# 1AC

### 1AC – Prices Adv

Contention 1 is Prices –

#### Best new studies prove that U.S. drug prices have skyrocketed in recent years because of lack of competition. That shuts off access to vital drugs and balloons debts.

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

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

The skyrocketing price of prescription medication continues to plague the pharmaceutical industry. For example, an analysis of one million Medicare patients between 2010 and 2017 found that the average dosage-unit price of brand-name drugs increased by 313 percent even after accounting for rebates.2 [FN 2] 2 Robin Feldman, The Devil in the Tiers, J.L. & BIOSCI. 1, 19 (2021). The RAND Corporation found in 2021 that the price of brand-name prescription drugs in the U.S. is 256 percent of the prices in thirty-two OECD countries combined, ranging from 170 percent of prices in Mexico to 779 percent of prices in Turkey (ANDREW W. MULCAHY ET AL., RAND CORP., INTERNATIONAL PRESCRIPTION DRUG PRICE COMPARISONS: CURRENT EMPIRICAL ESTIMATES AND COMPARISONS WITH PREVIOUS STUDIES 26 (2021), <https://www.rand.org/content/dam/rand/pubs/research_reports/RR2900/RR2956/RAND_RR2956.pdf>). [End FN] Similarly, one in four Americans have difficulty affording their medications, and three in ten say costs have prohibited them from taking their medications as prescribed.3 With rising out-of-pocket costs and patients dangerously rationing medication, these prices are causing real pain for American patients. Diabetic patients, for example, paid nearly $6000 a year out of pocket for insulin in 2016, and patients with arthritis saw the price of Humira rise to $1552 a month in 2019.4 As difficult as the burdens are for any patient, the burden of paying high prices lands particularly hard on lower-income groups, threatening access to life-saving treatments and creating further gaps in equity across society.

Since the passage of legislation in the early 1980s, the nation has pinned its hopes on the disciplining effects of generic drugs. Generics are expected to enter the market rapidly when a drug’s patent protection expires, driving prices down to competitive levels.5 Something, however, is seriously amiss. Although generics continue to enter the market in record numbers, drug prices, out-of-of pocket costs, and real spending on drugs continue to soar unabated. The pharmaceutical industry is a complex and convoluted market, with significant distortions and inefficiencies.6 Among these problems, however, one cannot expect generic competitors to create a disciplining effect on prices, if brand companies are able to collude with their generic competitors.

In a landmark decision nearly a decade ago, the Supreme Court opened the door for antitrust suits against brand and generic pharmaceutical companies who engage in collusive settlements to delay the time for the generic to come to market. With these “pay-for-delay” agreements, brand-name companies offer prospective generic competitors cash in exchange for the generic’s promise not to enter the market until an agreed-upon date. Laying the groundwork for the lawsuit that would eventually lead to the Actavis decision, the Federal Trade Commission (FTC) published a study estimating that pay-for-delay agreements cost American consumers $3.5 billion annually, a figure that has been cited repeatedly by scholars and policy-makers alike.7 Similar concerns led Congress, in 2003, to require that brand and generic manufacturers file settlement agreements concerning the manufacture, marketing, or sale of generic drugs with the FTC and tasked the FTC with publishing an annual report on the state of pay-for-delay. 8

As this article will demonstrate, the $3.5 billion figure vastly understates the landscape. To understand the state of pay-for-delay agreements, this article leverages a range of methodologies to present an in-depth examination of the burden that pay-for-delay imposes, both on individual patients and society at large. Specifically, the analysis demonstrates the cost of unavailable generic options in drug markets that suffer pay-for-delay schemes. The findings are alarming, and far exceed the FTC estimate.

● Pay-for-delay settlements cost the U.S. population at least $6.4 billion annually: Calculations ranged from $6.4 billion to as high as $36.1 billion per year in total costs based on list prices, as the postponement of generic options required the continued usage of expensive brands.

● Pay-for-delay settlements saddled American patients with more than $600 million in annual out-of-pocket costs: Patients each year collectively paid between $610 million and $2.8 billion more out-of-pocket as a result of pay-for-delay.

● Pay-for-delay settlements cost the Medicare Part D program at least $2.3 billion annually: The government paid between $2.3 and $13.1 billion more each year to fund Part D because of pay-for-delay.

Moreover, although the Supreme Court’s landmark decision in Actavis opened the door for antitrust litigation, courts have failed to utilize the pathway provided. This article explores the modern legal landscape that has instead emerged since the Supreme Court’s historic pronouncement.

The article proceeds as follows. Part I describes pay-for-delay agreements, exploring the literature on the potential harm of such agreements among pharmaceutical competitors. Part II presents a new analysis demonstrating that the cost of pay-for-delay to American consumers is far greater than anyone has recognized, and well beyond the $3.5 billion figure cited by the FTC in 2010. We applied six different methodologies to provide as fair and broad a view as possible. The range of methodologies show that at a minimum, the cost of pay-for-delay settlements on the U.S. population between 2006 and 2017 is a minimum of $6.4 billion per year—almost double that of the FTC’s estimate. The methodology with the largest result suggests that the cost could be as high as $36 billion per year—10 times higher. Part III argues that courts are allowing this costly problem to flourish unchecked. This part reviews pay-for-delay decisions since Actavis, arguing that the courts have failed to properly analyze such cases from the perspective of all three notions inherent in the words “pay,” “for,” and “delay.” Finally, Part IV offers a path forward through the doctrinal haze.

#### Monopoly drug pricing is the primary driver of U.S. healthcare spending – doesn’t benefit R&D

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Ezekiel J. Emanuel, 3-23-2019, "Big Pharma’s Go-To Defense of Soaring Drug Prices Doesn’t Add Up," Atlantic, https://www.theatlantic.com/health/archive/2019/03/drug-prices-high-cost-research-and-development/585253/

How is it that pharmaceutical companies can charge patients $100,000, $200,000, or even $500,000 a year for drugs—many of which are not even curative?

Abiraterone, for instance, is a drug used to treat metastatic prostate cancer. The Food and Drug Administration initially approved it in 2011 to treat patients who failed to respond to previous chemotherapy. It does not cure anyone. The research suggests that in previously treated patients with metastatic prostate cancer, the drug extends life on average by four months. (Last year, the FDA approved giving abiraterone to men with prostate cancer who had not received previous treatment.) At its lowest price, it costs about $10,000 a month.

Abiraterone is manufactured under the brand name Zytiga by Johnson & Johnson. To justify the price, the company pointed me to its “2017 Janssen U.S. Transparency Report,” which states: “We have an obligation to ensure that the sale of our medicines provides us with the resources necessary to invest in future research and development.” In other words, the prices are necessary to fund expensive research projects to generate new drugs.

This explanation is common among industry executives. To many Americans, it can seem plausible and compelling. It’s easy to conjure images of scientific researchers in their protective gear and goggles carefully dropping precious liquids into an array of Erlenmeyer flasks, searching for a new cure for cancer or Alzheimer’s. But invoking high research costs to justify high drug prices is deceptive.

No matter the metric, drug prices in the United States are extreme. Many drugs cost more than $120,000 a year. A few are even closing in on $1 million. The Department of Health and Human Services estimates that Americans spent more than $460 billion on drugs—16.7 percent of total health-care spending—in 2016, the last year for which there are definitive data. On average, citizens of other rich countries spend 56 percent of what

Excessive drug prices are the single biggest category of health-care overspending in the United States compared with Europe, well beyond high administrative costs or excessive use of CT and MRI scans. And unlike almost every other product, drug prices continue to rapidly rise over time. HHS estimates that over the next decade, drug prices will rise 6.3 percent each year, while other health-care costs will rise 5.5 percent. Basic economic principles suggest that drug prices should be going down, not up: For most drugs, manufacturing volumes are increasing, and little new research is being conducted on those already on the market.

Reducing these high drug prices has become a major political concern—and a rare bipartisan cause for Democrats and Republicans to rally around, albeit with disagreement about how to actually get it done. In his State of the Union address last month, President Donald Trump called the price discrepancy between the United States and other countries “unacceptable” and “unfair,” and vowed to “stop it fast.” In a Senate Finance Committee hearing on drug pricing a few weeks later, Senator Ron Wyden of Oregon compared the way the drugmaker AbbVie protects the exclusivity of one of its drugs to the way Gollum protects his ring.

Yet every time Congress debates doing something about drug prices, the industry—and the advocacy groups it funds—vociferously returns to the point that lower prices will thwart innovative research. The fear of missing a cure for Alzheimer’s or Lou Gehrig’s disease or depression contributes to stalling reform. But there are many reasons to question the widely held notion that high drug prices and innovative research are inextricably linked.

The most telling data on a disconnect between drug prices and research costs has received almost no public attention. Peter Bach, a researcher at Memorial Sloan Kettering, and his colleagues compared prices of the top 20 best-selling drugs in the United States to the prices in Europe and Canada. They found that the cumulative revenue from the price difference on just these 20 drugs more than covers all the drug research and development costs conducted by the 15 drug companies that make those drugs—and then some.

To be more precise, after accounting for the costs of all research—about $80 billion a year—drug companies had $40 billion more from the top 20 drugs alone, all of which went straight to profits, not research. More excess profit comes from the next 100 or 200 brand-name drugs.

Drug companies tend to say they are unique in needing to spend a higher proportion of their capital on research than almost any other industry. But of all the companies in the world, the one that invests the most in research and development is not a drug company. It’s Amazon. The online retailer spends about $20 billion a year on R&D, despite being renowned for both low prices and low profits. Among the 25 worldwide companies that spend the most on research and development—all more than $5 billion a year—seven are pharmaceutical manufacturers, but eight are automobile or automobile-parts companies with profit margins under 10 percent. Amazon’s operating margin is under 5 percent. Meanwhile, the top 25 pharmaceutical companies reported a “healthy average operating margin of 22 percent” at the end of 2017, according to an analysis by GlobalData.

If you watch television, you know part of the answer to where this extra money is going: sales and advertising. Of the 10 largest pharmaceutical companies, only one spends more on research than on marketing its products. But it’s hard to figure out what it actually costs drug companies to conduct the research required to get FDA approval and bring a single drug to market. The pharmaceutical industry and its advocates tend to peg the cost of creating and bringing to market just one new drug at $2.6 billion. This figure comes from a cost report published in October 2016 by the Tufts Center for the Study of Drug Development.

There are several reasons to suspect that number is unreliable. According to the Tufts Center’s website, more than a quarter of its budget comes from “unrestricted grants” from pharmaceutical companies and their partners. And no one can verify Tufts’ analyses and claims: The authors say the data come from research spending on 106 drugs produced by 10 of the top 50 multinational pharmaceutical companies, but the underlying data are deemed proprietary and confidential.

Tufts also uses a cost-accounting methodology that appears to significantly inflate its estimate. About 45 percent of Tufts’ $2.6 billion figure is attributed to the amount companies would pay to lenders and shareholders for the capital they invest in research. Tufts uses an interest rate of 10.5 percent a year, but investment bankers tend to use just 6 percent in their economic models. That one change would reduce the Tufts estimate by about a quarter of its total figure. That’s not to mention other factors the Tufts team leaves out that reduce the cost of drug development, such as tax credits the federal government offers for research and development.

When asked about these issues, the report’s chief author, Joseph DiMasi, noted that one other study with public data, published in 2009, comes to similar results. He argues that even if we exclude the cost of capital, $1.4 billion per FDA-approved drug is a high price—and the cost has been growing at about 8.5 percent annually.

But in November 2017, a study published in JAMA Internal Medicine examined the costs of developing 10 cancer drugs approved by the FDA from 2006 to 2015 and provided a strong contrast to the Tufts study from a year before. Its authors, from Memorial Sloan Kettering and the Oregon Health and Science University, used annual financial disclosures from the Securities and Exchange Commission for companies that had only one cancer drug approved but had on average three or four other drugs in development. They found that companies took an average of 7.3 years to win FDA approval, at a median cost of $648 million. Only two drugs had research costs over $1 billion. Adding in the cost of capital at 7 percent increased the median research and development cost to $757 million—less than a third of the Tufts estimate.

Pharmaceutical companies often claim that the research costs of unsuccessful drugs also have to be taken into account. After all, 90 percent of all drugs that enter human testing fail. But most of these failures occur early and at relatively low costs. About 40 percent of drugs fail in preliminary Phase I studies, which assess a drug’s safety in humans and typically cost just $25 million a drug. Of the drugs that clear this first phase of testing, about 70 percent fail during Phase II studies, which assess whether a drug does what it is supposed to do. The research costs of these studies are still relatively low compared with overall R&D costs—on average, under $60 million a study.

The 2017 JAMA Internal Medicine study incorporated all research costs on drugs not yet on the market into its final calculations. The pharmaceutical companies it examined had an average drug success rate of 23 percent, which the Tufts researchers argue is too high to accurately represent the amount of money that failed drugs would usually add to a company’s research costs. But cancer drugs, specifically, do have a success rate of 20 to 25 percent—so the selection of only successful companies does not seem to be the difference.

Joaquin Duato, the vice chairman of Johnson & Johnson’s executive committee, argues that critics fail to deal with the realities of drug R&D. He told me that last year, Johnson & Johnson had $41 billion in prescription-drug sales, of which $8.4 billion went to R&D and $4.5 billion went to sales and marketing. Other costs included manufacturing, finance, IT, taxes, and more. This funds research on 100 candidate drugs, which result in one or two FDA approvals a year. “For drug companies, the return on capital is in the mid-teens, which is nowhere near tech-company returns,” Duato said.

Nevertheless, some former pharmaceutical-company executives say that research costs do not determine drug prices—and they explain how. In his book A Call to Action, Hank McKinnell, a past CEO of Pfizer, wrote under the heading “The Fallacy of Recapturing R&D Costs”:

How do we decide what to charge? It’s basically the same as pricing a car … A number of factors go into the mix. These factors consider cost of business, competition, patent status, anticipated volume, and, most important, our estimate of the income generated by sales of the product. It is the anticipated income stream, rather than repayment of sunk costs, that is the primary determinant of price.

Raymond Gilmartin, a former Merck CEO, once said to The Wall Street Journal: “The price of medicines is not determined by their research costs. Instead, it is determined by their value in preventing and treating disease.”

Exorbitant drug prices have two bad effects. First, high costs mean that lots of patients are unable to take their medications. A recent study in the Journal of Clinical Oncology assessed patients’ access to 38 different oral cancer drugs and found that 13 percent of cancer patients did not buy approved chemotherapy drugs if they had a co-payment of $10 a month, while 67 percent did not when they had to pay $2,000 or more. Another study showed that 25 percent of diabetic patient underuse their insulin because of cost.

Second, the high drug prices distort research priorities, emphasizing financial gains and not health gains. Cancer drugs are routinely priced at about $120,000 to $150,000 a year, and more than 600 cancer drugs are now being tested on humans. This can lead to great societal benefits: The United States is expected to face 1.76 million new cancer cases and more than 600,000 cancer deaths in 2019 alone. But many of the drugs that companies are pursuing have low promise, where the health gains are small—weeks of added life, not big cures. While even this short extra time can be valuable to individual families, too much investment in oncology means not enough in drugs for other illnesses whose treatments cannot be so highly priced.

Consider antibiotics. The Centers for Disease Control and Prevention ranks antibiotic-resistant infections as one of the nation’s top health threats. An estimated 2 million Americans become infected with such bacteria each year, and 23,000 die. A superbug that is resistant to all known antibiotics is an imminent threat. Yet because antibiotics are generally cheap, for most pharmaceutical and biotechnology companies they are not a primary focus. The Pew Charitable Trusts reports that only about 42 new antibiotics with the potential to treat serious bacterial infections were in clinical development for the U.S. market in December 2018. Six hundred drugs for cancer and only 42 for serious infections seems like profit maximization, not a case of sensible research priorities that reflects “value in preventing and treating disease.”

