also by circumstances abroad. This can give rise to an individual **incentive for strategic self-restraint** toward trade partners in similar economic trouble. Under conditions of widespread crisis, government leaders **fear** the **repercussions** that their own use of trade protection may have on the behavior of trade partners at a time when they cannot afford the economic cost of a trade war. Institutions provide **monitoring** and a venue for **leader interaction** that **facilitates coordination** among states. Here the key function is to reinforce expectations that any move to protect industries will trigger similar moves in other countries. Such coordination often draws on shared historical analogies, such as the Smoot–Hawley lesson, which form a focal point to shape beliefs about appropriate state behavior. Much of the literature has focused on the more visible action of legal enforcement through dispute settlement, but this only captures part of the story. Our research suggests that tools of informal governance such as leader pledges, guidance from the Director General, trade policy reviews, and plenary meetings **play a real role** within the trade regime. In the absence of sufficiently stringent rules over flexibility measures, compliance alone is insufficient during a global economic crisis. These **circumstances** trigger **informal mechanisms** that complement legal rules to **support cooperation**. During widespread crisis, legal enforcement would be inadequate, and informal governance helps to bolster the system. Informal coordination is by nature difficult to observe, and we are unable to directly measure this process. Instead, we examine the variation in responses across crises of varying severity, within the context of the same formal setting of the WTO. Yet by focusing on discretionary tools of protection—trade remedies and tariff hikes within the bound rate—we can offer conclusions about how systemic crises shape country restraint independent of formal institutional constraints. Insofar as institutions are generating such restraint, we offer that it is by facilitating informal coordination, since all these instruments of trade protection fall within the letter of the law. Future research should explore trade policy at the micro level to identify which pathway is the most important for coordination. Research at a more macro-historical scope could compare how countries respond to crises under fundamentally different institutional contexts. In sum, the determinants of protection include economic downturns not only at home but also abroad. Rather than reinforcing pressure for protection, pervasive crisis in the global economy is shown to generate countervailing pressure for restraint in response to domestic crisis. In some cases, **hard times bring more, not less, international cooperation**.

**No “wag the dog” lashout---checks solve.**

David **French 17**. Senior writer for National Review. “We Have Enough Checks on the President’s Power to Order a Nuclear Strike.” National Review. November 16, 2017. <https://www.nationalreview.com/corner/we-have-enough-checks-presidents-power-order-nuclear-strike/>

As it is, the president possesses the **exclusive legal authority** to order a nuclear attack. No general can decide to use our most deadly weapons, even if the forces under his command face complete destruction and only a nuclear strike can save his troops. A general facing a crumbling front and an imminent military disaster has only conventional weapons at his command. At the same time, the president doesn’t have to consult with Congress before using our nation’s ultimate weapons. It’s one reason why the American commander-in-chief is rightly described as the most powerful man in the world. **But it’s not unchecked power**. Every American president is subjected to important constitutional and military restraints. The most important constitutional safeguard against the kind of man who’d launch a truly rogue strike — initiate genocidal war on impulse — is **the 25th Amendment**. A man so unhinged is incapable of serving as president, and the Constitution provides for his emergency removal if the vice president and a “majority of the principal officers of the executive departments” determine that the president is “unable to discharge the powers and duties of his office.” Moreover, a proper reading of the Constitution also limits the president’s authority to initiate any kind of war, including nuclear war. The Constitution reserves the power to declare war to Congress. The commander-in-chief, by contrast, is responsible for waging war. When our constitutional system is functioning, the only time the president should be able to act without Congress is when he’s **responding immediately** to an actual or imminent attack on the United States, on Americans abroad, or to an attack on American allies when we’re under a Senate-ratified defense obligation. Even then, he should turn to Congress as soon as possible to ratify his defensive response and authorize offensive military action. As we know, however, a number of American presidents have disagreed with this constitutional formulation and have taken it upon themselves to wage war without congressional approval. And they’ve done so without facing any constitutional consequence. In other words, one of our constitutional safeguards has already failed — at least in the face of lower-stakes conflicts. Thus, we have to consider a nightmare scenario. What if a president snaps — acting before his cabinet can remove him — and orders an indefensible, rogue nuclear strike? The answer is simple. **The military wouldn’t comply**

It’s officers are bound by law to refuse lawless commands, and the modern American military has profound cultural and moral restraints against the kind of world-changing mass murder that would result from a rogue strike. It won’t happen. In fact, it’s doubtful that it would happen even in the face of more defensible temptations to launch a first strike. Our nation has suffered conventional military disasters (for example, deep in North Korea during the first year of the Korean War) without resorting to nuclear weapons, and it’s hard to imagine a single general recommending a nuclear strike in the absence of actual or imminent opposition use of **w**eapons of **m**ass **d**estruction. Our military is built to fight and win wars through the use of conventional weapons . . . and conventional weapons alone. Of course one can always imagine a different, dystopian future where our current safeguards would be inadequate. But as much as I’ve critiqued Trump on other grounds, I have no fear that he’ll attempt a rogue strike. In fact, his actual military policies since assuming office have been quite **moderate**, and his military operations have not just been successful, they’ve been conducted **squarely in compliance with the laws of armed conflict**.

## 2NC

### CP

#### FDA solves

Arti K. Rai and Barak D. Richman 18. 5-22-18. Arti Rai, Elvin R. Latty Professor of Law and co-Director of The Center for Innovation Policy at Duke Law. Barak D. Richman, JD, PhD, is the Katherine T. Bartlett Professor of Law and Business Administration at Duke University. “A Preferable Path For Thwarting Pharmaceutical Product Hopping” <https://www.healthaffairs.org/do/10.1377/hblog20180522.408497/full/>

**An FDA Alternative: The Suitability Petition** In contrast to judges and juries, the FDA is in an exceptionally good position **to determine when product hops** **lack evidence** **of genuine innovation** **and** to **allow generic competition in that circumstance**. The FDA could do so by embracing a Congressionally-authorized route known as a “suitability petition.” The FDA’s authority is created by the Hatch-Waxman Act of 1984, the statute that provides the pathway to generic competition. The Hatch-Waxman Act typically requires that a generic drug have the same route of administration, dosage form, and strength as the branded drug. (21 U.S.C. §§ 355(j)(2)(A)). However, the Hatch-Waxman Act also authorizes the FDA to permit a generic to enter the market via petition even if it has a different route of administration, dosage form, or strength. The plain language of Hatch-Waxman Act states that the FDA “shall approve such a petition unless” it finds that additional studies must be conducted to show the safety and effectiveness of those features of the generic that differ from the branded drug. (21 U.S.C. §§ 355(j)(2)(C)). If the FDA had exercised its authority under this second “suitability” pathway as Namenda XR was entering the market, it could have permitted the generic producer of the Namenda IR dosage to serve as a generic alternative to Namenda XR. The FDA could have rejected the suitability petition only if additional data was necessary to show that the Namenda IR dosage was as safe and effective as the Namenda XR dosage. Unfortunately, the FDA has placed two independent barriers in the path of suitability petitions. First, instead of following Hatch-Waxman Act’s plain language that different routes of administration, dosage form, and strength shall be permitted unless there is good reason to be concerned about differences in safety and efficacy, the FDA **has relied on a definition of therapeutic equivalence** formulated prior to Hatch-Waxman Act that requires perfect identity along those three axes. Second, under longstanding policy, formalized in regulation in 2016 (21 CFR 314.93(e)1(vi)), the FDA rejects a suitability petition by a generic firm if it proposes an administration, dosage, or strength that *that was previously approved for a branded drug.* **Of course, this is presumably the case for every product hop.** Because of the FDA’s position, the generic manufacturer that wants to enter as an alternative to the hopped drug must prove that the patents that cover the new drug are invalid. This is a daunting hurdle, not because the patents are valid—to the contrary, the empirical evidence shows that the U.S. Patent and Trademark Office routinely makes mistakes and that many of these formulation patents will be found invalid if challenged—but simply because the cost of mounting patent challenges is quite significant. **To remove these barriers to suitability petitions, the FDA simply needs to revise its own policies.** Nothing in the language of Hatch-Waxman Act requires the FDA to maintain the two barriers it has adopted—to the contrary, a more natural reading of Hatch-Waxman Act suggests precisely the opposite of the FDA position. And although there is nothing in the legislative history indicating the precise reason why Congress included a suitability pathway, recent scholarship on this legislative history shows that the overall thrust of Hatch-Waxman Act was a strong “thumb on the scale” in favor of competition. **For these reasons, the FDA would be well within its power to issue regulations that would prevent many product hops**.