The simple explanation for excessive drug prices is monopoly pricing. Through patent protection and FDA marketing exclusivity, the U.S. government grants pharmaceutical companies a monopoly on brand-name drugs. But monopolies are a recipe for excessive prices. A company will raise prices until its profits start to drop.

To address the problem of high prices and reduced access to drugs, Johnson & Johnson advocates eliminating rebates to pharmacy benefit managers and insurers, which would increase price transparency and lower patient co-pays. But it would not necessarily lower total drug prices. The proposal avoids the standard economic response to monopoly pricing: price regulation. Every other developed country regulates drug prices, often through price negotiations pegged to cost-effectiveness analysis or some other measure of clinical benefit.

Will R&D go down if the United States follows this model? Not necessarily. Remember, the high drug prices fund R&D but also marketing, manufacturing, administrative expenses, and profits at the companies. Lower revenue from lower drug prices could reduce marketing, administration, and excessive profits before R&D costs have to be reduced.

Where cuts are made is up to drug companies. Their claims of lower R&D costs appear designed to generate fear, but as some former executives themselves have acknowledged, there is no necessary link between a decline in drug prices and a decline in R&D. Drug companies could make other choices that maximally improve the health of all Americans.

#### Specifically – Biologics account for 93% of the cost.

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Avik Roy, 3-8-2019, "Biologic Medicines: The Biggest Driver Of Rising Drug Prices," Forbes, https://www.forbes.com/sites/theapothecary/2019/03/08/biologic-medicines-the-biggest-driver-of-rising-drug-prices/?sh=16fb5a2618b0

The topic of high prescription drug prices is now the dominant policy issue on Capitol Hill. The new Congress has held a half-dozen hearings on the topic. But one issue that is at the heart of high prices has attracted little attention: the role of biologic drugs in rising drug costs.

In 2017, according to data from the IQVIA Institute, biologic drugs represented 2 percent of all U.S. prescriptions, but 37 percent of net drug spending. Since 2014, biologic drugs account for nearly all of the growth in net drug spending: 93 percent of it, in fact.

Why is that? And what are biologic drugs in the first place? I’ll try to explain.

The FDA regulates traditional and biologic drugs differently

In the old days, most FDA-approved drugs are what we call small molecules: traditional medicines with relatively simple chemical structures. For example, Lipitor (atorvastatin), a best-selling cholesterol-lowering drug, is comprised of 76 atoms, and is exceedingly cheap to manufacture. On the other hand, biologic drugs (or large molecules) like monoclonal antibodies are complex proteins, manufactured in living cells: a costlier process. Humira (adalimumab), the nation’s top drug by revenue, contains 20,067 atoms.

Biologic drugs are the wheelhouse of the biotechnology industry. Innovators in the 1970s and 1980s, like Genentech and Amgen, learned how to insert modified DNA sequences into harvested hamster cells, in order to make genetically engineered proteins that could treat diseases. For example, Epogen, Amgen’s first blockbuster drug, is a genetically engineered version of human erythropoietin: a protein that stimulates your bone marrow to produce more red blood cells. Because erythropoietin is normally produced in the kidney, people with kidney disease often have anemia that can be treated with Epogen.

Because biologic drugs are manufactured using different techniques than traditional, small molecule drugs, Congress and the FDA have chosen to regulate these two categories in different ways. Traditional drugs are governed by the Food, Drug, and Cosmetic Act: the law that originally created the Food and Drug Administration. Biologic medicines are governed by a different law, the Public Health Service Act.

In both cases, the FDA expects drugmakers to conduct clinical trials that demonstrate that a new drug is safe and effective. In both cases, the FDA scrutinizes manufacturing plants to ensure that medicines are consistently made from batch to batch.

Where things really change, in terms of FDA regulation, is after drugs have been on the market for a long time, with patents about to expire.

#### Budgetary overstretch driven by healthcare causes global instability.

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(Stuart S., “Global Power: Key Issues,” in *The Future of US Global Power: Delusions of Decline*, Palgrave, p. 57-58)

In the first instance, structural26 budget deficits are more likely to be symptoms of incipient overstretch then prima facie evidence of national decline. Overstretch suggests a need to realign commitments and resources, hence spending and revenues. In principle, persistently large deficits demand adjustments that need not materially impact the underlying drivers of longer-term prosperity. In contrast, if fiscal imbalances prove sufficiently chronic, they can eventually trigger growth-inhibiting alterations in microeconomic incentives. In such cases, incipient overstretch can mutate into a more primary threat to the system's underlying dynamism.

In its classical formulation, “imperial overstretch” refers to unrestrained and exorbitant foreign military campaigns. The latter can be said to redound to the detriment of great powers by crowding out more productive capital investments. Yet in contrast to widespread impression, the US fiscal challenge does not primarily reflect out-of-control defense spending and the burden of foreign entanglements. If this were the case, then the feasibility of financing an ever-expanding global power projection would be brought into question. This neither minimizes the sizable resources the US commits to military-related spending nor denies that cutbacks in such spending can help facilitate overall fiscal adjustment. Rather, the point is that an endemic failure to rein in explosive economy-wide health care costs with the latter's implications for public sector health insurance programs – the real fiscal challenge – will do more to endanger macroeconomic stability and eventually erode the material foundation of US power (see chapter 8).

By viewing (health-care driven) fiscal deficits as a necessary manifestation of overstretch is misguided for a more basic reason. The root of the US fiscal problem involves unsustainable commitments – particularly in the area of health expenditure – made by government to its citizens. It is decidedly not a question of any dearth of national resources to adequately meet the health needs of the population at large. As the richest country in the world, the US possesses more than enough resources to achieve this goal. The relevant political and social question is whether the population’s basic health requirements are best met via ever-expanding entitlements requiring increasingly higher levels of taxation.

#### And – It’s a leading cause of death and suffering

WestHealth 20 – Citing new study

New Study Predicts More Than 1.1 Million Deaths Among Medicare Recipients Due to the Inability to Afford Their Medications: Beneficiaries skipping medications is causing early death and worsening medical conditions that will cost Medicare an extra $177.4 billion over the next 10 years, Nov. 19, 2020, https://www.westhealth.org/press-release/study-predicts-1-million-deaths-due-to-high-cost-prescription-drugs/

More than 1.1 million Medicare patients could die over the next decade because they cannot afford to pay for their prescription medications, according to a new study released today by the West Health Policy Center, a nonprofit and nonpartisan policy research group.

If current drug pricing trends and associated cost-sharing continue, researchers estimate cost-related non-adherence to drug therapy will result in the premature deaths of 112,000 beneficiaries a year, making it a leading cause of death in the U.S., ahead of diabetes, influenza, pneumonia, and kidney disease. Millions more will suffer worsening health conditions and run up medical expenses that will cost Medicare an additional $177.4 billion by 2030 or $18 billion a year for the next 10 years.

### 1AC – Innovation Adv

Contention 2 is Innovation –

#### Innovation is plummeting despite skyrocketing prices. Only competition rebalances patent incentives to solve both problems

Feldman 18 – Distinguished Professor of Law Chair & Director of the Center for Innovation, UC Hastings Law

Robin Feldman, Arthur J. Goldberg Distinguished Professor of Law, Albert Abramson ’54 Distinguished Professor of Law Chair, and Director of the Center for Innovation, May your drug price be evergreen, *Journal of Law and the Biosciences*, Volume 5, Issue 3, December 2018, pp. 590–647, https://doi.org/10.1093/jlb/lsy022

Out of the 106 top-selling drugs from between 2005 and 2014, more than 70% had their protection cliff extended at least once and more than 50% had their protection cliff extended more than once. The magnitude of the behavior highlights the extent to which stifling competition has become the norm in the pharmaceutical industry. When more than 70% of best-selling drugs had their protection extended, it is clearly the go-to approach for profitability.149

One can easily anticipate such maneuvering to continue going forward, particularly given the top-selling drugs going off patent. Between 2014 and 2020, an estimated $253 billion in worldwide drug sales is at risk due to expiration of patents on blockbuster drugs.150 Without societal action, the future is likely to look like more of the same.

V. SOLUTIONS

As described in the opening of this article, the intellectual property system in general and the patent system in particular are designed to provide an opportunity for innovators to garner a return. Competition may be held in abeyance for a limited time, but those who receive the benefit must pay for the privilege by disclosing sufficient information that competitors will be able to step in. This design reflects the deeply rooted notion that providing a period of exclusivity for inventors is intended to rebound to the benefit of society as a whole, not simply to the benefit of the inventors. The patent protection should end, returning the market to a competitive state.

This foundational structure of the patent system—one that delicately balances innovation and competition—is crumbling, whittled away across time as one good idea after another creates a special carve-out. Each carve-out, standing on its own, presents an appealing cause. Together, however, the result is a complete undermining of the system for pharmaceutical innovation as the repeated addition of protections, one after another, pushes competition further into the future, threatening innovation in the process. The behavior is not limited to a few bad apples. Our research reveals that it is endemic to the pharmaceutical industry.

In short, this is not an image of innovation and competitive entry. It is an image of a system that provides for repeated creation of competition-free zones, pushing a competitive market further and further out into the future. The problem is not only pervasive and persistent, but it is also growing across time.

The impact created by these repeated competition zones is not some abstract problem that our grandchildren may face. Rather, the nation's pharmaceutical system is in crisis today, with prices soaring to heights that distort both individual and government budgets.151 These dire circumstances bring calls for price controls, for government marching in to direct drug production, and for other strong measures.152 The US Government's history of directly managing pharmaceutical innovation, however, has been disappointing. In fact, prior to the Bayh-Dole Act of 1980, the federal government took responsibility for handing out licenses for innovation developed through government-funded research. Bayh-Dole shifted that responsibility from the federal government to universities, precisely because the government failed so miserably in this role. There is little reason to expect a different result this time.153

Competition is a powerful and effective tool, however, and paving the way for competition whenever it is possible remains the optimal approach. When the government itself bestows benefits that are stifling competition, society has both an obligation and an opportunity to act. One cannot, however, enter into such action lightly; it must be designed with thought and care. Pharmaceutical research and development are expensive, and companies must have sufficient incentive to travel down that risky road. Nevertheless, by incentivizing game-playing rather than innovation, society has clearly missed the mark.

#### Artificially shielding patents from scrutiny incentivizes pseudo-innovation – companies will develop the 50th version of Aspirin and not big breakthroughs

Elhauge and Krueger 12 – Petrie Professor of Law, Harvard Law School and Executive Director, Legal Economics

Einer Elhauge & Alex Krueger, “Solving the Patent Settlement Puzzle,” Texas Law Review, Vol. 91:283

Exceeding the optimal patent exclusion period is likewise inefficient for several reasons. First, the economic literature shows that patent profits that exceed the optimal level result in excessive investments in innovation that reduce social welfare compared to the optimal investments in innovation. Second, excessive patent protection can produce a net reduction in innovation by precluding subsequent innovations by others.

Third, settlements that over-reward the patent holder with a longer exclusion period than it deserves reduce the net reward for true innovation by increasing the reward more for less-deserving patents than for more deserving patents. As the proof below shows and the Second Circuit has already pointed out, settlements that exclude entry increase patent-holder profits more for weaker patents than for stronger patents. For example, the holder of a weak patent that is only 5% likely to be deemed a valid innovation could use such a settlement to secure exclusion throughout the entire patent term, even though its patent is 95% likely to be deemed a non-innovation, while the holder of an ironclad patent that is 100% likely to be deemed a true innovation could not increase its exclusion period through settlement because it would already expect 100% exclusion from litigation. Thus, settlements with an excessive exclusion period reduce the net reward for investing in a true innovation that leads to a stronger patent rather than in a pseudo-innovation that leads to a weaker patent. When a firm faces a choice between investing in true innovation or pseudo-innovation, this artificially reduced net reward for true innovation will distort its choice, and can reduce the rate of true innovation because it is generally harder, more costly, or less certain than pseudo-innovation.

#### Specifically – increasing competition is key to drive the revolution in biologics. Those are ground-breaking new treatments derived from living organisms, such as new vaccine tech and bacteriophages.

Carrier 20 – Michael A. Carrier is a leading authority in antitrust and intellectual property law with expertise in the pharmaceutical, high-technology, and music industries.

Carrier, Michael A. "Don't Die! How Biosimilar Disparagement Violates Antitrust Law." Northwestern University Law Review Online, 115, 2020-2021, p. 119-145. HeinOnline, <https://heinonline.org/HOL/P?h=hein.journals/nulro115&i=119>.

Competition is the key to low prices in the pharmaceutical industry. For decades, Americans have benefitted from affordable generic versions of brand-name drugs. But now, as biologics enter the market, we stand on the precipice of a revolution. In fact, biologics, which can cost patients hundreds of thousands of dollars per year, are predicted to be the "fastest growing segment of drug spending in the coming years."1

The hope, then, is that competition from follow-on products, known as biosimilars, will lower prices for patients. But pharmaceutical companies' campaign of biosimilar disparagement threatens to block this goal. Biologics are large, complex molecules derived from living organisms, most commonly proteins.2 According to the FDA, biologics "often represent the cutting-edge of biomedical research and, in time, may offer the most effective means to treat a variety of medical illnesses and conditions" that have "no other treatments available."3 Monoclonal antibodies, the most frequently developed type of biologic,4 include blockbuster products such as infection-reducing Neulasta, 5 as well as Humira and Remicade,7 both of which treat arthritis, colitis, and Crohn's disease. In targeting unhealthy cells without harming healthy cells, monoclonal antibodies have dramatically increased survival rates.9 Other types of biologics include vaccines, blood products, and gene therapies.10

#### Because they’re living, they are uniquely complex and expensive to synthesize, and no two are exactly alike

Carrier and Minniti 18 – Distinguished Professor, Rutgers Law School, Rutgers Law School, J.D. 2017

Michael A. Carrier and Carl J. Minniti III, BIOLOGICS: THE NEW ANTITRUST FRONTIER, UNIVERSITY OF ILLINOIS LAW REVIEW, 1/12/2018, <https://www.illinoislawreview.org/wp-content/uploads/2018/01/Carrier.pdf>

The science underlying biologics is profoundly different from that of small-molecule drugs. Small molecules are created through a series of chemical reactions known as chemical synthesis. This process is relatively predictable, allowing generics to imitate brand drugs at low cost. Put another way, brands and generics can put the same pieces of a puzzle together in the same way to create the same image. Biologics, in contrast, blow up that paradigm, emphasizing not the individual pieces of the puzzle but the way the puzzle is constructed. Because “the product is the process” and the use of living cells to create biologics is inherently sensitive, there is higher variability and follow-ons cannot precisely replicate the original product. Challenges in biologic development stem from not only the complexity of the molecule but also from changes during the product’s maturation. Unlike the “single and mono-molecular entity” making up small molecules, the final form of biologics is “a complex mix of the same protein molecule under various structurally close [protein-varying] isoforms.” The complicated nature of biologic development is revealed by the uncertainties in the structure of a protein, a typical biologic. A protein includes four structural levels: primary, secondary, tertiary, and quaternary. The primary structure consists of the amino acid sequence, which is essential for biologic activity. Even though drug developers can replicate an amino acid sequence, individualized production and purification methods result in unpredictable structural folding at the secondary, tertiary, and quaternary levels (each of which addresses larger three-dimensional structures). This unpredictability has dramatic effects, determining whether a drug confers therapeutic or toxic effects. Adding to the complexity, even if a biosimilar manufacturer could replicate the structure of the biologic, post-translational modifications to the structure could result in undetectable differences causing adverse patient reactions. Most therapeutic proteins induce a reflexive antibody response against the therapy introduced into the patient’s body. For that reason, immunogenicity—a triggered unwanted immune response—plays a critical role in biologic development. As a patient’s body attempts to fight off foreign proteins, certain product-related factors elicit particular responses, including molecule design, impurities, and post-translational modifications. The development of biologics is particularly difficult and unpredictable because the immunogenic response to proteins cannot be replicated in animal models to simulate an immune response in humans. If variability in biologic development and immunogenicity is a concern for the biologic manufacturer in making its own product, a follow-on maker will confront even higher hurdles. While these entities can rely on patent disclosures and other materials in the public domain, they will lack access to critical information the biologic manufacturer protects as a trade secret. Because biologics are “so closely defined by their manufacturing process,” this secrecy blocks competition. Finally, the effects of complexity and secrecy are exacerbated by the difficulty of even analyzing a protein’s structure. The ability to use analytic techniques to demonstrate clinical comparability is more limited than for small-molecule drugs, with a biosimilar manufacturer not able to show that its product is identical to the biologic product. Unlike generic versions of small-molecule drugs, which are chemically identical to brand versions, the structural variability and complexity inherent in biologic development cause follow-on versions to strive for, at most, similarity. These differences have direct effects on the relevant markets.