#### FDA better

Arti K. Rai and Barak D. Richman 18. 5-22-18. Arti Rai, Elvin R. Latty Professor of Law and co-Director of The Center for Innovation Policy at Duke Law. Barak D. Richman, JD, PhD, is the Katherine T. Bartlett Professor of Law and Business Administration at Duke University. “A Preferable Path For Thwarting Pharmaceutical Product Hopping” <https://www.healthaffairs.org/do/10.1377/hblog20180522.408497/full/>

The Path Forward Many cases in which pharmaceutical firms have been accused of product hopping and sued under the antitrust laws have involved changes of dosage, strength, or route of administration. In cases that involve only cosmetic changes—that is, when there is no reason to believe that the change altered safety and efficacy—**the FDA could approve a suitability petition and allow a generic to enter the market, injecting much-needed price competition**. Additionally, the threat of a suitability petition would give originator manufacturers a strong incentive to abandon any plan to hop a drug with an expiring patent simply by making a cosmetic change. In some cases, the originator might produce comparative data showing that its new drug product is in fact safer or more efficacious than its prior product. **Such comparative data might give the FDA reason to reject a suitability petition**, **and thus presumably protect against the threat of a petition in the first instance.** But this activity would be socially valuable: the originator would have proved that its new drug represented a meaningful innovation. In the Actavis case, in contrast, Namenda XR was only tested against a placebo and was not compared to Namenda IR. It is precisely because the Namenda hop is so typical—that is, the new drug offers only a cosmetic change—that suitability petitions can be a meaningful tool to combat high pharmaceutical prices. The case illustrates an unfortunately common strategy that inappropriately extends monopoly pricing, but one that the FDA could readily thwart to offer patients immediate relief from high costs, **rather than asking lay judges and juries to try to redress the problem many years after the fact.** FDA Commissioner Gottlieb has asked the policy community to offer ideas to address unsustainable pharmaceutical prices. We applaud his decision to do so, but **to solve the costly problem of product hopping, the** **FDA need look no further than its own statutory authority.** **Without any further action on the part of Congress, the FDA could revise its agency rules and begin inviting suitability petitions.**

#### Court enforcement impossible

Fielding 2016. Joseph Fielding. Associate Editor, Cardozo Law Review. J.D. Candidate (June 2017), Benjamin N. Cardozo School of Law; B.A., Muhlenberg College. “From Pay-For-Delay To Product Hopping: The Limited Utility Of Antitrust Law In The Pharmaceutical Industry” http://cardozolawreview.com/wp-content/uploads/2018/08/FIELDING.38.5.pdf

C. Actavis v. Schneiderman: Remedies The nature of the remedy granted by the court in Schneiderman suggests that antitrust laws may be an inappropriate tool with which to address the product-hopping problem. According to the Supreme Court, antitrust remedies are designed “both to avoid a recurrence of the violation and to eliminate its consequences.”169 Typically, monetary damages are imposed on an offending firm in order to both eliminate the consequences of its anticompetitive conduct and to deter future firms from attempting similar conduct.170 Both the Sherman Act171 and the Clayton Act172 contain provisions that explicitly allow for monetary damages in antitrust actions.173 Although the Actavis case is still being litigated in the district court,174 it seems probable that monetary damages will occupy the large part of any consent agreement between the offending pharmaceuticals and the FTC. The goal of the FTC in such an agreement will be to eliminate any incentive to engage in payfor-delay settlements by making the risk of antitrust liability larger than the reward of pay-for-delay profits.175 In Schneiderman, however, the court granted an injunction against Forest that required it to continue to produce and sell IR at the same quantity and prices as it had before initiating the hard-switch.176 While courts often utilize conduct injunctions to restore competitive conditions,177 conduct injunctions178 that require specific action on the part of the defendant are rare because they require judicial oversight.179 Instead, conduct injunctions are usually granted in refusal-to-deal cases, whereby they force a monopolist to deal with would-be competitors.180 As commentators have noted, **conduct injunctions** that require judicial oversight **are “costly to implement**, **both in the direct costs of administration and the indirect costs of deterring efficient conduct**.”181 The oversight in this particular case is not particularly onerous. The court only needed to ensure that Forest continued to sell IR until its patent expired, allowing generics to enter the market via state substitution laws. In this case, the time span from the trial court’s initial injunction182 to the expiration of the IR patent183 was only six months. **However, the small time-window present in the facts of this case may not be true for all instances of product hopping**. If, for example, Forest had initiated a hard-switch two or three years prior, then a conduct injunction of the kind the Second Circuit granted would require the court to continually monitor IR production and sales for multiple years. **These administrative burdens make the kind of conduct injunction** that the Schneiderman **court granted both uncommon and unattractive**. As several amicus briefs filed on behalf of Forest have emphasized, because antitrust law rarely grants injunctions ordering firms to continue a certain behavior,184 and because one of the central rights granted by a patent is the right not to produce a good,185 **antitrust law is an inappropriate tool for dealing with the product-hopping problem.**

#### Just Closing the loophole is better

Fielding 2016. Joseph Fielding. Associate Editor, Cardozo Law Review. J.D. Candidate (June 2017), Benjamin N. Cardozo School of Law; B.A., Muhlenberg College. “From Pay-For-Delay To Product Hopping: The Limited Utility Of Antitrust Law In The Pharmaceutical Industry” http://cardozolawreview.com/wp-content/uploads/2018/08/FIELDING.38.5.pdf

CONCLUSION Product hopping is, to be sure, problematic. As the Schneiderman court noted, if Forest were allowed to shift the Namenda IR market to Namenda XR before generics became available, consumers would end up paying almost $300 million more for memantine therapy, third-party payors would pay almost $1.4 billion more, and Medicare would, over ten years, foot a bill of at least $6 billion.186 These costs would all result from the inability of generics to use state substitution laws to compete in the memantine drug market. However, increased costs resulting from a lack of competition does not, in itself, signal an antitrust violation. After all, Forest was granted a patent for Namenda XR, and that patent entitles it to a level of freedom from competition.187 Absent abuse of the XR patent—and simply selling XR and excluding generic manufacturers from making or selling XR does not constitute abuse188—Forest should be able to use its patent to maintain whatever market exclusivity it can until the patent expires. If product hopping feels slimy, it is not because a pharmaceutical company can limit competition in the market for a new drug. **That is what pharmaceutical patents were designed do: grant exclusivity** in order to incentivize companies to spend the massive amounts of money that go into researching and developing new drugs.189 Instead, product hopping feels slimy because it grants exclusivity for drugs that are not really new, or at least not innovative. What feels wrong about Forest being able to shut out competition in the memantine market is that Namenda XR and Namenda IR essentially do the same thing.190 They are both memantine drugs, and they both treat Alzheimer’s.191 The only difference between Namenda IR and Namenda XR, medically speaking, is that you have to take Namenda IR twice a day.192 The problem is not that Forest tried to use its patent to exclude generic competition, but that it obtained a patent on a drug that is essentially the same as its predecessor drug. The patent itself is the problem, not how it is used. Patent laws express a social bargain in which market exclusivity is exchanged for innovation.193 Product hopping violates this bargain by giving drug manufacturers market exclusivity without requiring that they provide any real innovation. Giving Namenda XR, which treats Alzheimer’s patients in essentially the same way as the preexisting Namenda IR, the same exclusivity as a pioneer drug, which would treat Alzheimer’s patients in a new and perhaps more effective way, seems wrong. Forest is getting more than it gives. If the heart of what makes product hopping a problem is not its anticompetitive effect, but the insufficiently innovative patents that companies use to product-hop, **then patent law—not antitrust law—is the appropriate tool for solving the problem**. What this solution looks like is uncertain. The Patent and Trademark Office (PTO) could create stricter standards that would make it harder to obtain patents for compounds that add little to the state of medical knowledge.194 At the same time, courts could formulate new tests in patent litigation suits that make it easier to challenge add-on drugs like Namenda XR.195 Heightening standards for granting pharmaceutical patents, however, would represent a significant change in how the pharmaceutical industry operates and would likely require congressional action. The 2003 amendments to the Hatch-Waxman framework suggest that regulatory reform of the pharmaceutical approval process is a realistic possibility,196 but what those standards would look like is hard to either project or propose. **Another solution might involve the FDA, which stands in the best position to detect product-hopping schemes**.197 Through the provisions of Hatch-Waxman, the agency not only compiles a list of all relevant patents associated with approved drugs,198 but also serves as a gatekeeper for any new drugs that enter the market.199 Therefore, Congress could empower the FDA to flag drug applications for add-on drugs and reexamine those patents that may lead to a product-hopping scenario. However, courts should not take the nebulous nature of producthopping solutions as license to shoehorn antitrust law into a place it does not rightly belong. If a pharmaceutical company is granted a patent, it should be able to use that patent according to the express terms of the Patent Act without fear of antitrust scrutiny.200 Regulatory gaming like product hopping may be anticompetitive, but it is anticompetitive by the book. **And rather than prosecute this kind of loop-holing for being anticompetitive, the appropriate solution is to close the loopholes.**

### Court PTX

#### Normal means for the aff would be a 5-4 ruling with Kavanaugh and Roberts voting with the liberals---this link is extremely unique to antitrust and resolves court backlash

Stohr 20 (Greg Stohr, Bloomberg News, Kavanaugh Emerges as Man-in-Middle With Court Set to Shift Right, 9-23, <https://news.bloomberglaw.com/us-law-week/kavanaugh-emerges-as-unlikely-liberal-hope-for-court-swing-vote>, y2k)

“Kavanaugh would by default become the most logical person to play the pivot role,” said Carter Phillips, a lawyer at Sidley Austin who has argued 79 Supreme Court cases.

That would mean to some degree supplanting Chief Justice John Roberts, who has held the balance of power for the past two years, largely backing conservative results but joining with the liberal wing to strike down an abortion regulation and preserve the DACA deferred-deportation program.

Confirmed in 2018 after a bitter fight, Kavanaugh is hardly an ideal choice for Democrats, even if they ignore the lingering raw feelings stemming from the sexual assault allegations that almost derailed his nomination. Kavanaugh angrily denied the allegations before winning confirmation on a 50-48 vote.

In his two terms on the court, Kavanaugh has established himself as a consistent conservative. He has backed religious freedoms, voted against LGBT workers and sided with Trump on presidential powers and immigration issues. Kavanaugh has also supported property rights and the death penalty and voted to shield partisan gerrymanders from constitutional challenges.

Unlike fellow Trump appointed Justice Neil Gorsuch, Kavanaugh hasn’t shown any inclination to side with the liberal wing and flip the outcome of a blockbuster case. Only once, in an antitrust dispute, has he joined the court’s liberals in a 5-4 ruling in an argued case.

When Gorsuch and Roberts voted to interpret federal job-discrimination law as protecting gay and transgender workers this year, Kavanaugh was in dissent. Even as he wrote that gay people “have advanced powerful policy arguments and can take pride in today’s result,” Kavanaugh said Congress would have to change the law to give them job protections.

The Eight Remaining Supreme Court Justices: Who Are They?

In other areas, Kavanaugh has emerged as more of a centrist and an incrementalist than fellow Trump appointee Gorsuch. Kavanaugh has agreed with Roberts more than with any other justice so far, according to statistics compiled by Scotusblog.

Abortion Opinion

When he voted in favor of a Louisiana abortion regulation this year, Kavanaugh wrote separately to underscore that he wasn’t offering an ultimate verdict on the law. Doctors were challenging a requirement that they get privileges at a local hospital, and Kavanaugh said they hadn’t yet proven they would be unable to obtain those rights.

“In my view, additional factfinding is necessary to properly evaluate Louisiana’s law,” he wrote. Kavanaugh had previously urged his colleagues in a private memo to sidestep the abortion dispute, CNN’s Joan Biskupic reported in July.

Kavanaugh has also suggested he is less willing than Gorsuch to overturn the court’s past decisions, says David Strauss, a constitutional law professor at the University of Chicago School of Law. That could prove important when the court is inevitably asked to overturn the 1973 Roe v. Wade decision, which legalized abortion nationwide.

“Justice Kavanaugh is more committed to what you might call traditional judging -- following precedent, deferring to the political branches, doing what Congress wanted to do even if it didn’t express itself perfectly,” Strauss said. “Justice Gorsuch is more inclined just to reject positions that he thinks are wrong.”

Health-Care Fight

Kavanaugh has proven reluctant to throw out an entire statute just because one part is unconstitutional. That will be a central issue when the court on Nov. 10 takes up a Trump-backed bid to throw out the Affordable Care Act and its protections for people with pre-existing conditions.

“Constitutional litigation is not a game of gotcha against Congress, where litigants can ride a discrete constitutional flaw in a statute to take down the whole, otherwise constitutional statute,” Kavanaugh wrote in July in a case involving the federal ban on robocalls to mobile phones.

Ginsburg’s Death Injects New Doubt Into Fate of Obamacare

In other areas of the law as well, Kavanaugh has shied away from absolutist positions. This year he joined a 6-3 decision that said the Clean Water Act applied to some pollution discharges that don’t go directly into a major body of water. In 2019 he joined Roberts and the liberals in halting the death sentence of a man unless he was allowed to have a Buddhist spiritual adviser in the death chamber with him.

And after the court heard its first gun-rights case in a decade last year, Kavanaugh joined Roberts and the liberals by voting to drop the case because New York City and the state of New York changed the handgun-transportation laws that were being challenged.

Kavanaugh, however, later said the court should have heard a challenge to a New Jersey law that requires people to show a “justifiable need” to get a carry permit.

Court’s Legitimacy

All that could leave Kavanaugh as an occasional, if not frequent, supporter of Roberts’s efforts to protect the court’s institutional legitimacy by trying to avoid polarizing rulings.

Kavanaugh isn’t likely to change his approach just because the court gets a new member, said Helgi Walker, a Washington lawyer with Gibson Dunn & Crutcher and a former law clerk to Thomas.

“I think he has a firm jurisprudence of his own, and he’s committed to what he believes is the right approach, and I don’t see changes in the composition of the court changing his course,” Walker said.

But a new justice could put Kavanaugh in a different position, forcing him to decide whether conservatives will accomplish long-sought legal goals, or at least how quickly.

“There was some speculation when Justice Kavanaugh was appointed that he would give the chief ‘cover’ by voting with him when he agreed with the liberals in 5-4 cases,” Strauss said. “That didn’t happen very much last term, but if there is a real threat to the court, I can see that changing.”

#### Antitrust regulation is low *across the board*

Joshua Wright 21—Law professor at George Mason University, executive director of the Global Antitrust Institute, former member of the Federal Trade Commission. ("5 questions for Joshua D. Wright on antitrust and Big Tech," February 18, 2021, from American Enterprise Institute, https://www.aei.org/economics/5-questions-for-joshua-d-wright-on-antitrust-and-big-tech/)

What would it mean if policymakers used antitrust law to break up four or five Big Tech companies?

It would be historic, and it would also be wrong-headed. For one, we’re in the middle of a pandemic, in a time where lots of people are really benefiting from the goods and services these firms provide. Furthermore, the world’s most successful and innovative companies are here in the US, and, from a competitive policy lens, our antitrust regime has largely avoided ex-ante regulation of these firms.

A signature feature of the US system is that our antitrust laws do not punish companies for competing successfully and becoming large — or even becoming a monopoly. You can’t make an antitrust cause of action out of successful innovation in the US. Instead, the US punishes abuses of monopoly power — you can’t climb to the top of the ladder and then burn it down. We have antitrust cases for that, some of which the government can win if they go to court and prove that the firms are monopolists and harm competition. That’s a feature, not a bug, of the US system.

### 2nd adv

#### The perm links – creates regulatory uncertainty which is the worst of all worlds

Shepherd 2020. Joanna M. Shepherd. Vice Dean and Thomas Simmons Professor of Law at Emory University School of Law. “The Legal and Industry Framework of Pharmaceutical Product Hopping and Considerations for Future Legislation”

V. **Consequences of Overly Broad or Vague Legislation** Legislation defining anticompetitive product hopping should aim to facilitate generic entry and lower drug prices. However, if the enacted legislation is too broad or overly vague, **it could instead harm consumers** by reducing innovation and increasing health care spending. First, **overly broad legislation would deter** important future **innovations**. Most innovation in the pharmaceutical industry involves development of next-generation improvements, such as creating new products that expand therapeutic classes, increase available dosing options, remedy physiological interactions of known medicines, or improve other properties of existing medicines.35 According to FDA data, two-thirds of new drug approvals are for these incremental innovations.36 The World Health Organization has found that over 60 percent of the drugs needed to combat prevalent diseases have resulted from incremental innovation.37 **Overly broad legislation would deter these important incremental innovations** that are critical to improving health outcomes. Second**, legislation that fails to provide clear guidance will create uncertainty** for brand innovators. This uncertainty can deter innovation in the pharmaceutical industry. Brand drug companies are the ones largely responsible for pharmaceutical innovations; in the last decade, they have spent over half a trillion dollars on R&D, and they currently account for over 90 percent of the spending on the clinical trials relied on by brands and generics alike.38 But if brand companies cannot reliably predict when their conduct will be considered anticompetitive, **they will have less incentive to engage in costly R&D** in the first place. The companies will not spend the billions of dollars39 it typically costs to bring a new drug to market when they cannot be certain that, years down the road, introducing that new drug will not expose them to damaging litigation, market-stopping injunctions, or penalties. **If producthopping legislation increases the uncertainty around the introduction of new products**, **innovation will suffer**.40 The consequences of this reduced innovation will be felt by consumers. Research shows that pharmaceutical innovation has greatly benefitted consumer health. Empirical estimates indicate that, on average, each new drug brought to market saves 11,200 life-years each year. 41 Another study finds that the health improvements from each new drug can save $19 billion in illness-related wage loss.42 Moreover, because new effective drugs reduce medical spending on doctor visits, hospitalizations, and other medical procedures, data show that for every incremental $1 spent on new drugs, total medical spending decreases by more than $7.43 Brand companies are largely responsible for pharmaceutical innovation. Thus, actions that reduce brand innovation will have dramatic effects on consumer health and health care spending in the long term.