C. Markets

Biologics’ complexity is accompanied by their timeliness, with a follow-on biosimilars market poised to explode. This development is even more crucial given that many blockbuster small-molecule drugs are in the midst of losing patent protection, with nearly $200 billion in brand sales subject to generic competition by 2025. The end of a “golden age” for small-molecule block- busters has resulted in drug companies developing biologics, planning to receive as much as 50% of their revenues from the medications in the near future. Such a development will be profitable, with an average daily cost of $45 for a biologic vastly exceeding that of a $2 daily cost for a small-molecule drug. The biologic market, worth $46 billion in 2002, is expected to increase to $390 billion worldwide by 2020. The top-selling U.S. drug of 2015, immune system-treating biologic Humira, amassed more than $8 billion in sales. Other top-selling biologics include arthritis-treating Enbrel (nearly $6 billion) and arthritis-, Crohn’s disease-, and colitis-treating Remicade (more than $4 billion). The rise of biologics could be met with an onslaught of biosimilars, with biologics worth $67 billion in global sales witnessing the expiration of patents by 2020. But despite the clear market opportunity, biosimilar introduction has been relatively slow. One fundamental reason is that, unlike generics requiring expenditures of roughly $2 million, biosimilar development, involving more intensive and uncertain research and development, costs as much as $200 million. Congress enacted the Biologics Price Competition and Innovation Act of 2009 (“BPCIA”) in 2010, but it took until 2015 for the FDA to approve the first biosimilar: Zarxio, Sandoz’s follow-on version of Amgen’s billion-dollar neutropenia (anti-infection) therapy, Neupogen. As of the date of this Article, the FDA has approved only seven biosimilars. In addition to Zarxio, Mvasi received approval as a biosimilar to the $6.75 billion cancer therapy Avastin, and five biosimilars are follow-on versions of three blockbuster inflammatory disease treatments, each in the top ten drugs sold in the United States: (1) Amjevita and Cyltezo, biosimilars to the $8.3 billion Humira; (2) Erelzi, a biosimilar to the $5.9 billion Enbrel; and (3) Inflectra and Renflexis, biosimilars to the $4.6 billion Remicade. Early indications point to biosimilars lowering costs. For example, both Zarxio and Inflectra are sold at a 15% discount from the biologic price. And according to Renflexis sponsor Merck, the biosimilar product “will be introduced in the U.S. at a list price (wholesaler acquisition cost) of $753.39, representing a 35% discount off the current list price of Remicade.” In the small-molecule setting, the entry of a single generic modestly lowers price. As the previous paragraph showed, early returns from the biosimilars market are analogous. But while the entry of multiple small-molecule generics results in significant price erosion (50% with 2 generics and 75% with at least 6), we predict that the reductions may be more modest given attempts to recoup biosimilar development costs, which greatly exceed those incurred by generics. The market effects of biologics and biosimilars also will be shaped by the relevant laws and regulations.

#### Scenario A is Breakthroughs – COVID is only the first warning shot. Continued vaccine development is key to survival

EID = Emerging Infectious Disease

Excler et al. 21 – Jean-Louis Excler, International Vaccine Institute, Seoul, Republic of Korea; Melanie Saville, Coalition for Epidemic Preparedness Innovations (CEPI), London, UK; Seth Berkley, Gavi, the Vaccine Alliance, Geneva, Switzerland; Jerome H. Kim, International Vaccine Institute, Seoul, Republic of Korea

Jean-Louis Excler, Melanie Saville, Seth Berkley, and Jerome H. Kim, "Vaccine development for emerging infectious diseases," Nat Med 27, 591–600, 4-12-2021, <https://www.nature.com/articles/s41591-021-01301-0>

Newly emerging and reemerging infectious viral diseases have threatened humanity throughout history. Several interlaced and synergistic factors including demographic trends and high-density urbanization, modernization favoring high mobility of people by all modes of transportation, large gatherings, altered human behaviors, environmental changes with modification of ecosystems and inadequate global public health mechanisms have accelerated both the emergence and spread of animal viruses as existential human threats. In 1918, at the time of the ‘Spanish flu’, the world population was estimated at 1.8 billion. It is projected to reach 9.9 billion by 2050, an increase of more than 25% from the current 2020 population of 7.8 billion (https://www.worldometers.info). The novel severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) responsible for the coronavirus disease 2019 (COVID-19) pandemic1,2,3 engulfed the entire world in less than 6 months, with high mortality in the elderly and those with associated comorbidities. The pandemic has severely disrupted the world economy. Short of lockdowns, the only means of control have been limited to series of mitigation measures such as self-distancing, wearing masks, travel restrictions and avoiding gatherings, all imperfect and constraining. Now with more than 100 million people infected and more than 2 million deaths, it seems that the addition of vaccine(s) to existing countermeasures holds the best hope for pandemic control. Taken together, these reasons compel researchers and policymakers to be vigilant, reexamine the approach to surveillance and management of emerging infectious disease threats, and revisit global mechanisms for the control of pandemic disease4,5.

Emerging and reemerging infectious diseases

The appearance of new infectious diseases has been recognized for millennia, well before the discovery of causative infectious agents. Despite advances in development of countermeasures (diagnostics, therapeutics and vaccines), world travel and increased global interdependence have added layers of complexity to containing these infectious diseases. Emerging infectious diseases (EIDs) are threats to human health and global stability6,7. A review of emerging pandemic diseases throughout history offers a perspective on the emergence and characteristics of coronavirus epidemics, with emphasis on the SARS-CoV-2 pandemic8,9. As human societies grow in size and complexity, an endless variety of opportunities is created for infectious agents to emerge into the unfilled ecologic niches we continue to create. To illustrate this constant vulnerability of populations to emerging and reemerging pathogens and their respective risks to rapidly evolve into devastating outbreaks and pandemics, a partial list of emerging viral infectious diseases that occurred between 1900 and 2020 is shown in Table 1.

[[Figure Omitted]]

Although nonemerging infectious diseases (not listed in Table 1), two other major mosquito-borne viral infections are yellow fever and dengue. Yellow fever, known for centuries and an Aedes mosquito-borne disease, is endemic in more than 40 countries across Africa and South America. Since 2016, several yellow fever outbreaks have occurred in Angola, Democratic Republic of Congo, Nigeria and Brazil to cite a few10, raising major concerns about the adequacy of yellow fever vaccine supply. Four live attenuated vaccines derived from the live attenuated yellow fever strain (17D)11 and prequalified by the WHO (World Health Organization) are available12.

Dengue is an increasing global public health threat with the four dengue virus types (DENV1–4) now cocirculating in most dengue endemic areas. Population growth, an expansion of areas hospitable for Aedes mosquito species and the ease of travel have all contributed to a steady rise in dengue infections and disease. Dengue is common in more than 100 countries around the world. Each year, up to 400 million people acquire dengue. Approximately 100 million people get sick from infection, and 22,000 die from severe dengue. Most seriously affected by outbreaks are the Americas, South/Southeast Asia and the Western Pacific; Asia represents ~70% of the global burden of disease (https://www.cdc.gov/dengue). Several vaccines have been developed13. A single dengue vaccine, Sanofi Pasteur’s Dengvaxia based on the yellow fever 17D backbone, has been licensed in 20 countries, but uptake has been poor. A safety signal in dengue-seronegative vaccine recipients stimulated an international review of the vaccine performance profile, new WHO recommendations for use and controversy in the Philippines involving the government, regulatory agencies, Sanofi Pasteur, clinicians responsible for testing and administering the vaccine, and the parents of vaccinated children14.

Two bacterial diseases, old scourges of humanity, are endemic and responsible for recurrent outbreaks and are increasingly antimicrobial resistant. Cholera, caused by pathogenic strains of Vibrio cholerae, is currently in its seventh global pandemic since 1817; notably, the seventh pandemic started in 196115. Global mortality due to cholera infection remains high, mainly due to delay in rehydrating patients. The global burden of cholera is estimated to be between 1.4 and 4.3 million cases with about 21,000–143,000 deaths per year, mostly in Asia and Africa. Tragic outbreaks have occurred in Yemen and Haiti. Adding to rehydration therapy, antibiotics have been used in the treatment of cholera to shorten the duration of diarrhea and to limit bacterial spread. Over the years, antimicrobial resistance developed in Asia and Africa to many useful antibiotics including chloramphenicol, furazolidone, trimethoprim-sulfamethoxazole, nalidixic acid, tetracycline and fluoroquinolones. Several vaccines have been developed and WHO prequalified; these vaccines constitute a Gavi-supported global stockpile for rapid deployment during outbreaks16.

Typhoid fever is a severe disease caused by the Gram-negative bacterium Salmonella enterica subsp. enterica serovar Typhi (S. Typhi). Antimicrobial-resistant S. Typhi strains have become increasingly common. The first large-scale emergence and spread of a novel extensively drug-resistant (XDR) S. Typhi clone was first reported in Sindh, Pakistan17,18, and has subsequently been reported in India, Bangladesh, Nepal, the Philippines, Iraq and Guatemala19,20. The world is in a critical period as XDR S. Typhi has appeared in densely populated areas. The successful development of improved typhoid vaccines (conjugation of the Vi polysaccharide with a carrier protein) with increased immunogenicity and efficacy including in children less than 2 years of age will facilitate the control of typhoid, in particular in XDR areas by decreasing the incidence of typhoid fever cases needing antibiotic treatment21,22.

A model of vaccine development for emerging infectious diseases

The understanding of emerging infectious diseases has evolved over the past two decades. A look back at the SARS-CoV outbreak in 2002 shows that—despite a small number of deaths and infections—its high mortality and transmissibility caused significant global disruption (see Table 1). The epidemic ended as work on vaccines was initiated. Since then, the disease has not reappeared—wet markets were closed and transmission to humans from civets ceased. Consequently, work on vaccines against SARS-CoV ended and its funding was cut. Only a whole inactivated vaccine23 and a DNA vaccine24 were tested in phase 1 clinical trials.

Following a traditional research and development pipeline, it takes between 5 and 10 years to develop a vaccine for an infectious agent. This approach is not well suited for the needs imposed by the emergence of a new pathogen during an epidemic. Figure 1 shows a comparison of the epidemic curves and vaccine development timelines between the 2014 West African Ebola outbreak and COVID-19. The 2014 Ebola epidemic lasted more than 24 months with 11,325 deaths and was sufficiently prolonged to enable the development and testing of vaccines for Ebola, with efficacy being shown for one vaccine (of several) toward the end of the epidemic25,26. What makes the COVID-19 pandemic remarkable is that the whole research and development pipeline, from the first SARS-CoV-2 viral sequenced to interim analyses of vaccine efficacy trials, was accomplished in just under 300 days27. Amid increasing concerns about unmitigated transmission during the 2013–2016 Western African Ebola outbreak in mid-2014, WHO urged acceleration of the development and evaluation of candidate vaccines25. To ensure that manufacturers would take the Ebola vaccine to full development and deployment, Gavi, the Vaccine Alliance, publicly announced support of up to US$300 million for vaccine purchase and followed that announcement with an advance purchase agreement. Ironically, there had been Ebola vaccines previously developed and tested for biodefense purposes in nonhuman primates, but this previous work was neither ‘ready’ for clinical trials during the epidemic nor considered commercially attractive enough to finish development28.

[[Figure Omitted]]

From these perceived shortcomings in vaccine development during public health emergencies arose the Coalition for Epidemic Preparedness Innovations (CEPI), a not-for-profit organization dedicated to timely vaccine development capabilities in anticipation of epidemics29,30. CEPI initially focused on diseases chosen from a list of WHO priority pathogens for EIDs—Middle East respiratory syndrome (MERS), Lassa fever, Nipah, Rift Valley fever (RVF) and chikungunya. The goal of CEPI was to advance candidate vaccines through phase 2 and to prepare stockpiles of vaccine against eventual use/testing under epidemic circumstances. CEPI had also prepared for ‘disease X’ by investing in innovative rapid response platforms that could move from sequence to clinical trials in weeks rather than months or years, such as mRNA and DNA technology, platforms that were useful when COVID-19 was declared a global health emergency in January 2020, and a pandemic in March 202031,32.

CEPI has been able to fund several vaccine development efforts, among them product development by Moderna, Inovio, Oxford–AstraZeneca and Novavax. Providing upfront funding helped these groups to advance vaccine candidates to clinical trials and develop scaled manufacturing processes in parallel, minimizing financial risk to vaccine developers. The launch of the larger US-funded Operation Warp Speed33 further provided companies with funding—reducing risks associated with rapid vaccine development and securing initial commitments in vaccine doses.

Vaccine platforms and vaccines for emerging infectious diseases

Vaccines are the cornerstone of the management of infectious disease outbreaks and are the surest means to defuse pandemic and epidemic risk. The faster a vaccine is deployed, the faster an outbreak can be controlled. As discussed in the previous section, the standard vaccine development cycle is not suited to the needs of explosive pandemics. New vaccine platform technologies however may shorten that cycle and make it possible for multiple vaccines to be more rapidly developed, tested and produced34. Table 2 provides examples of the most important technical vaccine platforms for vaccines developed or under development for emerging viral infectious diseases. Two COVID-19 vaccines were developed using mRNA technology (Pfizer–BioNTech35 and Moderna36), both showing safety and high efficacy, and now with US Food and Drug Administration (FDA) emergency use authorization (EUA)37,38 and European Medicines Agency (EMA) conditional marketing authorization39,40. While innovative and encouraging for other EIDs, it is too early to assert that mRNA vaccines represent a universal vaccine approach that could be broadly applied to other EIDs (such as bacterial or enteric pathogens). While COVID-19 mRNA vaccines are a useful proof of concept, gathering lessons from their large-scale deployment and effectiveness studies still requires more work and time.

[[Figure Omitted]]

While several DNA vaccines are licensed for veterinary applications, and DNA vaccines have shown safety and immunogenicity in human clinical trials, no DNA vaccine has reached licensure for use in humans41. Recombinant proteins vary greatly in design for the same pathogen (for example, subunit, virus-like particles) and are often formulated with adjuvants but have longer development times. Virus-like particle-based vaccines used for hepatitis B and human papillomavirus are safe, highly immunogenic, efficacious and easy to manufacture in large quantity. The technology is also easily transferable. Whole inactivated pathogens (for example, SARS-CoV-2, polio, cholera) or live attenuated vaccines (for example, SARS-CoV-2, polio, chikungunya) are unique to each pathogen. Depending on the pathogen, these vaccines also may require biosafety level 3 manufacturing (at least for COVID-19 and polio), which may limit the possibility of technology transfer for increasing the global manufacturing capacity.

Other vaccines are based on recombinant vector platforms, subdivided into nonreplicating vectors (for example, adenovirus 5 (Ad5), Ad26, chimpanzee adenovirus-derived ChAdOx, highly attenuated vectors like modified vaccinia Ankara (MVA)) and live attenuated vectors such as the measles-based vector or the vesicular stomatitis virus (VSV) vector. Either each vector is designed with specific inserts for the pathogen targeted, or the same vector can be designed with different inserts for the same disease. The development of the Merck Ebola vaccine is an example. ERVEBO is a live attenuated, recombinant VSV-based, chimeric-vector vaccine, where the VSV envelope G protein was deleted and replaced by the envelope glycoprotein of Zaire ebolavirus. ERVEBO is safe and highly efficacious, now approved by the US FDA and the EMA, and WHO prequalified, making VSV an attractive ‘platform’ for COVID-19 and perhaps for other EID vaccines26 although the −70 °C ultracold chain storage requirement still presents a challenge.

Other equally important considerations are speed of development, ease of manufacture and scale-up, ease of logistics (presentation, storage conditions and administration), technology transfer to other manufacturers to ensure worldwide supply, and cost of goods. Viral vectors such as Ad5, Ad26 and MVA have been used in HIV as well as in Ebola vaccines42. Finally, regulatory authorities do not approve platforms but vaccines. Each vaccine is different. However, with each use of a specific technology, regulatory agencies may, over time, become more comfortable with underlying technology and the overall safety and efficacy of the vaccine platform, allowing expedited review and approvals in the context of a pandemic43. With COVID-19, it meant that the regulatory authorities could permit expedited review of ‘platform’ technologies, such as RNA and DNA, that had been used (for other conditions) and had safety profiles in hundreds of people.

#### It’s a constant arms race.

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David M. Morens and Anthony S. Fauci, "Emerging Infectious Diseases: Threats to Human Health and Global Stability," PLoS Pathog 9(7): e1003467, 7-4-2013, <https://journals.plos.org/plospathogens/article?id=10.1371/journal.ppat.1003467>

Will We Ever Eliminate Emerging Infectious Diseases?

While it has become possible to eradicate certain infectious diseases (smallpox and the veterinary disease rinderpest), and to significantly control many others (dracunculiasis, measles, and polio, among others), it seems unlikely that we will eliminate most emerging infectious diseases in the foreseeable future. Pathogenic microorganisms can undergo rapid genetic changes, leading to new phenotypic properties that take advantage of changing host and environmental opportunities. Influenza viruses serve as a good example of emerging and reemerging infectious agents in their ability to rapidly evolve in response to changing host and environmental circumstances via multiple genetic mechanisms. New “founder” influenza viruses [21] appear periodically, cause a pandemic, raise widespread population immunity, and then, in response to human immune pressures, evolve and persist for decades using multiple genetic evolutionary mechanisms to sustain continual immune escape. The 1918 influenza pandemic virus is one example: over the past 95 years, its descendants have evolved continually by antigenic drift, intra-subtypic reassortment, and antigenic shift, the latter producing new pandemics in 1957 and 1968 [14]. Even the genetically complex 2009 pandemic H1N1 influenza virus is a descendant of the 1918 virus [14]. Such continuous genetic hyper-evolution forces us to develop new influenza vaccines containing new antigens on an annual basis.

In the meantime, new human diseases keep emerging. As noted, in late 2012 the novel MERS coronavirus emerged in Saudi Arabia [13], and in early 2013 a new H7N9 avian influenza virus became epizootic in Eastern China, causing 132 spillover infections of humans (as of June 7, 2013), with 28 percent case fatality [10], [22]. Its pandemic potential, if any, remains to be determined. Whether or not such outbreaks become more widespread, they nonetheless attract global attention and require significant international effort to monitor and contain. Microbial advantages can be met and overcome only by aggressive vigilance, ongoing dedicated research, and rapid development and deployment of such countermeasures as surveillance tools, diagnostics, drugs, and vaccines.

We appear to be entering a new era in which several important emerging, reemerging, and stable infectious diseases are becoming better controlled (e.g., hepatitis B, rabies, Haemophilus influenzae type B, and even to some extent HIV/AIDS). However, our success in stopping the many new emerging diseases that will inevitably appear is not assured. We have many tools in our armamentarium, including preparedness plans and stockpiles of drugs and vaccines. But each new disease brings unique challenges, forcing us to continually adapt to ever-shifting threats [1]–[10], [23]. The battle against emerging infectious diseases is a continual process; winning does not mean stamping out every last disease, but rather getting out ahead of the next one.

#### The tempo and threat level are rising faster than ever – pandemics outweigh climate change and nuclear war

Dhillon 17 – former senior govt advisor on pandemic control; MD, Instructor-Harvard Med School, Physician-Brigham and Women’s Hospital in Boston

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In 2003 a doctor with SARS unknowingly infected several guests while staying at a Hong Kong hotel, and overnight the virus reached across the globe. China is currently battling a bird flu that kills nearly half of the people infected. If Ebola, which transmits through fluids, were spread by air, or if Zika, which has reached over 50 countries, were as deadly as Ebola, we would be facing an unprecedented catastrophe. An uncontrolled outbreak or bioterror attack could result in a contagion that kills over 30 million people.

We fear it is only a matter of time before we face a deadlier and more contagious pathogen, yet the threat of a deadly pandemic remains dangerously overlooked. Pandemics now occur with greater frequency, due to factors such as climate change, urbanization, and international travel. Other factors, such as a weak World Health Organization and potentially massive cuts to funding for U.S. scientific research and foreign aid, including funding for the United Nations, stand to deepen our vulnerability. We also face the specter of novel and mutated pathogens that could spread and kill faster than diseases we have seen before. With the advent of genome-editing technologies, bioterrorists could artificially engineer new plagues, a threat that Ashton Carter, the former U.S. secretary of defense, thinks could rival nuclear weapons in deadliness.

The two of us have advised the president of Guinea on stopping Ebola. In addition, we have worked on ways to contain the spread of Zika and have informally advised U.S. and international organizations on the matter. Our experiences tell us that the world is unprepared for these threats.

We urgently need to change this trajectory. We can start by learning four lessons from the gaps exposed by the Ebola and Zika pandemics.

Faster Vaccine Development

The most effective way to stop pandemics is with vaccines. However, with Ebola there was no vaccine, and only now, years later, has one proven effective. This has been the case with Zika, too. Though there has been rapid progress in developing and getting a vaccine to market, it is not fast enough, and Zika has already spread worldwide.

Many other diseases do not have vaccines, and developing them takes too long when a pandemic is already under way. We need faster pipelines, such as the one that the Coalition for Epidemic Preparedness Innovations is trying to create, to preemptively develop vaccines for diseases predicted to cause outbreaks in the near future.

Point-of-Care Diagnostics

Even with such efforts, vaccines will not be ready for many diseases and would not even be an option for novel or artificially engineered pathogens. With no vaccine for Ebola, our next best strategy was to identify who was infected as quickly as possible and isolate them before they infected others. Because Ebola’s symptoms were identical to common illnesses like malaria, diagnosis required laboratory testing that could not be easily scaled. As a result, many patients were only tested after several days of being contagious and infecting others. Some were never tested at all, and about 40% of patients in Ebola treatment centers did not actually have Ebola.

Many dangerous pathogens similarly require laboratory testing that is difficult to scale. Florida, for example, has not been able to expand testing for Zika, so pregnant women wait weeks to know if their babies might be affected. What’s needed are point-of-care diagnostics that, like pregnancy tests, can be used by frontline responders or patients themselves to detect infection right away, where they live. These tests already exist for many diseases, and the technology behind them is well-established. However, the process for their validation is slow and messy. Point-of-care diagnostics for Ebola, for example, were available but never used because of such bottlenecks.

Greater Global Coordination

We need stronger global coordination. The responsibility for controlling pandemics is fragmented, spread across too many players with no unifying authority. In Guinea we forged a response out of an amalgam of over 30 organizations, each of which had its own priorities. In Ebola’s aftermath, there have been calls for a mechanism for responding to pandemics similar to the advance planning and training that NATO has in place for its numerous members to respond to military threats in a quick, coordinated fashion.

This is the right thinking, but we are far from seeing it happen. The errors that allowed Ebola to become a crisis replayed with Zika, and the WHO, which should anchor global action, continues to suffer from a lack of credibility.

Stronger Local Health Systems

International actors are essential but cannot parachute into countries and navigate local dynamics quickly enough to contain outbreaks. In Guinea it took months to establish the ground game needed to stop the pandemic, with Ebola continuing to spread in the meantime. We need to help developing countries establish health systems that can provide routine care and, when needed, coordinate with international responders to contain new outbreaks.

Local health systems could be established for about half of the $3.6 billion ultimately spent on creating an Ebola response from scratch. Access to routine care is also essential for knowing when an outbreak is taking root and establishing trust. For months, Ebola spread before anyone knew it was happening, and then lingered because communities who had never had basic health care doubted the intentions of foreigners flooding into their villages. The turning point in the pandemic came when they began to trust what they were hearing about Ebola and understood what they needed to do to halt its spread: identify those exposed and safely bury the dead.

With Ebola and Zika, we lacked these four things — vaccines, diagnostics, global coordination, and local health systems — which are still urgently needed. However, prevailing political headwinds in the United States, which has played a key role in combatting pandemics around the world, threaten to make things worse. The Trump administration is seeking drastic budget cuts in funding for foreign aid and scientific research. The U.S. State Department and U.S. Agency for International Development may lose over one-third of their budgets, including half of the funding the U.S. usually provides to the UN. The National Institutes of Health, which has been on the vanguard of vaccines and diagnostics research, may also face cuts. The Centers for Disease Control and Prevention, which has been at the forefront of responding to outbreaks, remains without a director, and, if the Affordable Care Act is repealed, would lose $891 million, 12% of its overall budget, provided to it for immunization programs, monitoring and responding to outbreaks, and other public health initiatives.

Investing in our ability to prevent and contain pandemics through revitalized national and international institutions should be our shared goal. However, if U.S. agencies become less able to respond to pandemics, leading institutions from other nations, such as Institut Pasteur and the National Institute of Health and Medical Research in France, the Wellcome Trust and London School of Hygiene and Tropical Medicine in the UK, and nongovernmental organizations (NGOs have done instrumental research and response work in previous pandemics), would need to step in to fill the void.

There is no border wall against disease. Pandemics are an existential threat on par with climate change and nuclear conflict. We are at a critical crossroads, where we must either take the steps needed to prepare for this threat or become even more vulnerable. It is only a matter of time before we are hit by a deadlier, more contagious pandemic. Will we be ready?

#### Independently – Antibiotic resistance will cause extinction – boosting the innovation pipeline is necessary

Talkington 20 – oversees teams of policy experts, scientists, and advocates for Pew’s work on public health issues, including the rise of antibiotic-resistant bacteria,

Kathy Talkington, "The U.S. Is Not Prepared to Combat 'Existential Threat' of Antibiotic-Resistant Superbugs," The Pew Charitable Trusts, 7-27-2020, <https://www.pewtrusts.org/en/research-and-analysis/articles/2020/07/27/the-us-is-not-prepared-to-combat-existential-threat-of-antibiotic-resistant-superbugs>

At the July launch of the AMR Action Fund, Admiral Brett P. Giroir, U.S. assistant secretary for health, said the following:

"Antimicrobial resistance, I do believe, is the existential threat of this century."

Giroir’s warning is dire—but it’s not new. For years, leading public health and national security experts around the world have sounded the alarm about the growing threat posed by antibiotic-resistant bacteria. Commissions led by world-renowned economists, declarations from the United Nations General Assembly, urgent threat reports from the Centers for Disease Control and Prevention, and more have all come to the same conclusion: Antimicrobial resistance is a known and certain danger—and the global level of preparedness does not match the magnitude of the threat.

In June, The Pew Charitable Trusts sent a letter to the leaders of the Senate Committee on Health, Education, Labor, and Pensions, providing recommendations for how the U.S. can better prepare for future pandemics. The letter highlighted the urgent need for government incentives to help fix the broken antibiotic market. Pew recently reiterated this call to action in partnership with the World Health Organization.

There is widespread and longstanding consensus that such incentives are needed to revitalize and sustain the woefully inadequate antibiotic pipeline. Without them, antibiotic developers will continue to go bankrupt, and innovation will continue to stagnate. Now is the time for action. Policymakers must ensure that the U.S. is not caught flat-footed when the inevitable superbug outbreak hits. Some threats we cannot begin to anticipate, but when it comes to antibiotic-resistant bacteria, there’s no excuse for being unprepared.

#### Only new bacteriophage breakthroughs at-scale will solve ABR

Principi et al. 19 – Nicola Principi, Professor Emeritus of Pediatrics, Università degli Studi di Milano, Milan, Italy, Ettore Silvestri and Susanna Esposito, Department of Surgical and Biomedical Sciences, Pediatric Clinic, Università degli Studi di Perugia, Perugia, Italy

Nicola Principi, Ettore Silvestri, and Susanna Esposito, "Advantages and Limitations of Bacteriophages for the Treatment of Bacterial Infections," Front. Pharmacol. 10:513, 5-8-2019, <https://www.frontiersin.org/articles/10.3389/fphar.2019.00513/full#h4>

Potential Advantage of Bacteriophage (BP) Use to Treat Bacterial Infections

Theoretically, there are no bacteria that cannot be lysed by at least one BP. In this regard, BPs are significantly more effective than antibiotics, as, although some antimicrobial drugs have a very large spectrum of activity, an antibiotic able to kill all the bacterial species does not exist. However, the most attractive characteristic of BPs is their specificity of action, i.e., their ability to kill only the pathogen that they can recognize.

They have a very narrow spectrum of activity, which avoids the most important problem strictly related to the antibiotic administration, i.e., the influence on the entire microbiome with elimination of potentially beneficial bacteria, the overgrowth of secondary pathogens and the emergence of resistant bacteria (Domingo-Calap and Delgado-Martínez, 2018). Use of BPs without modification of the microbiota has been reported by several studies in both animals and humans. In mice, oral administration of four T4-like BPs effective against diarrhea-associated E. coli did not lead to any collateral damage of non-pathogenic bacteria of the same species (Chibani-Chennoufi et al., 2004). In humans, data confirming the specificity of BP action were shown in the study conducted by Sarker et al. (2012). These authors administered for 2 days an oral cocktail of nine T4-like E. coli BPs to 15 healthy adults. After a wash-out of 5 days, even though the given BPs could be detected in the feces of almost all treated subjects, no modification of gut microbiota composition was evidenced.

In comparison to antibiotics, BPs are supposed to have several other advantages. It is thought that BPs are significantly safer and better tolerated, as they replicate only in the target bacterium but cannot infect mammalian cells. This conclusion seems supported by all the experiences gathered in the past in Eastern Europe and all the studies carried out more recently in experimental animals and humans, which have not reported significant adverse events following BP administration (Kakasis and Panitsa, 2018). Moreover, administration is easier, as BPs do not need repeated administrations shortly after one another over several days, as is commonly required for antibiotics because they can remain in the human body for relatively prolonged periods of time, i.e., up to several days (Bogovazova et al., 1991, 1992). In general, very few doses are needed because of the increase in BP concentration in the site of infection after the initial administration. Contrarily to antibiotics, their effect is limited to the site of infection that can be reached, even when bacteria are situated in a body organ or system in which antimicrobials can hardly penetrate. A lytic phage, EC200(PP), active against S242, a fatal neonatal meningitis E. coli strain, was evaluated in models of meningitis with 100% fatality. Though low titres of the BP were detected in the central nervous system, treatment 1 and 7 h post-infection rescued 100% of pups (Pouillot et al., 2012).