#### Their evidence assumes a level of virulence that has literally never occurred

Wendy Orent 15, anthropologist and freelance science writer whose work has appeared in The Washington Post, The LA Times, The New Republic, Discover, and The American Prospect, instructor in science journalism @ Emory, Ignore predictions of lethal pandemics and pay attention to what really matters, LA Times, 1/3/15, http://www.latimes.com/opinion/op-ed/la-oe-orent-pandemic-hysteria-20150104-story.html

Prophets of doom have been telling us for decades that a deadly new pandemic — of bird flu, of SARS or MERS coronavirus, and now of Ebola — is on its way. Why are we still listening? If you look back at the furor raised at many distinguished publications — Nature, Science, Scientific American, National Geographic — back in, say, 2005, about a potential bird flu (H5N1) pandemic, you wonder what planet they were on. Nature ran a special section titled — “Avian flu: Are we ready?” — that began, ominously, with the words “Trouble is brewing in the East” and went on to present a mock aftermath report detailing catastrophic civil breakdown. Robert Webster, a famous influenza virologist, told ABC News in 2006 that “society just can't accept the idea that 50% of the population could die. And I think we have to face that possibility.” Public health expert Michael T. Osterholm of the University of Minnesota, at a meeting in Washington of scientists brought together by the Institute of Medicine, warned in 2005 that a post-pandemic commission, like the post-9/11 commission, could hold “many scientists … accountable to that commission for what we did or didn't do to prevent a pandemic.” He also predicted that we could be facing “three years of a given hell” as the world struggled to right itself after the deadly pandemic. And Laurie Garrett, author of what must be the urtext for pandemic predictions, her 1994 book “The Coming Plague,” intoned in Foreign Affairs that “in short, doom may loom.” Although she followed that with “But note the may,” the article went on to paint a terrifying picture of the avian flu threat nonetheless. And such hysteria still goes on: Whether it's over the MERS coronavirus, a whole alphabet of chicken flu viruses, a real but not very deadly influenza pandemic in 2009, or a kerfuffle like the one in 2012 over a scientist-crafted ferret flu that also was supposed to be a pandemic threat. Along the way, virologist Nathan Wolfe published “The Viral Storm: the Dawn of a New Pandemic Age,” and David Quammen warned in his gripping “Spillover” that some new animal plague could arise from the jungle and sweep across the world. And now there's Ebola. Osterholm, in a widely read op-ed in the New York Times in September, wrote about the possibility that scientists were afraid to mention publicly the danger they discuss privately: that Ebola “could mutate to become transmissible through the air.” “The Ebola epidemic in West Africa has the potential to alter history as much as any plague has ever done,” he wrote. And Garrett wrote in Foreign Policy, “Attention, World: You just don't get it.” She went on to say, “Wake up, fools,” because we should be more frightened of a potential scenario like the one in the movie “Contagion,” in which a lethal, fictitious pandemic scours the world, nearly destroying civilization. But there were fewer takers this time. Osterholm's claims about Ebola going airborne were discounted by serious scientists, and Garrett seemingly retracted her earlier hysteria about Ebola by claiming that, after all, evolution made such spread unlikely. The scientific world has changed since 2005. Now, most scientists understand that there are significant physical and evolutionary barriers to a blood- and fluid-borne virus developing airborne transmission, as Garrett has acknowledged. Though Ebola virus has been detected in human alveolar cells, as Vincent Racaniello, virologist at Columbia University, explained to me, that doesn't mean it can replicate in the airways enough to

allow transmission. “Maybe … the virus can get in, but can't get out. Like a roach motel,” wrote Racaniello in an email. H5N1, we understand now, never went airborne because it attached only to cell receptors located deep in human lungs, and could not, therefore, be coughed or sneezed out. SARS, or severe acute respiratory syndrome, caused local outbreaks after multiple introductions via air travel but spread only sluggishly and mostly in hospitals. Breaking its chains of transmission ended the outbreak globally. There probably will always be significant barriers preventing the easy adaptation of an animal disease to the human species. Furthermore, Racaniello insists that there are no recorded instances of viruses that have adapted to humans, changing the way they are spread. So we need to stop listening to the doomsayers, and we need to do it now. Predictions of lethal pandemics have — since the swine flu fiasco of 1976, when President Ford vowed to vaccinate “every man, woman and child in the United States” — always been wrong. Fear-mongering wastes our time and our emotions and diverts resources from where they should be directed — in the case of Ebola, to the ongoing tragedy in West Africa. Americans have all but forgotten about Ebola now, because most people realize it isn't coming to a school or a shopping mall near you. But Sierra Leoneans and Liberians go on dying.

# 1NR

**COVID-related enforcement is key to effective recovery---it’s a key priority**

**OECD 20** (The Role of Competition Policy in Promoting Economic Recovery – Note by the United States, 12-2, <https://www.ftc.gov/system/files/attachments/us-submissions-oecd-2010-present-other-international-competition-fora/economic_recovery_us.pdf>, y2k)

1. The Antitrust Division of the **D**epartment **o**f **J**ustice (DOJ) and the U.S. **F**ederal **T**rade **C**ommission (FTC) (collectively the Agencies) offer this joint submission in response to the Competition Committee’s review of the **role** of **competition policy** in promoting **economic recovery**. In this paper, we highlight some **key steps** that the Agencies have taken to respond to the present **COVID-19 crisis** in the United States and to help promote **a rapid** and **sustained economic recovery.**

2. The U.S. antitrust agencies have undertaken initiatives in several categories to help spur recovery from the COVID-19 crisis, including stepped-up criminal enforcement, policy guidance to health and emergency-related government agencies, and expedited review of private sector cooperative efforts. The Agencies strongly believe that **competition policy** has an important role to play in the **COVID-19 recovery** process and intend to continue to engage in partnership with domestic and international counterparts to ensure the protection of competition and consumers.

2. Deterrence of Cartel Activity, Price Gouging, and Other Harmful Activity

3. Deterrence of **unlawful commercial activities** has long been **a key mission** of the Agencies, rendered even more **critical** by the **social** and **economic disruptions** caused by the COVID-19 crisis.1 While most Americans have acted to help their neighbors and communities during the past year, **crisis-related disruption** increases the risk that some individuals will make **unlawful windfall profits** at the expense of **public safety** and **the health** and **welfare** of their fellow citizens.2

4. While hoarding and exploitation are not themselves antitrust violations, such behaviors are often accompanied by criminal antitrust collusion, price fixing, and bid rigging, and other attempts to take advantage of the public. As with other natural disasters, the COVID-19 crisis increases the risk that individuals and organizations will engage in these unlawful commercial activities, necessitating increased vigilance by the Agencies.

2.1. COVID-19 Hoarding and Price Gouging Task Force

5. To coordinate enforcement efforts, the Attorney General in March 2020 announced the creation of the COVID-19 Hoarding and Price Gouging Task Force.3 The Task Force is charged with developing effective enforcement measures and best practices, and coordinating nationwide investigation and prosecution of illicit activities. Because **health care products** and **markets** are central in **responding to the health care crisis** and eventually to **economic resilience** and **recovery**, the Task Force focuses on **protecting** the availability of those **products** designated **essential** by the Department of Health and Human Services (HHS) under Section 102 of the Defense Production Act. The DOJ consults with HHS during this process, including advising on the antitrust implications of COVID-19 for affected markets and products.

6. The Task Force is currently being led by a coordinating U.S. Attorney, with assistance as needed from the Antitrust Division’s Criminal Program. Each United States Attorney’s Office, as well as other relevant Department components, is directed to designate an experienced attorney to serve as a member of the Task Force. The Antitrust Division’s role in the Task Force involves investigating allegations of criminal antitrust harms, such as price fixing and bid rigging, and responding to citizen complaints about collusive or anticompetitive disaster-related behavior.

2.2. Procurement Collusion Strike Force

7. The DOJ is also stepping up efforts to combat crisis-related disruption through the newly-created Procurement Collusion Strike Force (PCSF). COVID-19 recovery will require **substantial** **investment** by national, state, and local authorities, with $3.48 trillion appropriated to date.4 The size and pace of such efforts unfortunately create opportunities for **fraud** and **collusion** affecting government **procurement** and **grant-making**. Through the creation of the PCSF, DOJ is dedicating significant resources to help identify and prevent these unlawful activities.5

8. The PCSF is an interagency partnership dedicated to protecting taxpayer-funded projects from antitrust violations and related crimes at the federal, state, and local levels. Under the umbrella of the PCSF, prosecutors from the Antitrust Division’s five criminal offices and 13 U.S. Attorneys’ Offices have partnered with agents from the FBI and four federal Offices of Inspector General, including the U.S. Postal Service and Department of Defense, to conduct outreach and training for procurement officials and government contractors on antitrust risks in the procurement process.

9. Since its creation in 2019, over 50 federal, state, and local government agencies have already sought training and assistance from the PCSF, as well as opportunities to work with the PCSF on investigations. So far, the PCSF has led over a dozen interactive virtual training programs for approximately 2,000 criminal investigators, data scientists, and procurement officials.6 Over a third of the Antitrust Division’s current investigations relate to public procurement, and the PCSF marks an important effort to marshal enforcement resources to tackle these cases. Several grand jury investigations already have been opened as a direct result of the work of the PCSF. In addition to playing a meaningful role in COVID-19 economic recovery, the PCSF will continue to be an important resource for detecting fraud and collusion in government procurement for years to come.

2.3. Protecting Competition in Labor Markets

10. The DOJ and FTC are working to protect competition in labor markets, which have been subject to significant dislocation due to the economic impact of COVID-19. In April 2020, the Agencies issued a statement warning that antitrust enforcers are closely monitoring improper employer coordination that may disadvantage workers.7 The statement affirmed that antitrust laws with respect to hiring and employment remain fully in effect despite the crisis, and stated that “COVID-19 does not provide a reason to tolerate anticompetitive conduct that harms workers, including doctors, nurses, first responders, and those who work in grocery stores, pharmacies, and warehouses, among other essential service providers on the front lines of addressing the crisis.”8

11. Given the special **impact** of COVID-19 on **medical staffing** and **employment**, the Agencies are focused on preventing **employers**, including health care staffing companies and recruiters, from engaging in **collusion** or other **anticompetitive** conduct in **labor markets**, such as agreements to lower wages or to reduce salaries or hours worked. This announced focus continues the Agencies’ policy of devoting resources to preventing labor malpractice in critical industries, especially health care. As one example, the DOJ in April 2020 reached a significant resolution in the criminal investigation of Florida Cancer Specialists (FCS) for entering into a market allocation agreement that gave FCS a monopoly for services in a densely populated part of southwest Florida. As part of the deferred prosecution agreement reached in that case, the Division obtained a $100 million fine – the statutory maximum – and FCS agreed to waive certain non-compete provisions for current and former employees, including physicians and other healthcare professionals.9 In another important matter, early this year, the FTC investigated, and the parties abandoned a proposed tie-up between two providers of nursing staff. The proposed merger had likely anticompetitive effects in multiple localities across the country on markets both for nursing services and for private duty nursing care.10

2.4. Consumer Protection

12. The FTC has worked aggressively to address consumer protection issues arising from the COVID-19 pandemic. Since late March, as the coronavirus emerged, the FTC has received nearly 225,000 consumer complaints relating to COVID-19, including concerns about fraud related to the government’s economic impact payments.11 In addition, the FTC has been monitoring the marketplace for unsubstantiated health claims, illegal robocalls, privacy and data security concerns, online shopping fraud, and a variety of other scams related to the economic fallout from the COVID-19 pandemic.

13. Acting on this market information, the FTC has pursued a rigorous warning letter program and filed law enforcement actions for injunctive and other relief in federal courts.12 In the health claims area, for example, the FTC and the Food and Drug Administration (FDA) have, to date, issued over 90 joint warning letters to marketers regarding claims that their products will treat, cure, or prevent COVID-19.13 The FTC on its own has issued more than 225 additional warning letters to marketers.14 The letters warn recipients that their conduct is likely to be unlawful, that they could face serious legal consequences if they do not immediately stop, and require a response to the FTC within 48 hours. In nearly every instance, companies that have received FTC warning letters have taken quick steps to correct or eliminate their problematic claims. The FTC also has issued warning letters, in conjunction with the Small Business Administration, to companies making potentially misleading claims about federal loans or other temporary small business relief.15

14. The FTC has also filed court actions involving COVID-19 health claims, distribution claims, and government stimulus check claims.16 For example, the FTC filed four lawsuits in federal district courts against online merchandisers for failing to deliver on promises that they could quickly ship products like face masks, sanitizer, and other personal protective equipment (PPE) related to the coronavirus pandemic.17

15. Finally, the FTC has launched numerous consumer education campaigns, including a website on COVID-19 scams and a resource page that contains brochures, graphics, and videos in multiple languages.18

3. Guidance and Cooperation to Peer Agencies as Part of a Coordinated, GovernmentWide Response Effort

16. The FTC and DOJ also have **shared** their **competition expertise** with other international and federal agencies in order to facilitate **COVID-19 response** and **recovery** while preserving competitive markets. Among other efforts, the Agencies have been working closely with the Federal Emergency Management Agency (FEMA) to develop a Voluntary Agreement governing cooperation among industry participants seeking to respond to the pandemic.19 The purpose of the Agreement is to **maximize** the effectiveness of the **manufacture** and **distribution** of critical healthcare resources **nationwide** to respond to the pandemic. Organized under the authority granted by the Defense Production Act, participants to the Agreement receive antitrust immunity for actions taken to carry out the Agreement. Before the Agreement can become effective, however, the Attorney General must find that the purposes of the Agreement may not be achieved through a voluntary agreement having less anticompetitive effects. These efforts also have helped inform the Agencies’ responses to business review letters seeking approval for cooperation in the production of critical health care products, as discussed below.

3.1. International Advocacy

17. U.S. enforcers also have been leveraging our existing bilateral relationships and ties to multilateral organizations, such as the International Competition Network (ICN) and the Organisation for Economic Co-operation and Development (OECD), to increase communication and cooperation.

18. In the immediate aftermath of the declaration of a state of national emergency in the United States, the Agencies played a key role in facilitating communication and cooperation among international enforcers by collecting and sharing on a regular basis rapidly developing information on how COVID-19 has impacted competition law enforcement efforts around the world. After DOJ successfully developed a regular internal process for collecting and disseminating this information, the ICN integrated this project into its ongoing work streams. In early April, as the economic impact of COVID-19 and possible enforcement challenges began to emerge, the ICN Steering Group issued a statement on key considerations related to competition law enforcement during and after the COVID-19 pandemic.20 The Agencies contributed with the FTC serving as a lead drafter of the statement recognizing the importance of competition to economies in crisis and urging agencies to remain vigilant regarding anti-competitive conduct. The statement also calls for transparency of operational and policy changes during the crisis and advocates for competition as a guiding principle for economic recovery efforts in the aftermath of the pandemic.

19. Since spring 2020, the Agencies have participated in several virtual events hosted by the ICN, the OECD, and the United Nations Conference on Trade and Development on international cooperation, investigations and competition law policy in the wake of COVID-19.21 In September 2020, the U.S. Agencies hosted the ICN 2020 Virtual Conference, which brought together enforcers from around the world to discuss antitrust developments, including how to address enforcement and policy challenges raised by COVID-19.

3.2. Doctrinal Responses

20. While procedural aspects of the Agencies’ work have changed as a result of COVID-19, the Agencies’ view of key U.S. antitrust standards has not changed. The Agencies have reiterated that the antitrust laws are flexible enough to account for changing market conditions, even during uncertain times.22

21. In particular, the Agencies continue to take the view that the failing firm defense is “narrow in scope,” and should be invoked selectively.23 The Agencies have continued to reiterate in speeches and publications that they will not relax the stringent conditions that define a genuinely “failing” firm and continue to apply the test set out in the U.S. Horizontal Merger Guidelines24 and reflected in our long-standing practice, and that they will require the same level of substantiation as was required before the COVID pandemic.25 As such, while it is possible that more firms may fail as a result of an economic crisis such as COVID-19, the view of the United States is that economic dislocation, on its own, does not provide a compelling reason why the assets of failing firms should be purchased by close competitors.

3.3. Competition Advocacy

22. The Agencies are continuing to advocate for changes to regulations that may impede competition, which may cause even greater harm in the context of the COVID-19 crisis. For example, the Agencies have submitted multiple letters to state legislatures in recent years expressing their concerns over “certificate of need” laws26 and other restrictions on the availability of health care resources.27 Given the extraordinary disruptions created by COVID-19, the United States views protecting the free functioning of health care markets as even more urgent, and the Agencies plan to continue our advocacy to remove regulatory impediments to competition in the health care sector.

23. Directly relating to the COVID-19 public health emergency, FTC staff submitted a comment to the Centers for Medicare & Medicaid Services (CMS) on its Interim Final Rule with Comment Period (IFC).28 The FTC comment supported the IFC’s provisions that reduce or eliminate restrictive Medicare payment requirements for telehealth and other communication technology-based services during the public health emergency. FTC staff noted that if telehealth practitioners’ entry is limited or reimbursement requirements are overly restrictive, consumers’ access to care and choice of practitioner might be unnecessarily restricted, especially in areas where there is a shortage of healthcare professionals. The IFC’s rule would reduce restrictions on Medicare reimbursement for telehealth services. This is especially important, not only to enhance the use of telehealth to care for Medicare beneficiaries, but also to encourage private payers to expand the use of telehealth. Reducing or eliminating restrictions on reimbursement of telehealth services could potentially enhance competition, improve access and quality, and decrease health care costs in both the public and private sectors. By connecting widely separated providers and patients, telehealth can alleviate primary care and specialty shortages.

24. The FTC continues to advocate against states issuing certificates of public advantage (COPA). For example, in September 2020 FTC staff submitted a public comment opposing issuance of a COPA to the Texas Health and Human Services Commission. FTC staff expressed concern that the proposed merger at issue would lead to significantly less competition for healthcare services in Midwest Texas.29

25. The FTC and its staff have also analyzed potential competitive concerns associated with professional regulations in the health care sector, including licensure and scope of practice.30 For example, FTC staff sent advocacy letters to the Texas Attorney General and the Texas Medical Board relating to regulations that could harm competition by impeding access to surgical and other health care services provided by certified registered nurse anesthetists.31 FTC staff recommended that Texas maintain only CRNA supervision requirements that advance patient protection and avoid adopting regulations that impede CRNA practice.

26. DOJ hosted a virtual joint workshop with the USPTO in July 2020 that included debate on the role of innovation and public-private collaboration in responding to the COVID-19 pandemic.32 The workshop, entitled “Promoting Innovation in the Life Science Sector and Supporting Pro-Competitive Collaborations: The Role of Intellectual Property,” comprised 10 sessions over two days. Panelists included leading figures from industry, government agencies, prominent research labs, the non-profit sector, academia, and the broader legal and economic community. Members of the public were also able to submit questions throughout the event.