Using the new cost-effective, large-scale DNA sequencing and DNA synthesis technologies, BPs can be engineered to be able to overcome some limitations of antibiotic treatment. A good example of this is given by the evidence that BPs can disperse biofilm, a structure that makes infections difficult to eradicate with standard antibiotic therapy even if bacteria are sensitive to the administered drug. In an in vitro study, Lu and Collins engineered a BP affective against an E. coli producing biofilm to express a biofilm-degrading enzyme (Lu and Collins, 2007). A simultaneous attack to the bacterial cells and the biofilm matrix was possible. The results were very encouraging, as the engineered BP reduced bacterial biofilm cell count by approximately 99.9%. Moreover, BP genetic modifications can help to fight bacterial resistance to antibiotics. Edgar et al. (2012) introduced in lysogenic phages the genes rpsL and gyrA, which confer sensitivity in a dominant fashion to two antibiotics, streptomycin and nalidixic acid, respectively. They found that, after engineering, the minimal inhibitory concentrations of bacterial strains previously defined resistant to these drugs were significantly reduced to levels usually found in sensitive pathogens.

Finally, the use of BPs might be less expensive than that of antibiotics whose targets are multidrug-resistant pathogens. In a small group of patients suffering from methicillin-resistant Staphylococcus aureus infection, Miedzybrodzki et al. (2007) found that use of BPs significantly reduced healthcare costs.

#### Scenario B is Leadership – the U.S. remains ahead of China in biotech now, BUT declining innovation will change that

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Scott Moore, author of *Rethinking China’s Rise: How to Compete and Cooperate on the Environment, Technology, and Beyond*, In Biotech, the Industry of the Future, the U.S. Is Way Ahead of China, February 17, 2021, <https://www.lawfareblog.com/biotech-industry-future-us-way-ahead-china>

A continuing refrain from Washington in recent years has been that the United States is falling behind China in the development of critical emerging technologies. In some fields, this may be true. But not in biotechnology. To be sure, China’s biotech sector is growing at a torrid pace, and some of its firms are becoming leaders in certain areas, such as cancer treatment. Yet the U.S. retains a dominant position in research, development and commercialization, accounting for almost half of all biotech patents filed from 1999 to 2013. The triumph of its biotechnology industry during the coronavirus pandemic, producing two highly effective vaccines using an entirely new approach based on messenger RNA, and in record time, shows that the U.S.’s competitive edge in biotechnology remains largely intact. And that has important implications as Washington gears up for a sustained period of geopolitical competition with Beijing.

Biotech is such a critical area for technological competition between the U.S. and China because it is transforming fields from medicine to military power. The great advances of the 19th century, like chemical fertilizers, resulted from mastering chemistry. In the 20th century, mastery of physics led to nuclear energy—and, more ominously, nuclear weapons. In the 21st century, biology offers a similar mix of peril and promise. This was illustrated dramatically by the award of the 2020 Nobel Prize for the discovery of an enzyme system known as CRISPR-Cas9, which allows an organism’s genomes to be edited with high precision. It is a transformational breakthrough. But while CRISPR shows great promise in the development of new cures for long-untreatable diseases, it could also lead to a whole new generation of deadly bioweapons.

That’s a prospect that increasingly alarms U.S. intelligence officials. In 2016, then-Director of National Intelligence James Clapper warned Congress that “[r]esearch in genome editing conducted by countries with different regulatory or ethical standards than those of western countries probably increases the risk of the creation of potentially harmful biological agents or products.” Although Clapper didn’t name specific countries, it soon became clear that he was referring mainly to China. Four years later, his successor, John Ratcliffe, issued a far more pointed warning that “China has even conducted human testing on members of the People’s Liberation Army in hope of developing soldiers with biologically enhanced capabilities. There are no ethical boundaries to Beijing’s pursuit of power.” Such capabilities are almost certainly only speculative—but they underscore why biotech leadership is so important for national security as well as economic competitiveness.

Beijing has long envied the United States’s dominant position in biotechnology and spent heavily to overtake it. Biotech has been a priority sector for state investment since the 1980s, and by one estimate Beijing had poured some $100 billion into the sector by 2018. Nowhere did it lavish more attention or invest more of its propaganda power than in developing a coronavirus vaccine. State media have spent months crowing that “China is working around the clock for breakthroughs in COVID-19 vaccines.” Yet despite this push, China’s vaccine program quickly took on a Potemkin air. In February 2020, barely two months after the onset of the pandemic and after a supposedly crash vaccine effort, a military doctor stood in front of a Chinese flag to receive what was billed as an experimental vaccine dose but was widely suspected to be a staged photo op. Now, having spent months talking up its two primary vaccine candidates to developing countries like Brazil and Indonesia, both of which have entered into purchase agreements with Chinese biotech firms, Chinese officials face severe mistrust among their nation’s overseas partners.

For China’s leaders, the disappointing returns on their big bet on biotechnology look likely to cause them more headaches at home as well as abroad—there are already signs that affluent Chinese place more trust in foreign-developed coronavirus vaccines than the homegrown ones produced at such great expense. For U.S. officials, though, China’s relative underperformance in vaccine development presents an opportunity to reassert the United States’s leadership in biotechnology and public health and bolster the nation’s depleted soft power in the process. The Biden administration has already signaled it will reengage in multilateral bodies such as the World Health Organization.

Yet the U.S. shouldn’t stop there. Washington should begin thinking now about how to emulate the success of the President’s Emergency Plan for AIDS Relief (PEPFAR)—which, though imperfect, is widely regarded as one of the most successful single public health interventions in history—to address growing disparities in access to coronavirus vaccines between countries. At the moment, vaccine supplies are controlled largely by rich countries, creating the risk of moral and public health failure if the gap persists. While COVID-19, the respiratory disease caused by the novel coronavirus, differs in many respects from AIDS, PEPFAR combined research, prevention, and access to therapeutics. Developing a comparable institutional structure to close the coronavirus vaccine access gap is the right thing to do—but it would also go a long way to restoring America’s battered global reputation.

At the same time, the United States can’t afford to rest on its laurels in biotechnology, or any other field. Aside from China, other nations like Singapore and Israel have also invested heavily to develop their biotechnology sectors, with Israel in particular giving rise to a thriving biotech industry. U.S. public investment in basic scientific research and development has meanwhile been on the decline for decades, and there are worrying signs that America’s once world-beating innovation ecosystem is less productive, and less entrepreneurial, than it once was. Despite strengths in translational research, moreover, the frontiers of biology increasingly sit at the intersection with other disciplines like computer science, meaning that funding agencies, universities and other organizations need to break down disciplinary silos. Boosting support for biotechnology research, while reforming how that money is used, will go a long way toward shoring up the United States’s leading position in the global biotech sector.

The U.S. biotechnology sector also faces other threats, not least growing espionage and intellectual property theft by foreign actors, especially those linked to China. Several high-profile cases brought by the U.S. Department of Justice’s China Initiative have involved biotechnology researchers, and American biotech firms have been top targets for cyber theft and intrusion. Sustained outreach to researchers and research institutions is critical to preventing such theft. But efforts to clamp down on the threats posed by espionage and intellectual property theft can easily go too far and must preserve the researcher mobility and data-sharing that is essential to doing cutting-edge science.

Beyond its shores, the United States should work with its partners and allies to enhance export controls on dual-use biotechnology—used for both peaceful and military gain—especially DNA templates. Many forms of genetic material and synthetic biology products are already subject to U.S. export controls, but gaps remain, and screening for genetic sequence orders relies primarily on voluntary regulation by biotech firms. Better coordinating export controls among major economies and U.S. allies can dramatically reduce the risk of sophisticated bioweapons development in the decades to come.

When it comes to biotechnology, the industry of the future, the U.S. remains well ahead of its rivals, including China. That’s something Americans can, and should, take pride in. But the U.S. must make proactive investments and undertake significant reforms now to ensure that things stay that way.

#### Biotech lead will be the key determinant

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Rob Carlson, also managing director at Bioeconomy Capital, an early-stage venture capital firm; and Chad Sbragia, also former director of the China Research Group for the U.S. Marine Corps and now a research staff member at the Institute for Defense Analyses; and Kate Sixt, also assistant director of the Strategy, Forces and Resources Division at the Institute for Defense Analyses, where she leads the Chemical, Biological, Radiological, and Nuclear Analysis group; BEYOND BIOLOGICAL DEFENSE: MAINTAINING THE U.S. BIOTECHNOLOGY ADVANTAGE, 14 September 2021, https://warontherocks.com/2021/09/beyond-biological-defense-maintaining-the-u-s-biotechnology-advantage/

From 2007 to 2008, tainted supplies of Chinese-manufactured heparin, a common blood thinner, led to 81 deaths across the United States. This should have been a wake-up call to the Department of Defense. Over the last two decades, biotechnology has become a key component of American supply chains, perhaps accounting for 20 percent of the chemicals the U.S. military uses. Those supply chains now span the globe and contain a significant amount of material produced in China. Remarkably, the full extent of the military’s dependence on Chinese biotechnology is unknown because the U.S. government is not assessing it. These dependencies extend beyond pharmaceuticals to fundamentals such as solvents and polymers. Just try and paint an aircraft without xylenes. If you’ve never thought about how difficult it would be, well that’s exactly the problem.

The Department of Defense has historically viewed biotechnology narrowly in relation to military medicine and biodefense. As a result, the vital role of biotechnology in military readiness and national security remains poorly understood. Biowarfare and bioterrorism are real risks, but approaching the nation’s biotechnology security needs only in these terms will leave the country ever more vulnerable.

China, by contrast, has been integrating biotechnology into its strategic development and elevating biotechnology to a key component of national security. China’s military-civil fusion development strategy makes biotechnology a core priority for the People’s Liberation Army. This strategy has one goal: to bring together China’s civilian and military industrial bases in order to better project power. To that end, China has cornered supply chains in multiple sectors, including pharmaceuticals ingredients and other important chemicals.

Stephanie Rogers, the Defense Department’s acting principal director for biotechnology, recently declared that “the nation that leads the world in biotechnology will accrue enduring economic, societal, and defense gains.” Unfortunately, this awareness has yet to be reflected in government policy. Biotechnology security is national security — for the United States and for China. The Department of Defense should recognize biotechnology’s role as a foundational technology and make biotechnology development and supply chain security a priority.

Maintaining America’s Biotechnology Advantage

Biotechnology in the United States is a significant contributor to the economy. By one estimate, in 2017, U.S. biotechnology revenues exceeded $400 billion, or 2 percent of gross domestic product, substantially surpassing better-measured sectors such as mining. Bioeconomy revenues have grown at an average rate of 10 percent annually for two decades. Notably, U.S. biotechnology revenues alone were approximately equal to worldwide semiconductor revenues for 2017. Biotechnology now supplies critical medicines, and, as more than 90 percent of the corn and soy grown in the United States is genetically modified, biotechnology feeds the armed forces. Industrial biotechnology is responsible for upward of 20 percent of chemicals produced in the United States, suggesting a similar proportion of chemicals used in the military are also biologically derived. And these impressive figures may still be significant underestimates: Using a different methodology, the U.S. National Academy of Sciences recently concluded that the biotechnology industry contributes 5 to 7 percent of U.S. gross domestic product. Biotechnology, therefore, may already constitute an even larger share of the military supply chain.

As biotechnology continues to mature, its contribution to physical and economic security will become even more significant. Tools are now being deployed that enable the engineering and biomanufacturing of materials that will eventually not only displace petrochemicals but also surpass them in production scale and performance. Over the next ten to twenty years, biological production could soon supply up to 60 percent of physical inputs across the global economy, and biotechnology could have a “direct economic impact of up to $4 trillion a year.”

While the United States is arguably still leading in biotechnology, it risks losing this lead to China. In China, biotechnology is a national development and a security matter. China’s Innovation Driven Development Strategy emphasizes biotechnology’s essential role in the country’s economic development, while the Military-Civil Fusion Development Strategy seeks to ensure that biotechnology research is also oriented toward the country’s military and broader security goals. Chinese biotechnology revenues are reported to be of a similar size to those in the United States, although they are subject to even lesser clarity in reporting.

While China continues its licit and illicit acquisition efforts targeting the U.S. biotechnology sector, it is also shifting its attention to domestic innovation. In time, this will provide the People’s Liberation Army with new capabilities and increase both America’s and the Pentagon’s reliance on Chinese biotechnology products.

Recommendations As early as 1958, the Department of Commerce was tracking the economic contribution of semiconductors, even though they made up less than 0.1 percent of the gross domestic product. Yet, today, the U.S. government has made no equivalent effort to track the much more significant role of biotechnology. This illiteracy is a national security issue. American and Chinese bioeconomies are in competition, and Beijing asserts that it is investing with the intent to take, and to then maintain, the lead. To sustain America’s advantage, the U.S. Department of Defense should better understand its reliance on biotechnology and increase investment in it accordingly. The Pentagon’s recent investment in the BioIndustrial Manufacturing and Design Ecosystem is a notable step in the right direction. However, the seven-year budget for this project is approximately the cost of a single F-35A. For an investment that could impact the entire defense supply chain, this is inadequate. We recommend the following plan of action for the Department of Defense to take its place alongside the Departments of Commerce and State in the broader interagency effort to secure America’s biotechnology advantage. First, in close coordination with the Department of Commerce, the Department of Defense should make a systematic effort to better understand the role of biotechnology in the economy, supply chains, and manufacturing. This, in turn, should inform additional oversight and regulatory controls. The responsibility to understand, prepare for, and respond to biotechnology threats is balkanized, spread across at least nine departments and agencies. Vulnerabilities in the bioeconomy will affect the Department of Defense in terms of readiness, soldier health, and the ability to fulfill missions. Addressing those vulnerabilities begins with a sustained, comprehensive effort to understand the role of biotechnology in industry today, as well as how that industry contributes to defense supply chains, and how military acquisition policy shapes biotechnology. To that end, the Pentagon should work with the Department of Commerce to create domestic reporting codes for biotechnology revenues and employment for the quarterly and annual economic census, and further incorporate those codes into the North American Industrial Classification System. Institutionalizing the gathering of these data is the first step toward sustainable policymaking and rational spending. The Department of Commerce should then consider adding import/export controls on biotechnology, while avoiding overly broad restrictions that suffocate innovation. Protecting foundational technologies using the Foreign Investment Risk Review Modernization Act and Export Control Reform Act will be critical for securing biotechnology. However, biotechnology competition is not exclusive to commercial activities. The Pentagon should assess critical vulnerabilities and dependencies to assist the other agencies in bringing China’s foreign biotechnology access in line with standards in other major markets. The Department of Defense has been asked to document and secure supply chains critical to defense applications and to the overall U.S. economy. This should also apply to biotechnology. Current Pentagon efforts to expand domestic biological manufacturing capabilities are an important start, but a broader effort is needed. An empowered deputy national security adviser could help oversee the relationship between the Pentagon and the National Economic Council to promote and secure the military’s broader technology needs. Second, the Department of Defense should better study the accomplishments and intent of China, especially the Chinese military, in developing biotechnology as a strategic technology. Once the Department of Defense better understands critical U.S. biotechnology dependencies on China, it can begin the work of reducing them. This requires an interagency examination to identify cross-cutting resources, develop mitigation strategies, formulate best practices to bolster innovation, and expand outreach to allies and partners to reduce systemic gaps China could exploit. Partnership with industry and allies will allow the U.S. government to understand and counter Beijing’s efforts to distort commercial activity in its favor. To this end, the Department of Defense should mirror the National Security Council’s effort by creating an emerging technology portfolio within Office of the Under Secretary of Defense-Policy. While other technology offices in the Department of Defense are internally focused, an entity in this office that concentrates externally on foundational technology competition is required. Such an office may be able to address uncertainties in assessments of Chinese biotechnology revenues and capabilities. Finally, in coordination with the Department of State, the Department of Defense should identify opportunities for dialogue with the People’s Liberation Army about biotechnology-related security issues. It is time to include biotechnology in the dialogue mechanisms that compose bilateral U.S. defense relations with the People’s Liberation Army. This dialogue should prioritize the ethics of biotechnology in the context of future conflicts, the escalatory risks this technology creates, and the possibility of cooperation where the interests of the two nations intersect. Both sides should work toward a common understanding related to ethics, policies, and standards when operationalizing biotechnology. This will help avoid miscalculation and promote strategic stability. Unlike the U.S. government, Chinese leadership has a carefully considered position on the importance of biosafety and “biological problems” in national security. While these problems are understood to encompass traditional weapons concerns, they also extend to the health of the entire natural world in the context of ever-expanding applications of biotechnology. This position might provide an opportunity for constructive engagement at a time when tensions are rising. Conclusion The Pentagon needs to expand its approach to biotechnology beyond biodefense. If China maintains biological warfare aspirations, by all means address those. But defense planners should also address China’s broader approach to biotechnology and its integrated approach to civil-military fusion.