4. Facilitation of Cooperative Public and Private-Sector Efforts to Resolve the Crisis

27. The Agencies are working together to bolster the recovery by providing guidance relating to recovery-related collaborations on an expedited basis.33 In a joint statement in April, the Agencies emphasized the potential importance of pro-competitive collaborations between private firms to bring essential goods and services to communities in need. In addition to providing high-level collaboration guidelines consistent with previous DOJ and FTC policies, the statement contained guidance specific to COVID-related business activities, including reaffirming that the Agencies will account for exigent circumstances in evaluating collaborative efforts to address the spread of COVID-19, and that medical providers’ development of suggested practice parameters to assist in clinical decisionmaking will not be challenged, absent extraordinary circumstances.34

28. The Agencies also announced an expedited business review letter program, under which all COVID-19-related requests will receive responses within seven calendar days of the Agencies receiving all necessary information. This expedited process for COVIDrelated business review letters is an outgrowth of the Agencies’ role in advising other executive branch agencies on facilitating COVID-related cooperation within the antitrust laws, and each of the letters issued through the expedited process in 2020 addresses proposed conduct that is critical to COVID-19 response. Since March 2020, DOJ has issued the following four expedited business review letters:

1. A letter approving a collaboration by McKesson Corporation, Owens & Minor Inc., Cardinal Health Inc., Medline Industries Inc., and Henry Schein Inc to expedite and increase manufacturing for the distribution of personal protective equipment (PPE) and coronavirus-treatment-related medication in a way unlikely to lessen competition;35

2. A letter approving a collaboration by AmerisourceBergen with FEMA, HHS, and other government entities to “identify global supply opportunities, ensure product, quality, and facilitate product distribution of medications and other healthcare supplies to treat COVID-19 patients;”36

3. A letter approving a collaboration by Eli Lilly and Company, AbCellera Biologics, Amgen, AstraZeneca, Genentech, and GSK to “exchange limited information about the manufacture of monoclonal antibodies that may be developed to treat COVID19” in order to optimize COVID-19 vaccine production as part of Operation Warp Speed;37 and

4. A letter approving a collaboration by the National Pork Producers Council (NPPC) and the U.S. Department of Agriculture (USDA) “to address certain hardships facing hog farmers as a result of the COVID-19 pandemic.”38 29. The Agencies also pledged to expedite the processing of filings under the National Cooperative Research and Production Act, which provides flexible treatment of certain standards development organizations and joint ventures under the antitrust laws.

5. Revised Rules Regarding Merger Enforcement

30. The Agencies have adapted to changing work conditions and reallocated resources to maintain continuity of core operations and enforcement efforts. COVID-19 initially necessitated temporary changes to ensure the continuation of expeditious and thorough merger review.39 Changes made by both Agencies include (1) extending standard timing agreement provisions so that the post-compliance period runs for sixty to ninety days (instead of thirty days) for pending or proposed transactions that may be subject to a Second Request, (2) requiring all merger filings with the FTC and DOJ to be submitted via the FTC’s electronic filing system, and (3) committing to conducting all meetings and depositions by phone or video conference when possible, absent extenuating circumstances.40 For the initial period of only two weeks at the start of the COVID crisis, the Agencies also suspended the granting of early termination, which can shorten the waiting period for non-problematic mergers. The option of early termination was resumed in March, and timing of grants of early termination has returned to pre-pandemic levels.41

31. Notably, COVID-19 did not sideline other important efforts to improve the Agencies’ enforcement programs. Among other efforts, in June 2020, the Agencies for the first time issued joint Vertical Merger Guidelines.42 In September, the Division also issued a modernized Merger Remedies Manual. As an update to the 2004 edition, the new manual provides “greater transparency and predictability regarding the Division’s approach to remedying a proposed merger’s competitive harm,” including an emphasis on structural remedies and a renewed focus on enforcing consent decree obligations. The Division also has continued to follow through on its September 2018 commitment to modernize banking merger review, with the goal of expedited and efficient resolution for uncomplicated merger matters.43 Economic downturns, as often occur in the wake of disasters such as the COVID-19 crisis, may impact **merger activity**, which is why continuing to improve the Agencies’ approach to **reviewing** and **remedying** potentially anticompetitive mergers **remains a priority.**

**Antitrust agencies are focused on COVID and dodging new antitrust reforms to allocate limited resources**

**NRF 20** (Norton Rose Fulbright is a global law firm, COVID-19: Implications from an antitrust and competition law perspective, March, <https://www.nortonrosefulbright.com/en-us/knowledge/publications/bb6f3c5e/covid-19-implications-from-an-antitrust-and-competition-law-perspective>, y2k)

The current **COVID**-19 (coronavirus) crisis sweeping the world is having **a** hugely **disruptive** impact on **society** and **business**, and our first thoughts and best wishes are with our clients, colleagues and their families who are facing this unprecedented public health challenge. While we all focus on ensuring everyone stays healthy and safe, we are very conscious of the need for businesses to focus on the immediate challenges they face with government-imposed lockdowns, attempting to mitigate disruption to travel and supply chains, and potential illness and remote working issues within their teams. As companies address these concerns, there will be important implications from the perspective of global antitrust and competition enforcement in 2020 and potentially over a longer period of time.

We have already seen suspension of competition rules in a number of contexts to ensure essential services continue. In addition, businesses will require state support to survive as towns and cities are “locked-down” and business stalls. There are also **risks** around **competitors** **collaborating** during the crisis, potentially leading to “**crisis cartels**” or other **antitrust infringements**. Antitrust authorities will also see their **resources stretched,** with knock-on effects for investigation **timetables** and how authorities **prioritize** cases. We discuss these key issues below.

As a global pandemic, the impact of **COVID**-19 is **unprecedented** in recent times. Health and welfare are naturally the focus, but there are also significant legal and **economic** consequences, not least regarding **antitrust** and **competition**. Antitrust regimes also have a potentially **important role** to play in protecting **health** and **welfare** at this challenging time.

**State aid**

A critical role for antitrust enforcement during the crisis is state support for businesses in financial distress, and the individuals they employ. State support can take various forms, such as crisis loans, state guarantees and tax waivers or deferrals. It can distort markets, giving recipients of aid an unfair advantage when competing against other businesses – infringing state aid or anti-subsidy rules. But aid can also be approved if it is proportionate and meets the criteria for exemption.

The European Commission has already announced measures to streamline the usual EU state aid approval processes so that governments can move quickly enough to grant businesses the critical support they need. And exemptions for rescue and restructuring aid or exceptional circumstances, in particular, have been flagged as likely to apply.

Considerable financial support has already been proposed. In France, for example, President Emmanuel Macron has declared “war” on COVID-19, guaranteeing that no French business will face bankruptcy with “unlimited” state financial aid available. UK support – although no longer an EU Member State – remains subject to the EU state aid regime until the Brexit transition period ends (expected to be December 31, 2020). The European Commission also has four years after the end of the transition period to start investigating any UK aid granted during that period.

**Exploitation**

Another area where antitrust authorities are known to be taking an active role during the crisis is monitoring potentially excessive prices (or “price gouging”) and misleading practices – such as high prices for hand sanitizers or deceptive claims about the benefits of protective equipment – exploiting consumers.

Regimes differ, but exploitative conduct could potentially infringe abuse of dominance or monopolization rules, or consumer protection laws. A number of global authorities have issued warnings about this type of behavior, raising the possibility of enforcement actions to come if those warnings are ignored.

It is possible that algorithmic pricing could lead to price spikes without any deliberate attempt by companies to take advantage of the situation, adding complexity to whether there is an infringement in such circumstances.

**Collaboration**

Businesses that normally compete may also come under pressure to work together during the crisis – for example, food retailers or pharmaceutical companies – to ensure essential supplies reach those in need. Such collaboration may be encouraged by politicians or governments. We have seen competition rules suspended already in Norway (as between airlines), the UK and Germany (as between food retailers) and the US (as between medical suppliers and other industries that provide for the national defense). In all cases, these suspensions have been intended to allow production and/or supply of vital services during the crisis.

Nonetheless, businesses should not unilaterally decide to enter such arrangements to address perceived needs. They need to assess the competition risks before collaborating, and put appropriate safeguards into place. Absent a state compulsion defense (which is hard to prove), formal waiver or passage of relevant legislation, businesses need to satisfy themselves about the risks of collaboration, and not engage in conduct that continues to remain prohibited.

Safe harbors and existing guidance are available for certain types of collaboration that may become particularly relevant during the crisis – such as joint purchasing and specialization agreements under the EU regime. Businesses can utilize this to mitigate the effect of the crisis while remaining compliant with competition rules.

Before the crisis, the EU was also already reviewing its rules on horizontal collaborations and signaling a willingness to give more guidance to allow more collaboration in appropriate cases. Businesses should consider approaching the European Commission and other antitrust authorities for guidance where novel issues arise in these extreme circumstances.

Given the unprecedented scale of the crisis, we may see antitrust rules being relaxed in a way not seen before. In the Norwegian example, a three-month exemption from competition rules has been announced for airlines and other transport companies to allow them to coordinate to ensure critical services are maintained, but any agreement must be notified to Norway’s competition authority. To the extent similar approaches are adopted in other jurisdictions or sectors, it is vital the businesses concerned meet any qualifying requirements.