Securing biotechnology secures the nation. Maintaining the U.S. lead in biotechnology is critical to the nation’s economic and military resilience in war, peace, and the gray zone short of conflict. This requires better biotechnology collaboration — within the U.S. government, with allies and partners, and even, where possible, with competitors.

#### Retrenchment causes extinction

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Mira Rapp-Hooper, Stephen A. Schwarzman Fellow at the Council on Foreign Relations, 2020, Saving America’s Alliances: The United States Still Needs the System That Put It on Top, Foreign Affairs

The stakes of failing to reform the alliance system could scarcely be higher. If Washington does not act, it will miss the opportunity to protect its dearest interests on relatively favorable terms, before China’s growing power and Russia’s revanchism undermine the system’s proven guarantees. The reform agenda recommended here is vast, but it is far less burdensome than a U.S. foreign policy that cannot rely on allies. The United States can no more go it alone now than it could in the immediate postwar years. Whether the United States has alliances or not, American security and prosperity will still require an open and independent Asia and Europe. Even if Washington pulled back from both theaters, the United States would still face cyberattacks, financial and infrastructural disruptions, and assaults on its democratic institutions. And by retrenching, Washington would lose whatever readiness for conflict it currently has. If the country later joined a war abroad, it would have to do so only after significant time delays and without the allied cooperation that might have allowed it to prevail. Put simply, the United States might fall into a conflict that it could have instead deterred—one now waged with hypersonic speed and destruction.

#### Strong commercial innovation will be the key

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THE SINO-AMERICAN RACE FOR TECHNOLOGY LEADERSHIP, 2021, <https://warontherocks.com/2021/04/the-sino-american-race-for-technology-leadership/>

Setting the right foundation is crucial. Sound analytical judgments about China’s policies, plans, and prospects, along with a new framework for the relationship, are the starting point. Neither wholesale confrontation nor wholesale engagement are adequate to address U.S. concerns, but the relationship should be stable for this approach to have any chance of success. The view that economic competitiveness, innovation, and democratic norms are core components of national security should drive the development of a comprehensive strategy into which discrete policies of pressure, negotiation, multilateralism, high-level dialogue, and domestic measures fit. Industry should work closely with the government to ensure this perspective underpins U.S. policy, and the government should recognize that industry is central to the United States winning the technology race and therefore should get a vote on how to run it.

Out-competing and out-innovating China requires that America remain the world’s most attractive innovation hub, enticing the best talent, drawing in the most venture capital, and generating the largest revenues to support U.S. leadership of technology’s newest frontiers. It means continuing to “move fast and break things.” The ethos that made America a technology superpower can keep it so. It also means injecting some strategic realism into U.S. policy. As former Secretary of Defense William Cohen put it, China’s actions have caused the United States to say, “we can’t do business the way we’ve been doing business,” but, “we still have to do business.”

#### And, that will hinge on whether big pharma anticipates predictable and large net-revenues from pursuing innovative products

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James C. Robinson, the Leonard D. Schaeffer Professor, whose research and teaching focus on biotechnology and the healthcare delivery sectors, Competing With, And Learning From, China In The Global Pharmaceutical Innovation Race, 15 November 2021, https://www.healthaffairs.org/do/10.1377/forefront.20211110.463732/full/

The scale-up of pharmaceutical innovations generated by US biotechnology startups currently depends on product licensing by large pharmaceutical corporations. It works best for drugs eligible for the generous regulatory, tax, and subsidy provisions of the Orphan Drug Act of 1983, proving again the importance of public investment in ensuring commercial viability. Approximately half of the new drugs launched on the US market now are for orphan conditions. The ability of government to pick winners has been evident during the COVID-19 pandemic, as Operation Warp Speed financed vaccine product development, expansion of manufacturing capacity, and product distribution at a scale and speed exceeding the capacity of private investors. President Biden has proposed the creation of an Advanced Research Projects Agency for Health (ARPA-H) to fund cross-sectoral, high-risk research and R&D using the model of the Defense Advanced Research Projects Agency, the technology promoter responsible for the most fundamental innovations in defense in the past three decades, with $6.5 billion in dedicated funding. Yet, these proposals face adverse political headwinds.

For its part, the Chinese government provides direct subsidies for the scale-up of domestic firms that show the potential to become global leaders. Public funds account for 25 percent of total industry investment, and state development banks supplement these grants with low interest loans. Tax credits for business investment in applied product R&D, an effective policy instrument originally developed in the US, now are several times more generous in China.

Pricing And Product Demand

Innovation requires large-scale and predictable revenues to reward successful product launch. US pharmaceutical firms traditionally have enjoyed prices and revenues far in excess to those available in other nations. Congressional Democrats and the Biden administration have put forth proposals that would moderate drug prices, in turn, necessitating the expansion of other mechanisms for rewarding innovation. Some support would derive from initiatives to expand insurance coverage. High patent-protected drug prices would generate few revenues if manufacturers were to depend on patients for payment, as distinct from health insurers. Here again, the government already plays the decisive role. More than a third of the US population is covered by tax-financed public health insurance, and half has its private insurance subsidized through tax exclusions and premium subsidies. The Biden administration is committed to filling the remaining gaps in insurance coverage, which would support innovation by reducing the need for manufacturers to supply free drugs to the uninsured and finance copayment support programs for the underinsured. But further insurance expansion faces fierce opposition.

China favors domestic over foreign products in the design of its national drug formulary, with the intention of enabling its champions to achieve the economies of scale necessary to compete in global markets. For example, Chinese pharmaceutical firms have invested heavily in PD-1 oncology monoclonal antibodies. In 2020, the national formulary accepted four domestic PD-1 products and delisted foreign products in the therapeutic class. Access to the national formulary requires price discounts averaging 50 percent in the first year and further discounts in subsequent years. The low prices paid for foreign drugs in the domestic Chinese market will be accompanied by high prices charged for Chinese products launched in the US market. China interprets direct subsidies for product commercialization as an alternative to high prices as a reward for innovation, with the obvious advantage that governmental grants and loans are available only to Chinese firms. In contrast, the profits earned in the US market also accrue to foreign firms, which repatriate them to further develop their domestic innovation ecosystems.

China As Challenge And Opportunity

The challenge from China impacts each of the four pillars of pharmaceutical innovation, including the foundation in university research, the startup ecosystem, the scale-up of startups into global champions, and the assurance of predictable market demand. Unlike the imperative for rapid development of COVID-19 vaccines, the challenge from China cannot be dismissed as a once-in-a-century event. It is not going away.

Although the rise of China threatens the US life sciences industry, it also may indirectly support it. Fear of and competition with China may enable the US to overcome political gridlock and refurbish its science, revive its industry, and restore its erstwhile prominence.

### 1AC – Solvency

Contention 3 is solvency.

#### Pharma companies pay each other not to challenge weak patents, preventing drug competition. Antitrust law forbids some direct payments, but current standards create a perverse incentive to obfuscate deals

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

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

Our empirical results highlight the fact that pay-for-delay is a far more costly problem than previously recognized. The Supreme Court opened the door to deal with these settlements in Actavis, but in applying the decision, lower courts, competition agencies, and relevant parties have struggled with each of the three aspects of the phrase: “pay,” “for,” and “delay.” Despite the opinion’s expectation that lower courts would be able to provide structure to the rule of reason in a pay-for-delay inquiry, 125 that structure has not materialized in a meaningful manner. The problem arises in part from the nature of the rule of reason inquiry and in part from the forms of deals that have emerged. Although it is possible that the Justices never intended to allow pay-for-delay cases to move forward, the tone of the opinion belies such a cynical interpretation.

A. What Constitutes “Pay”

One might imagine that the notion of “pay” would be simple. Nevertheless, some courts have struggled with the question of what might constitute an exchange of value and whether the notion of payment can extend beyond cash. Beyond the notion of what types of value might be included in the notion of pay, the way in which the inquiry unfolds has created obstacles for parties and competition authorities to actually measure value in a way that would be satisfactory under a rule of reason analysis.

In particular, some parties have asserted that cash is king. From this perspective, the only exchange of value that might matter would be dollars changing hands. In the immediate wake of Actavis, some courts initially failed to recognize non-cash forms of compensation—such as no-authorized-generic clauses—as unexplained payments from brands to generics.126 Although higher courts eventually rectified decisions in Lamictal and Loestrin, for example, expanding the Actavis precedent to include methods of payments other than cash,127 damage was done. Effectively permitting certain forms of pay-for-delay—even temporarily—serves to incentivize similarly designed anticompetitive deals, at great cost to patients and society. 128 Protracted court battles also present a significant drain on regulatory bandwidth, particularly when every instance of anticompetitive conduct must be demonstrated to the courts.

In the sophisticated world of modern commerce, however, there are many ways to provide value beyond simply handing over bags stuffed with bills. For example, one of the most valuable assets for an entering generic is the 180-day period in which the first filing generic can enter the market free of competition from other generics. Generic companies may earn a substantial portion of their profit during this period of time.129 Brand-name companies, however, found a way to make that period of time into an asset that can substitute for a cash payment.

[FN]

126 See, e.g., In re Loestrin 24 Fe Antitrust Litig., 45 F. Supp. 3d 180 (D.R.I. 2014), vacated and remanded, 814 F.3d 538 (1st Cir. 2016); In re Lamictal Direct Purchaser Antitrust Litig., 18 F. Supp. 3d 560 (D.N.J. 2014), vacated and remanded sub nom. King Drug Co. of Florence v. Smithkline Beecham Corp., 791 F.3d 388 (3d Cir. 2015). The payment in the settlement litigated in Actavis was a cash transfer from the brand to the generic; subsequent pay-for-delay settlements have featured payment forms that are less easily enumerated, such as no-authorized generic agreements. In this case, the brand company—in lieu of a cash payment—agrees to not launch an authorized generic during the first-filing generic company’s 180-day exclusivity period, thereby boosting the generic company’s revenues.

128 Evidence since Actavis suggests that pharmaceutical companies hew closely to guidelines implied by court decisions. According to the FTC 2017 report, only 3 of 20 agreements with explicit compensation exceeded the $7M allowed by Actavis for litigation fees; moreover, following a spate of court cases finding that a no-AG promise amounted to anticompetitive payment, 2017 saw no settlement agreements that included a no-AG clause. See Betsy Lordan, FTC Staf Issues FY 2017 Report on Branded Drug Firms' Patent Settlements with Generic Competitors, FTC (Dec. 3, 2020), https://www.ftc.gov/news-events/press-releases/2020/12/ftc-staff-issues-fy-2017-report-branded-drug-firms-patent

[End FN]

The scheme springs from the fact that although a generic must obtain FDA approval to enter the market, the brand-name company already has such an approval in its pocket. Thus, the brand-name company may market its own generic version of a drug—called an authorized generic or a branded generic—without the need for a lengthy approval process.130 Although the Hatch-Waxman system does not explicitly provide for authorized generics in its legislation, court rulings have affirmed that nothing prevents the innovator company from marketing an authorized generic version of their branded drug.131

The launch of an authorized generic has significant consequences for a first-filing generic. According to the FTC, competing with an authorized generic can cost a generic first-filer up to 45% of its revenue during the exclusivity period.132 The ability to remove that threat becomes an asset that the brand-name company can hand to the generic, in exchange for an agreement to stay off the market. A brand-name company can promise not to introduce an authorized generic, particularly during the valuable 180-day period. The deal is a little like old movies portraying protectionist rackets, in which the neighborhood shakedown artist says, “Nice front window you have there. Be a real shame if it got smashed in.” Here, a brand-name company can say the equivalent of, “Nice 180-day exclusivity period. Be a real shame if you lost half of it. Tell you what, just stay off the market for a while, and it is all yours.”

As courts and competition authorities have become suspicious of these “no-authorized-generic” agreements, companies have developed ever-more-complex variations on the theme. Rather than explicitly promise to not compete by producing an authorized generic, a brand-name company can promise not to license any third parties to make authorized generics, while reserving the right to make an authorized generic itself. If the brand manufacturer has a limited track record of launching authorized generics, this agreement can have the same effect as the no-authorized generic clause.133 In yet another variation, the brand and generic can enter into an agreement in which the generic is obligated to pay a royalty amount, but that royalty will decline if the brand-name company launches a competing authorized generic.134

In other complicated variants, brand-name companies may give the generic who agrees to stay off the market a license to make an authorized generic version of their brand drug, with the generic paying a royalty to the brand.135 Particularly if the royalty payment that the generic must pay is less than the market value of the benefit, that excess value may be camouflaging a “reverse” flow of payments in exchange for the generic’s agreement to stay off the market.136

Courts and competition authorities now generally recognize that no-authorized-generic agreements can constitute a form of payment for the purposes of pay-for-delay, although it took some time to reach that point.137 Nevertheless, the law has not fully absorbed the anticompetitive potential of the complex variations. These convoluted variants are difficult to tease out, let alone establish sufficient proof through the rule of reason standards, making obfuscation a successful strategy. For example, the most-recent FTC reports showed 226 agreements between brand and generic companies that year, 138 a significant increase from the 170 settlements just two years prior.

139 Ninety percent of those agreements included a transfer of patent rights that were not at issue in the lawsuit. Many of these could easily constitute a transfer of value.140 Challenging even a simple no-authorized-generic agreement is no easy task. For example, although the judicial definition of payment now includes “no-authorized-generic” agreements,141 private plaintiffs or the government bears the burden of evaluating and presenting the terms of a no-authorized-generic agreement in terms of cash value.142 The requirement follows the logic that in order to demonstrate the unreasonably large nature of a payment, as the Actavis decision specified, plaintiffs generally are required to translate that agreement into a specific, quantifiable value to the court’s satisfaction. Thus, a plaintiff who wishes to challenge even a simple no-authorized-generic agreement as anticompetitive must be prepared to engage in an expensive and lengthy court battle, with no consistent approach to valuation.143 Consider the Effexor case.

The district court in Effexor rejected the plaintiffs’ valuation of a no-authorized-generic agreement, which was based on an estimation of what an authorized generic cost the generic manufacturer of a different drug with nearly identical sales.144 Plaintiffs were able to obtain a reversal on appeal,145 but obtaining the appellate decision, however, took three years beyond the time that had already passed for the trial court ruling. The more a deal reaches behind the back and around the ears, the harder it is tease out the value transfer and pin down a specific dollar equivalent.

[FN 141]

141 See, e.g., United Food & Com. Workers Loc. 1776 & Participating Emps. Health & Welfare Fund v. Teikoku Pharma USA, Inc., 74 F. Supp. 3d 1052, 1070 (N.D. Cal. 2014) (“I agree with the bulk of the recent decisions holding that courts need not restrict the definition of “payments” under Actavis to cash. See, e.g., In re Nexium (Esomeprazole) Antitrust Litig., 968 F.Supp.2d 367, 382 (D.Mass.2013) (rejecting a motion to dismiss because a no-authorized-generic term could be a payment for the delay because a broader definition of payment “serves the purpose of aligning the law with modern-day realities.”)”); see also Time Ins. Co. v. Astrazeneca AB, 52 F. Supp. 3d 705, 710 (E.D. Pa. 2014) (“reverse payments deemed anti-competitive pursuant to Actavis may take forms other than cash payments” when considering a no-authorized-generic agreement); King Drug, 791 F.3d at 403 (“We do not believe Actavis 's holding can be limited to reverse payments of cash. For the following reasons, we think that a no-AG agreement, when it represents an unexplained large transfer of value from the patent holder to the alleged infringer, may be subject to antitrust scrutiny under the rule of reason.”).

142 See Feldman & Misra, Fatal Attraction, supra note 8, at 259-260 (explaining how the often-onerous burden of proving anticompetitive harm under rule of reason rests on the plaintiffs); see also Feldman, Defensive Leveraging, supra note 51 (describing the difficulty of successfully pleading a rule of reason case).

[End FN]

The 2003 Medicare Modernization Act requires generic-brand agreements to be submitted to the FTC for review, 146 and the reports the FTC publishes from these insights can point other investigators to possible anticompetitive conduct.147 However, the FTC is limited in its resources to investigate individual cases; reports are frequently beset by publishing delays, offer only annualized statistics, and may fail to adequately appreciate the nuanced, rapidly evolving techniques used by drug companies.148

For example, in December 2020 the FTC finally released its annual report covering the year 2017. The report lists as examples of “possible compensation” arrangements including: declining royalty structures,149 AG licensing to subsequent filers, and agreements to not license AGs to third parties.150 The FTC declines to assess the anticompetitive quality of these arrangements as “beyond the scope of this report.”151 The report also finds zero cases of the no-authorized-generic agreements so prevalent a decade earlier. 152

It would be naïve, however, to assume that the end of simple no-authorized-generic clauses marks the end of authorized generics in pay-for-delay. Rather, anecdotal evidence suggests that the character of brand-generic patent settlements is simply changing in response to the spate of court rulings finding that no-authorized-generic clauses constitute payment under Actavis. 153

B. What Constitutes “For”

Similar to the notion of what constitutes “pay,” courts and agencies have struggled over whether a transfer of value in an agreement constitutes a payment for staying off the market or simply a payment for legitimate value provided by the generic.

Side deals come in many shapes and sizes including: 1) arrangements to promote other drugs in the firms’ portfolios; 154 2) licensing deals that allow the brand or generic to manufacture the other party’s drug;155 3) agreements authorizing the generic to manufacture and/or sell a brand’s “authorized generic” without filing for generic approval; 4) research and development collaboration on future projects; and 5) deals to supply the brand company with raw materials for manufacturing.156 Such side deals are rarely found outside the settlement context. According to one prominent academic in the field, “many—such as an arrangement by which a brand relies on a generic for its marketing expertise—belie common sense.”157

The valuation of agreements featuring noncash provisions is further complicated by the fact that the details of these settlements are kept secret.158 This shroud of secrecy makes it difficult to identify and quantify the value of noncash settlements. Even if the presence of side deals is suspected, plaintiffs will rarely, if ever, have access to the terms of those agreements. Several district courts have already dismissed pay-for-delay litigation for failing to plausibly allege a large and unjustified payment.159 For example, the district court in Actos dismissed the indirect purchasers’ claims that Takeda engaged in anticompetitive conduct by entering into settlement agreements with generic manufacturers.160 While the court shared the majority view that Actavis was not limited to settlements dealing with pure cash, it also held that to find an unlawful reverse payment involving non-cash settlement terms, the court “must be able to estimate the value of the term, at least to the extent of determining whether it is “large” and “unjustified.””161 Because the plaintiffs could not explain the basis for their assertions nor offer any method of calculating the value of the licensing side deal, there was no factual basis for the court to reasonably estimate the value of the settlement terms and evaluate the settlements’ alleged anticompetitive effect.

The legality of settlements featuring side deals continues to be challenged. While the majority view is that side deals are not immune to antitrust scrutiny, plaintiffs still bear the burden of pleading information sufficient to estimate the value of these agreements. To describe the task of determining whether these terms are “large” and “unjustified” as difficult is an understatement.

It is interesting to note that although the FTC’s reports on pay-for-delay settlements for fiscal years 2015162 and 2016163 reported no side deals, the most recent report for fiscal year 2017 listed three settlements with side deals.164 These side deals included an agreement in which the brand manufacturer assigned the generic manufacturer five patents unrelated to the litigated product at no cost, another in which the generic sold intellectual property related to the litigated product to the brand manufacturer, and a third in which the brand manufacturer acquired the generic manufacturer's potentially competing 505(b)(2) product that was the subject of the patent litigation.165 These indicators suggest there is reason for concern that side deals can be used to hide payments for delay and that courts and agencies would be unable to ferret out any anticompetitive conduct.

C. What Constitutes “Delay”

Creating a full sweep, courts have also struggled with the question of what constitutes delay. The uncertainty centers on whether an agreement in which the generic enters before the patents expire should be considered delay. Supporters of pay-for-delay settlements routinely argue that such settlements can be procompetitive because they facilitate early entry of a generic before a branded drug’s patents have expired.166

In such instances, consumers would benefit from lower prices sooner than if the Paragraph IV challenge had never taken place. In Actavis, the Supreme Court recognized this procompetitive potential, commenting that early entry settlements, or settlements permitting the patent challenger to enter the market before the patent expires, could “bring about competition . . . to the consumer’s benefit.”167

That argument, however, assumes the patent is valid and infringed.168 Various studies suggest that assumption is unwarranted. For example, a 2002 Federal Trade Commission report found that considering all the patent infringement cases between generic and brand manufacturers between 1992 and 2000, generic applicants prevailed in a staggering 73 percent of cases.169 Similarly, an academic analysis of Federal Circuit decisions between 2002 and 2004 in which the court made a final ruling on the merits of a pharmaceutical patent claim found that generic challengers had a 70 percent success rate.170

In a more recent analysis, a study of patent lawsuits filed in a federal district court between 2008 and 2009 found that accused infringers won 74 percent of the definitive merits rulings while patentees won only 26 percent of the time.171

In fact, the FDA has gone so far as to provide a registry of disputed patent information in order to address inaccurate or extraneous patent listings on new drugs.172 As the author has previously written, “one can never assume that just because a company holds a patent that the patent is either valid or validly applied to the drug at issue.”173

A patent that is invalid or not infringed would have no power to stop entry. Thus, if the generic had pursued the litigation to conclusion, the result could easily have moved the patent barrier out of the way, allowing the generic to enter right away. As a result, it would be nonsensical to say that there is no delay if the parties agreed to stay out of the market until the expiration date of a noninfringed patent. Nevertheless, some courts have failed to contemplate that possibility in analyzing agreements.

Consider In re Humira. 174 Plaintiffs alleged that AbbVie’s settlement agreements with biosimilar manufacturers, in which the biologic company granted licenses for biosimilars to market the Humira biosimilar in Europe in 2018 while delaying entry into the U.S. market until 2023, constituted an unlawful pay-for-delay scheme.175

In dismissing the lawsuit, the district court found that the settlements were permissible because they allowed AbbVie’s rivals to enter the U.S. market before the patents on Humira (the latest of which expires in 2039) expired.176 The court failed to recognize, however, that the settlements eliminated the possibility that the biosimilars might have entered the U.S. market earlier than the stipulated date if they had pursued the litigation to conclusion and prevailed. As with many cases, the patents might not have been valid or validly applied.

#### So-called “pay for delay” deals in the biologics context specifically do not yet fall within the legal scope of antitrust

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January 12, 2018, “BIOLOGICS: THE NEW ANTITRUST FRONTIER,” https://www.illinoislawreview.org/wp-content/uploads/2018/01/Carrier.pdf

In determining the appropriate antitrust analysis of settlements, an initial question centers on the application of FTC v. Actavis. We believe that, in a broad holding of general applicability, Actavis confirmed antitrust law’s vital role in evaluating the legality of settlements involving payment and delayed entry. The Court relied on an array of previous cases to confirm that its precedents “make clearthat patent-related settlements can sometimes violate the antitrust laws.”

To be sure, the Court was not offering an antitrust assessment of biologic settlements. Nor could it have given that no court—even now, several years later—has considered settlements under the BPCIA. But we believe the settingof complex pharmaceutical regulation under the BPCIA easily offers sufficient similarities to the Hatch-Waxman Act to allow application of Actavis’s broad principles. In addition, payment to avoid the risk of biosimilar competition presents the same concerns highlighted in Actavis.

The linchpin in the antitrust analysis of settlements is whether a generic is excluded from the market based on a patent or payment. Exclusion based on a patent generally does not present antitrust concern because it is commonly understood that patent-term split agreements, by which brands and generics divide the remaining patent term by selecting a time for generic entry, do not violate the antitrust laws. The reason is that the parties’ compromise on the entry date reflects the odds of success in patent litigation. The greater the likelihood the patent is valid and infringed, the later in the period generic entry would be expected. The lower the likelihood, the earlier entry would be expected. A brand, however, is likely to gain additional exclusivity not explained by a patent by supplementing the parties’ entry-date agreement with a payment to the generic.

The same distinction between patent and payment should apply in the setting of biologics. The biologic manufacturer is entitled to rely on its patent to exclude a generic. But it should not be able to pay a biosimilar to gain additional delay. In determining whether there is payment, the court should consider, as one of us has explained before, whether the biologic manufacturer conveys “a type of consideration not available as a direct consequence of winning the lawsuit.” If the biosimilar manufacturer is able to obtain such consideration, “its exclusion from the market cannot be traced to the strength of the [biologic] patent.” In such a case, “the [biologic maker] is providing compensation beyond what even a valid and infringed patent would justify.”224 And, presenting antitrust concern, the biosimilar delays entering the market because of this payment.

One example of a form of payment that could arise in this setting involves a biosimilar’s access to a biologic’s distribution or reimbursement networks. In contrast to distribution through wholesalers and specialty distributors (each of which obtains a portion of revenues, reducing a biosimilar’s profitability), biologics could offer access to a “manufacturer direct” channel which, in selling directly to purchasers (e.g., specialty pharmacies and large hospitals), removes the “middleman.” Setting up an efficient supply chain is difficult and expensive, and not all biologics will be able to implement such a scheme. As a result, if a biologic has already set up direct distribution, one form of payment to a biosimilar could be access to, and integration into, the valuable network, which it would not be able to obtain through patent litigation.

Another type of payment could involve Group Purchasing Organizations (“GPOs”) or Pharmacy Benefit Managers (“PBMs”). GPOs are collections of providers that pool resources to maximize economies of scale in drug purchasing and sometimes function as distributors, gaining control over products offered to downstream purchasers.228 PBMs also manage prescription drug pro

[FOOTNOTES BEGIN]

221. HERBERT HOVENKAMP, MARK D. JANIS, MARK A. LEMLEY, CHRISTOPHER R. LESLIE, & MICHAEL A. CARRIER, IP AND ANTITRUST: AN ANALYSIS OF ANTITRUST PRINCIPLES APPLIED TO INTELLECTUAL PROPERTY LAW § 16.01[f] (3d ed. 2016). 222. Carrier, Payment After Actavis, supra note 219, at 9. 223. Id. 224. Id. 225. Id. 226. NIAZI, supra note 21, at 354–56; see also Jack McCain, Connecting Patients with Specialty Products, BIOTECHNOLOGY HEALTHCARE, Summer 2012, at 8, https://www.ncbi.nlm.nih.gov/pmc/articles/ PMC3411231/. 227. NIAZI, supra note 21, at 354–56. 228. Id. at 352, 353.

[FOOTNOTES END]

grams for downstream buyers and, in some cases, after negotiating rebates with manufacturers, limit the drugs sold under their plans. This latter role ensures that they “are very important” to a biosimilar manufacturer in controlling access to a biosimilar product.

We envision a scenario by which a settlement could include payment in the form of a biologic bringing a biosimilar under its umbrella, granting access to certain GPO and PBM agreements to which it would otherwise not have access.

Where there is payment, the court should consider its size. The Actavis Court compared the payment’s size to litigation costs. It stated that payments that “amount to no more than a rough approximation of the litigation expenses saved through the settlement” could be justified. Litigation costs in the biologics setting will generally be higher than in the small-molecule setting. In contrast to litigation in the Hatch-Waxman setting, with a generic in the initial stage only needing to review the Orange Book, law firms must conduct substantial pre-application investigations to identify patents that could be raised in the patent dance.

Finally, where there is at-risk entry, a settlement could include a “payment” from the biologic to the biosimilar, but that payment could constitute a legitimate forgiveness of damages. This presents a nuanced case that could be explained by the results of patent litigation. In other words, if the biologic wins, it is entitled to recover damages from the biosimilar. But if the biosimilar wins, it will not be required to pay anything. As a result, a biologic firm’s partial waiver of damages that the biosimilar could have owed falls within the range of what the latter could have obtained through successful litigation. In short, just like it has done in the Hatch-Waxman setting, the distinction between patent and payment can provide an appropriate framework for the antitrust analysis of settlements between biologics and biosimilars.

#### The United States federal government should increase prohibitions on reverse settlements of biologics.

#### The plan solves – first, it establishes a rebuttable presumption of illegality for pay-for-delay deals. That incentivizes transparency instead of obfuscation

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

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

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

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

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

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

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

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

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

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

#### Second – settlements that either delay entry or are based on weak patents would be found anticompetitive. That effectively calibrates the patent system

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We propose several substantive changes to the antitrust approach to pay-for-delay settlements.

First, the key criterion in determining an unlawful agreement should be the existence of a restriction on generic entry—not the size or presence of a value transfer—considered in light of the strength of the category of patent in question. Arguably, the legitimacy of a pay-for-delay settlement is predicated on the strength of the underlying patent; in other words, pay-for-delay is only a problem insofar as the patent to which the deal relates is invalid or aimed at the wrong product, since the generic could enter the market immediately upon that determination. Much is at stake in these deals; several years of lost patent protection could translate into several billions of dollars of lost savings for the brand company. 57 Pay-for-delay agreements tend to settle litigation over a “secondary patent,” which is a patent on some feature of a drug other than the active pharmaceutical ingredient, such as a production process, a method of treatment, a salt or crystalline form, a new delivery mechanism, a new formulation, or even an ancillary aspect of a drug, such as the pill’s coating.58 Evidence shows that secondary patents form part of a deliberate strategy to prolong a drug’s effective period of patent protection.59 Though few patent cases reach a final decision on validity,60 secondary drug patents are frequently found invalid when challenged.61 Thus, secondary patents may over-reward a pharmaceutical drug’s actual innovative contribution with unwarranted extensions of effective patent protection, and both the brand and generic companies may have a good sense of the likelihood that a disputed secondary patent will survive a court challenge. For this reason, the category of the patent in question in a pay-for-delay agreement is highly germane to a meaningful examination of the potential illegality of the deal.