Businesses should also generally ensure that any legitimate collaboration does not spill over into problematic areas. Risks include going beyond what is necessary to achieve the beneficial aims, such as unrestricted exchanges of competitively sensitive information impacting how the parties will compete after the crisis or competition in other areas of their businesses.

**Financing arrangements**

An area where lenders in particular will need to work together is refinancing of syndicated loans. These arrangements are critical for banks to share risk in order to finance larger or riskier projects, but syndicated loans naturally involve close cooperation between banks – and the European Commission has recently looked at the risks that these discussions could give rise to anti-competitive conduct.

The main antitrust concern in refinancing or restructuring facilities in times of difficulty is the extent to which banks can discuss and potentially agree proposals to change or restructure loans. If banks work together, particularly in the context of a distressed borrower, this could lead to unequal bargaining power or inappropriate exchanges of competitively sensitive information. These risks can be managed through safeguards, but what is appropriate to share or discuss will depend on the circumstances of each case.

**Crisis cartels**

Another concern is so-called “crisis cartels” – competitors agreeing amongst themselves how to limit the impact on their businesses to survive the crisis. Competitors might, for example, agree not to undercut each other’s prices or agree how to reduce excess capacity while facing considerably reduced demand.

However, antitrust authorities do not typically treat crisis cartels any differently than other types of cartels – meaning there remains a risk of an antitrust violation with significant fines and other sanctions, including potential criminal violations in applicable jurisdictions. The general position is that businesses must continue to act independently and compete even during a crisis: this creates a high hurdle to justify a crisis cartel.

**Merger control**

While some M&A activity is on hold for now, lower share prices as a result of the crisis may trigger a spike in M&A deals – and therefore merger control filings. In the meantime, global merger reviews that are ongoing or about to commence will continue, but may face delay.

Antitrust authorities (like other employers) are managing disruption to their workforce as a result of the crisis – making completion of merger reviews within prescribed deadlines, or collection of information from parties affected by the crisis – more difficult.

The European Commission is asking parties to delay merger filings, as are a number of other antitrust authorities, and has used “stop the clock” powers to delay three Phase 2 investigations where parties have not responded to information requests. Such practices may become more prevalent. The US antitrust authorities have introduced a temporary eFiling procedure, and suspended possible early termination of Hart-Scott-Rodino waiting periods while it is in place.

Some businesses may seek mergers or joint ventures with competitors to help survive the crisis. These deals remain subject to merger control review, but “failing firm” or “flailing firm” analyses may permit some transactions that otherwise would have been prohibited.

**Prioritization**

As well as discouraging new merger filings, progress on other types of enforcement cases will generally slow where authorities are not tied to statutory case timetables. Authorities may also face **difficult decisions** about which cases to take forward (or potentially close) as they manage increasing **resource constraints**.

Some of the potentially significant proposed **antitrust reforms** that were expected in 2020 may also be **pushed back** while the **focus** is on **dealing with the crisis.**

**FTC is successfully prioritizing COVID cases BUT it’s facing resource constraints**

**Kaplan 7-28** (Peter Kaplan, Office of Public Affairs @ Federal Trade Commission, FTC Testifies Before House Energy and Commerce Subcommittee on Legislation to Modify the Commission’s Authority and Address Challenges Facing the Agency, 7-28, <https://www.ftc.gov/news-events/press-releases/2021/07/ftc-testifies-house-energy-commerce-subcommittee-legislation>, y2k)

In addition, the testimony notes, the FTC is facing **severe resource constraints** as it works to address the **soaring** number of global **mergers** and **acquisitions** and a large numbers of consumer complaints to the agency about a broad range of **pandemic-related marketplace abuses**. The Commission believes that additional resources are necessary to help it effectively achieve its mission.

In **spite** of these **challenges**, the FTC has worked **vigorously** to ensure that its critical work can **continue**, the testimony states. Since the beginning of the pandemic, thanks in part to the civil penalty authority provided by this Subcommittee in the COVID-19 **C**onsumer **P**rotection **A**ct, the Commission has **successfully** halted dozens of **COVID-related scams**. The agency also reached out to communities most affected by fraud, alerting the public to the threats posed by scams and those who facilitate them.

**DOJ anit-trust division is committed to COVID relief and preventing anticompetitive practices**

**Buice 20** (Amy, Smith Gambrell and Russell Law Firm, “COVID-19 and Competition: Antitrust Law During the Global Pandemic” https://www.sgrlaw.com/covid-19-and-competition-antitrust-law-during-the-global-pandemic/)

COVID-19’s rapid spread has necessitated collaborations to equip communities with the proper tools to combat the disease. Many have risen to the occasion and worked tirelessly to help protect the health and safety of the United States. As the DOJ and FTC (the “Agencies”) put it in their March 24th Joint Antitrust Statement, however, “others may use [COVID-19] as an opportunity to subvert competition or prey on vulnerable Americans.”[1]

The FTC, DOJ, and Trump Administration have taken measures to guide businesses on how to collaborate legally and have sent forceful reminders about the repercussions of violating antitrust laws during the pandemic. Thus, **it is as important as ever to understand the current landscape of antitrust laws**.

**DOJ and FTC dedication to continued enforcement of antitrust laws**

Since the beginning of the COVID-19 outbreak in the United States, the DOJ and FTC have sent a consistent message: **if you exploit this pandemic, you could be criminally prosecuted.** It is important to remain vigilant and understand that COVID-19 **is not a defense to antitrust** liability.

For example, on March 9, 2020, the DOJ issued a statement making clear it planned to hold violators of antitrust laws accountable in connection with the manufacturing, distribution, or sale of public health products such as face masks, respirators, and diagnostics.[2] According to Attorney General William P. Barr, “[t]he Department of Justice stands ready to make sure that bad actors do not take advantage of emergency response efforts, healthcare providers, or the American people during this crucial time.”[3] Thus, “individuals or companies that fix prices or rig bids for personal health protection equipment such as sterile gloves and face masks could face criminal prosecution.”[4] And, “competitors who agree to allocate among themselves consumers or public health products could also be prosecuted.”[5]

On March 24, 2020, the FTC and DOJ issued a Joint Antitrust Statement that said the Agencies will “not hesitate to seek to hold accountable” those who may use COVID-19 as an opportunity to harm competition.[6] The Agencies stated they stand ready to pursue violations of antitrust laws which include price fixing, bid rigging, and market allocation schemes. On April 13, 2020, the Agencies issued a joint statement saying collusion or anticompetitive conduct in labor markets, “such as agreements to lower wages or to reduce salaries or hours worked” **would not be tolerated**.[7]

**DOJ is focused on PPE violations**

**Hanusik 20** (HOMAS A. HANUSIK is a partner at Crowell & Moring LLP in Washington, DC. He specializes in white collar defense, SEC Enforcement, and internal investigations., COVID-19'S IMPACT ON WHITE-COLLAR CRIME ENFORCEMENT AND DEFENSE, 35 Crim. Just. 26, y2k)

Anticompetitive Behavior

Protecting the **health**, **safety**, and **well-being** of Americans during the COVID-19 crisis will require unprecedented **coop**eration among **governmental** and **private sector entities**. [\*31] Enforcement authorities are remaining watchful, however, for **anticompetitive** behavior. On March 9, 2020, DOJ announced its intention to hold **accountable** violators of **federal antitrust laws** in connection with the **manufacture**, **distribution**, or **sale** of **public health products** such as face masks, respirators, and diagnostics. Press Release, U.S. Dep't of Justice, Justice Department Cautions Business Community Against Violating Antitrust Laws in the Manufacturing, Distribution, and Sale of Public Health Products (Mar. 9, 2020, https://tinyurl.com/ DOJ-Antitrust. The **P**rocurement **C**ollusion **S**trike Force is also on high alert for **collusive practices** in the sale of **public health products** to federal, state, and local agencies. On April 13, 2020, the Antitrust Division and the Federal Trade Commission jointly cautioned companies that these agencies will vigorously prosecute anticompetitive conduct that harms workers, particularly those medical professionals, first responders, and other essential workers operating in the COVID-19 front lines. While praising companies and individuals that have "demonstrated extraordinary compassion and flexibility in responding to COVID-19," the agencies stated that they "will not hesitate to hold accountable" those that "may use [the crisis] to prey on American workers by subverting competition in labor markets." U.S. Dep't of Justice & Fed. Trade Comm'n, Joint Antitrust Statement Regarding COVID-19 and Competition in Labor Markets (Apr. 2020), <https://tinyurl.com/DOJ-Antitrust-Labor>.

**PPE Instead**

**Delrahim 20** (Makan Delrahim, Assistant Attorney General, U.S. Department of Justice Antitrust Division, Washington, D.C., USA, Tackling the COVID-19 challenge—a view from the DOJ, Journal of Antitrust Enforcement, Volume 8, Issue 2, July 2020, Pages 244–246, <https://doi.org/10.1093/jaenfo/jnaa032>, y2k)

The **A**ntitrust **D**ivision has also worked closely with other federal agencies, including the US Departments of Health and Human Services, Defense and Agriculture, the Federal Emergency Management Agency, the Centers for Medicare and Medicaid Services, and the White House Coronavirus Task Force, in order to ensure that **critical products**, such as **p**ersonal **p**rotective **e**quipment (PPE) and **medical supplies**, are **rapidly deployed** where they are needed most, including to **healthcare workers** on the frontline. To ensure greater clarity during these uncertain times, we released a joint statement with our colleagues at the Federal Trade Commission (FTC) detailing several types of collaborative activities among competitors that would be consistent with the antitrust laws, and outlined an accelerated business review process for companies that need it. Only 11 days later, the Antitrust Division issued our first business review letter pursuant to this expedited process. The letter explained that the Antitrust Division would not challenge the collaborative efforts of medical supplies distributors to work with federal authorities to expedite and increase manufacturing, sourcing, and distribution of PPE and certain medications necessary to treat COVID-19 patients.

In a second joint statement with the FTC, the Antitrust Division reaffirmed the importance of competition for American workers, particularly providers of essential services such as healthcare workers, as well as employees of key businesses such as grocery stores and pharmacies. We expressed our commitment to enforcing the antitrust laws against those who exploit the pandemic to engage in anticompetitive conduct in labor markets, such as by entering into unlawful wage-fixing and no-poach agreements.

Indeed, guided by the Attorney General, the **A**ntitrust **D**ivision has **prioritized** the criminal investigation and prosecution of **competition cases** related to **COVID**-19. Through the Antitrust Division’s Procurement Collusion Strike Force and other tools, we will hold accountable individuals and companies that use the pandemic as an opportunity to engage in criminal antitrust violations, including bid-rigging, price-fixing, and market allocation. The Strike Force, which the Antitrust Division launched last year, is an interagency partnership of law enforcement personnel and prosecutors across the Department, which aims to combat criminal antitrust violations affecting public procurement. Given its focus, the Strike Force is on high alert for collusive practices in the sale of important healthcare products to federal, state, and local agencies.

**Framing issue---law enforcement agencies have the freedom to prioritize and balance resources now despite the thumpers---the fiated nature of the aff makes it impossible to plan, so it is the only thing that disrupts the status quo enforcement**

**OECD 20** (The Role of Competition Policy in Promoting Economic Recovery, <https://www.oecd.org/daf/competition/the-role-of-competition-policy-in-promoting-economic-recovery-2020.pdf>, y2k)

Competition law and policy should not to be seen as a ‘political luxury good’ that economies can do without in times of crisis. Competition is a **fundamental staple** of economic **recovery** as clearly shown from **insights** from **previous** economic **crises.** There is an unprecedented level of **government interventions** to mitigate a deep recession caused by the **Covid**-19 pandemic. Competition advocacy has rarely been more important and can help for better policy decision making as government interventions may fail to account for unintended consequences on markets. A good decision-making process requires that all costs are fully taken into account, including those that relate to loss of competition. Competition authorities can contribute with their **unique skill sets,** by advocating and informing governments and regulators on the benefits of competition. Competition authorities should participate in the process of assessing the costs to competition of any state support measure. Whenever **resources** allow, competition authorities should assist in the design of the **government measures** and provide advice to minimise potential **competition distortions**. Competition principles should also inform the design of industrial policy measures to “build back better”. In their advocacy function, competition authorities can also propose pro-competitive structural reforms. Authorities may issue opinions and recommendations to government on legislation and regulation. They may also advocate for competitive tender processes for capacity and stockpiling of essential goods, as well as for infrastructure needs in the recovery phase. Competition authorities can support the economic recovery by **redirecting enforcement resources** towards **strategic markets** and **industries** considered important for the **recovery** process. Sectors that may take **priority** could include, for instance, those that have been strongly implicated in the **response to the crisis** or those that can generate positive spill-over on social welfare. Competition authorities need to **prioritise** **carefully** to ensure that their enforcement actions are contributing to the drive for economic recovery. They should take due consideration of economic conditions in markets, but apply competition rules strictly to ensure well-functioning markets in the long-term. In this way, competition authorities can provide an important contribution to the **speed** and **sustainability** of the economic **recovery**.

**Empirics---the expanded enforcement agenda in the 60s collapsed due to ambitious agenda---agencies will fumble in response to fiating new priorities**

**Jones 20** (Alison Jones is Professor of Law at King’s and a solicitor at Freshfields Bruckhaus Deringer LLP, Antitrust’s Implementation Blind Side: Challenges to Major Expansion of U.S. Competition Policy, The Antitrust Bulletin. 2020;65(2):227-255, y2k)

III. Obstacles to **Effective** Implementation

The proponents of change have set out a breathtaking agenda for reform. The various papers and reports are powerfully reasoned and argued but devote relatively little attention to the question of how their proposals can be achieved successfully. Rather many of them seem to be predicated on the assumption that any legislative changes required can be introduced rapidly and that the new, more aspiring, program can be driven home straightforwardly by agencies led by courageous leaders and supported by a larger staff that shares the vision for fundamental change.

The discussion below, and history, seems to indicate, however, that more courage and **more people** will not necessarily overcome the **implementation obstacles** that stand in the way of a program that requires **the rapid prosecution** of a large number of **complex cases** against **well-resourced** and **powerful** companies. Indeed, the criticisms levied at the current system, the proposals for more effective enforcement and reform, and the scale of the action being demanded bear some resemblance to those that led to a more re-invigorated and aggressive antitrust enforcement policy in the **1960s** and early 1970s. For example, at that time complaints that the FTC was in decay, was obsessed with trivial cases and failing to address matters of economic importance, anticompetitive conduct, and rising concentration,77 led the FTC to embark on a new, bold, and astoundingly **broad** enforcement program.78 In an effort to meet criticisms of it as a shambolic and failing institution, the FTC sought to upgrade its processes for policy planning, made concerted efforts to improve its human capital in management and case handling, and sought to improve substantive processes and the quality of its competition and consumer protection analysis.

In the end, FTC’s efforts to improve capability proved **insufficient** to support the **expanded enforcement agenda**, partly because the Commission failed to formulate an adequate plan to overcome the full range of **implementation obstacles.** The FTC seriously **overreached** because it did not **grasp**, or **devise strategies** to deal with, **the scale** and **intricacies** of its **expanded program of cases** and **trade regulation rules**, the **ferocious opposition** that big cases with **huge** remedial **stakes** would provoke from **large defendants** seeking to avoid divestitures, compulsory licensing, or other measures striking at the heart of their business, and **the resources** required to **deliver** good results. The Commission lacked the capacity to run **novel** shared monopoly **cases** that sought the break-up of the country’s eight leading petroleum refiners and four leading breakfast cereal manufacturers79 and **simultaneously** pursue an abundance of other **high stake**, **difficult matters** involving monopolization, distribution practices, and horizontal collaboration. The FTC also overlooked swelling political opposition, stoked by the vigorous lobbying of Congress, that its aggressive litigation program provoked.80

New legislation envisaged by reform advocates could ease the path for current government agencies seeking to reduce excessive levels of industrial concentration by arresting anticompetitive behavior of dominant enterprises (through interim and permanent relief) and by blocking mergers that pose incipient threats to competition. It seems clear, however, that such dramatic legislative proposals are likely to be fiercely contested through the legislative process and so will take time, and be difficult, to enact. Further, **even if** armed with a more powerful mandate, **the DOJ** and the **FTC** will still have to bring what are likely to be **challenging cases** applying the new laws (see Section F). The **adoption**, **setting up**, and **bedding** in of new legislation or regulatory structures and bodies is therefore unlikely to happen very **quickly** and is, consequently, unlikely to meet the demands of those seeking **urgent and immediate action now**.

These difficulties suggest that for the near future, at least, the agencies will have to achieve successful **extensions** of policy mainly through launching themselves into a number of **lengthy**, **complex investigations** and **litigation** based on the current regime. This means establishing violations under existing judicial interpretations of the antitrust laws and making a convincing case for the imposition of effective remedies, including structural relief.

**Plan causes a direct trade-off**

**McCareins 19** (Mark McCareins, Clinical Professor of Business Law; Co-Director, JDMBA Program, Why Antitrust Regulators Don’t Scare Big Tech, 8-19, <https://insight.kellogg.northwestern.edu/article/why-antitrust-regulators-dont-scare-big-tech>, y2k)

In McCareins’s view, these large businesses have to date played within the antitrust rules to keep markets competitive. **Large-scale** government investigations like the ones the **DOJ** and **FTC** plan could not only prove **costly** and **ineffective**, but could also **draw resources away** from targeting **actual** abuses in **other** markets.

**“It’s a trade-off**,” he says. “If regulators bring **a highly speculative case** in one of these big-name markets because they think it will show America that they are tough on regulation, and they lose—and while they’ve been doing that, **they let 20 other markets go unattended**—I don’t know if that’s a good **allocation** of our **prosecutorial resources**. The Antitrust Division’s loss earlier this year in the ATT/Time Warner merger litigation is an example of the **government rolling the dice** with a speculative case and **limited** resources. One would think with respect to the current tech investigations that the government cannot afford a repeat of the ATT/Time Warner outcome.”