Next, the United States should move closer to a presumptive standard in evaluating pay-for-delay settlements in order to achieve more efficient and effective antitrust enforcement. The pay-for-delay bills introduced in Congress will help achieve that goal, as would adopting a standard similar to that of the European Union that places emphasis on an agreement’s aim to restrict competition rather than downstream effects on the marketplace.62 Although intent can be difficult to establish under U.S. law—particularly if plaintiffs must find smoking-gun evidence of subjective intent—those difficulties can be overcome by designing standards that use objective criteria as a means of inferring a company’s likely intent. The category of patent and the failure to sue on the core chemical or biological patent could be part of those objective criteria. The reluctance to call pay-for-delay presumptively illegal in the United States reflects a desire to preserve the freedom to settle and to avoid clogging the courts with costly and protracted patent litigation. However, the current approach to pay-for-delay favors industry over patients, and unless the approach is changed, drug prices will remain supra-competitive for periods longer than the HatchWaxman regulatory regime intended. In addition, deterring the litigation in the first place would reduce the burden on the courts, as well as the burden on society.

Finally, regulatory disincentives may be a more effective deterrent of payfor-delay deals than monetary penalties. For example, the FTC and FDA could jointly prohibit a generic company that is found to have participated in pay-fordelay from eligibility for the 180-day exclusivity period for any Abbreviated New Drug Application (ANDA) that it files in the ensuing five years. Without exclusive marketing rights as the first generic to file an ANDA, the generic company stands to lose the bulk of its profits on any generic drug launched in that five-year period. By enticing generic companies with profitable settlements, brand companies have co-opted the paragraph IV challenge, initially intended to enable generic companies to challenge weak or invalid patents.63 As a penalty for participation in pay-for-delay deals, the generic company could be prohibited from filing a paragraph IV certification on any ANDA for a certain number of years, effectively making the company ineligible for the 180-day exclusivity period and shutting them out of pay-for-delay settlements—at least those arising from patent litigation. Regulatory disincentives can counterbalance the “carrots” in the Hatch-Waxman Act, thereby rewarding innovation and hastening competition when the time is ripe.

CONCLUSION

Settlement agreements to end patent disputes are common and not in and of themselves indicative or suggestive of antitrust infringement. Often, settlements are a favored alternative to continuing costly litigation. However, pay-for-delay settlements come at a steep cost to patients by delaying the entry of less expensive generic alternatives to brand drugs. The ability to wield competition laws effectively against these settlements is of major importance to regulators, policymakers, and patients. Shifting the focus of antitrust scrutiny to restrictions on generic entry vis-à-vis the strength of the category of underlying patent, and creating disincentives for generic companies to acquiesce to pay-for-delay deals, will help grease the wheels of the Hatch-Waxman Act and accelerate the path to affordable drug prices for U.S. patients.

#### Third – the plan is a tailored remedy. Zero risk of doctrinal spillover

Hemphill 6 – Associate Professor of Law, Columbia

C. Scott Hemphill, JD & MA in Econ-Stanford, MSc in Econ-LSE, AB-Harvard, Paying For Delay: Pharmaceutical Patent Settlement As a Regulatory Design Problem, 81 N.Y.U. L. Rev. 1553 (Nov. 2006), <https://www.nyulawreview.org/wp-content/uploads/2018/08/NYULawReview-81-5-Hemphill.pdf>

The particular shape of congressional intervention in the balance between innovation and access, together with important industry-specific features of the pay-for-delay problem in pharmaceuticals, serve to undercut the Patent Act-based case for an exception to the ordinary operation of antitrust law. The argument applies in different ways to the innovator-focused and infringer-focused arguments for an exception.

With respect to innovators, the practice in question is a poor fit with Patent Act policy, because permitting pay-for-delay settlements is a highly innovation-inefficient means of increasing the incentive to innovate. To see this, consider as a benchmark a competitive practice that had the effect of increasing the length of the patent term at no incremental expense to the patentee. Arranging a longer term might be expected to increase producer profits and consumer allocative losses in equal measure (assuming, among other things, that the pro ducer faces the same demand curve in each period). If the social bene efits of innovation increase proportionately with profits, then the ratio between innovation and deadweight loss is unchanged with respect to term length.

If instead, as is frequently presumed, additional profits have a declining impact upon the social benefits of incremental innovation, then a longer term entails a lower ratio-that is, less innovation "bang" for the additional deadweight loss "buck." Such a practice is difficult to justify by reference to Patent Act policy, for the reason introduced in Part III.A. Congress's selection of a particular patent term length implements a choice about the balance between innova tion and acceptable deadweight loss. If Congress had chosen a longer term, it would have implemented a more innovation-protective policy with respect to patentees; but Congress did not do that. A "reason able effectuation" of the Patent Act's innovation protectiveness does not require permitting a practice that is less innovation-efficient than, but otherwise identical to, a major innovation-protective term of the Patent Act. Therefore, to the extent that a privately-arranged term lengthening is less innovation-efficient than the current period of exclusivity, it cannot be insulated from antitrust attack by reference to the policies of the Patent Act.217

Pay-for-delay settlements resemble an increase in effective term length, but in an important respect they are even less innovation-effi cient. In exchange for receiving a reprieve from competition, the pat entee must make a sizable payment. This payment reduces its profits and hence the incremental innovation incentive gained by arranging for the extension. 218 This deficit in innovation efficiency makes the agreements more difficult to justify as a reasonable effectuation of the Patent Act. In short, the Patent Act's general policy of innovation protectiveness has, at best, a weak claim to insulating pay-for-delay settlements from antitrust attack.

Moving from the general case of patents to the specific case of pharmaceuticals further weakens the argument for insulation. As already noted, antitrust is *in pari materia* not only with patent law, but with industry-specific regulation as well. Compared to the Patent Act, the Hatch-Waxman Act provides within its domain a more specific and hence more relevant account of the congressionally implemented balance between innovation and competition.

The balance set by the Hatch-Waxman Act is a deliberate effort to promote consumer access through litigated challenges. For most drugs, the Hatch-Waxman Act is less innovation-protective than the Patent Act; as noted previously, the tax on blockbusters is a conces sion to consumer access at the expense of innovation. For a few drugs, it is actually more innovation-protective, thanks to the innovation sub sidy provided by the industry-specific delays. In either case, the ordi nary operation of the Act sets a particular balance between innovation and competition. The balance set for a particular drug is disrupted by a settlement favoring somewhat more innovation at the further expense of consumer access.

The disruption to the congressional balance caused by settlement, moreover, is difficult to understand in a way consistent with the Hatch-Waxman scheme. With the Patent Act, a general norm in favor of innovation might at least be relied upon; by contrast, the Hatch Waxman Act provides a calibrated outcome for different types of drugs. The Patent Act is silent about the role of litigation and the extent to which litigation can be avoided in the interest of preserving profits. In the Hatch-Waxman Act, by contrast, the promotion and delay of litigation are central preoccupations of the regulatory regime. An open-ended permission for innovators to set innovation policy by self-help is less plausible, as Congress has taken explicit steps to fill those gaps. Since litigation is the instrument by which the regulatory arrangement accomplishes its ends, it is difficult to argue that an end run on the instrument is consistent with the scheme. And given that the regime explicitly provides for innovation protection in certain cases-an effective lengthening of the patent term for certain drugs, but a limited one-it is implausible to attribute to that regime a toler ance for an additional, highly innovation-inefficient means to accrue additional profits.

The infringer's argument against antitrust liability is also weaker in the pharmaceutical context, compared to the general case. First, the generic firm lacks an innovator's interest. The generic firms simply make use of the Hatch-Waxman scheme to offer a bio equivalent drug. Even if a Patent Act policy favoring innovation helps some infringers, it cannot be thought to apply here.

Limiting the generic firm's ability to extract a benefit from unpromising litigation has some effect on an infringer's incentives, though not on its innovation incentives. To be clear, a limitation on settlement does not force the generic firm to see the litigation to com pletion-it can simply walk away from the suit.219 But a limitation on consumer-disregarding settlements does lower the value of the generic firm's abandonment option,220 an option that matters most when a party develops new information about its prospects during the course of litigation. The difference in reward implies that some marginal challenges will not be brought. There is little reason, however, to think that preserving the full value of this option is necessary to effec tuate a Hatch-Waxman Act policy of promoting challenges, not least because the incentive to challenge is already so large.

Second, and again unlike many infringers outside the pharmaceu tical context, the generic firm has deliberately stepped, not stumbled, into the infringement controversy. It does not move in uncertain ter rain filled with hidden patent dangers; the patents protecting pharma ceutical innovations are open and notorious, compiled in an FDA publication, Approved Drug Products with Therapeutic Equivalence, commonly known as the "Orange Book. ' '221 The generic firm volun teers for and seeks out the challenge by filing the Paragraph IV certifi cation, which invites a lawsuit by the innovator.222 Here, and unusually, Congress has recruited and offered to compensate generic firms to bring patent challenges. Far from being unwilling private attorneys general, generic firms have been deputized, in effect, to act on the public's behalf. The explicit use of litigation to achieve the balance undercuts the preference for settlement sometimes discerned in ordinary patent policy.

In summary, the analysis in this Part reinforces the conclusion from Part II that pay-for-delay settlements are properly accorded a presumption of illegality as unreasonable restraints of trade. It also undermines, in a domain-specific way, the patent policy arguments sometimes thought to justify a patent-based exception to antitrust as a general matter. Finally, the analysis offers industry-specific support for the proposition that pharmaceutical consumers do indeed have an entitlement to the average level of competition implied by litigation, a proposition more difficult to sustain as a general matter.

CONCLUSION

Examining pay-for-delay settlements from the perspective of regulatory design yields two main results. First, the industry-specific bounty renders feasible an allocatively harmful settlement in a surprisingly wide array of circumstances. Because only the first-filing generic firm has potential access to the exclusivity period, an innovator has an especially strong incentive to pay to neutralize that source of potential competition. Because a guaranteed bounty is a valuable source of compensation to a first-filing generic firm, settlements that divide the remaining patent term confer a noncash payment for delay. Allowing an innovator to make multimillion dollar payments up to the amount of saved litigation expense exacerbates the allocative harm.

Second, the Hatch-Waxman Act produces a specific pattern of encouragement to and limitations upon innovative activity. That industry-specific pattern, rather than the arguably innovation-protecttive policy of the Patent Act, provides the basis for an *in pari materia* analysis with antitrust law. The Hatch-Waxman Act's calibration between innovation and competition is disrupted if firms are free to engage in self-help. The resulting disruption is difficult to square with the policies that animate the Hatch-Waxman Act, particularly in light of the inefficiency of pay-for-delay settlements as a means to provide additional reward to innovators.

Beyond the analysis of pay-for-delay settlements and other competitive practices in the pharmaceutical industry, a careful engagement with regulatory facts and economic theory within a specific industry is a promising method of antitrust analysis. The approach advanced here requires a close look at the economic effects of the regulation and the legislative instrument by which it achieves those effects. The project entails two distinct though related inquiries: an inquiry into industry economics, including the technology of innovation and the dynamics of competition, and an inquiry into the effects of industry-specific regulation.

Such an economically aware and institutionally informed examination is particularly important in industries that are in a process of deregulation. Such industries are an area of renewed interest in antitrust, as exemplified by their inclusion in the work of the commission recently set up by Congress to consider alterations to existing antitrust aw. 223 Deregulation enlarges the domain of antitrust, as Herbert Hovenkamp has noted;224 it does so in part by altering the contours of liability. In some industries, the process of deregulation has occurred in an incomplete fashion, and partial deregulation may give rise to heightened antitrust concern.

Under partial deregulation, the regulatory regime manages the balance between innovation and competition by decentralized mechanisms, rather than by the central command of price regulation. Under full regulation, there may be little role for antitrust, given its redundancy upon a regulator actively managing the antitrust function. Under partial deregulation, however, redundancy is less likely. The use of a decentralized mechanism by Congress risks nullification by unilateral or concerted action by self-interested firms, with allocatively harmful effects. Where the mechanism is not well preserved by the industry-specific regulatory agency, there may be a heightened role for antitrust intervention.

One virtue of an industry-focused approach is the presence of built-in limiting principles. An antitrust decisionmaker can resolve one set of cases without having to reconsider an entire category of conduct. For example, a court can resolve pay-for-delay settlements in the pharmaceutical industry-a set of cases of great theoretical significance and practical importance-without reconsidering the relationship of antitrust and patent generally. Another consequence, of course, is that we therefore lack an answer to broader questions—here, whether consumer-disregarding settlements of patent litigation in other industries are actionable as antitrust violations. But in an area of legal and economic inquiry so complex, and in which we lack even basic information about the facts on the ground in other industries, including the prevalence and structure of such settlements, this limitation is a virtue rather than a vice.

### \*\*\*Extra

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#### Maintaining an edge in synth bio is key to effective biodefense and the US setting global rules of the road for CRISPR

Gronvall 15

Gigi Kwik Gronvall, PhD, Associate Professor of Environmental Health and Engineering-Johns Hopkins Bloomberg School of Public Health, Senior Scholar-Johns Hopkins Center for Health Security, and Senior Associate-UPMC Center for Health Security, US Competitiveness in Synthetic Biology, Health Security 13(6): 378–389, 2015, doi: 10.1089/hs.2015.0046

If the United States were to lose its competitive edge in synthetic biology and related technologies, there would be serious consequences for national security. Some negative effects would be strictly economic, resulting in a declining environment for businesses and workers to be productive in synthetic biology–related industries in the long term.20 This is important for national security because, as described in the US National Security Strategy (2015), “In addition to being a key measure of power and influence in its own right, [a strong economy] underwrites our military strength and diplomatic influence. A strong economy, combined with a prominent US presence in the global financial system, creates opportunities to advance our security.”21 Current forecasting would suggest that a loss of economic opportunities in synthetic biology could be immense: Fidelity Investments describes synthetic biology as “the defining technology of next century” for global investments.22 In 2012, the World Economic Forum ranked synthetic biology as the second key technology for the 21st century, after informatics.23 According to BCC research, a market analysis company, the synthetic biology market reached nearly $2.1 billion in 2012 and $2.7 billion in 2013. They expect the market to grow to $11.8 billion in 2018 with a compound annual growth rate of 34.4% over a 5-year period from 2013 to 2018.24

Losing competitiveness in synthetic biology could also limit specific security applications on the horizon that are essential for national defense. These include the development of medical countermeasures for responding to biological, chemical, or radiological weapons threats and new approaches to diagnostics. A US Department of Defense (DoD) report described how synthetic biology could bring major advances to the development of high-performance sensors, sensors for unusual signatures, clandestine sensing, and high-performance materials for national defense; these applications would not likely be available to DoD based on private sector funding alone.25 Synthetic biology may also offer the possibility for distributed manufacturing so that critical supply chains are less vulnerable to disruptions.

These next several years will likely be formative in setting the “rules of the road” for emerging synthetic biology research. Yet, the United States may be disadvantaged and limited in its ability to actively participate in fundamental conversations about the governance of synthetic biology if US experts are not technological leaders in synthetic biology, as the shaping of synthetic biology governance will be dominated by the nations and their experts who are at the leading edge of technology development. This is because formal regulations or standards usually lag well behind the development of new technologies. For a new technical area, regulations are often preceded by the development of standard practices in a field, as well as cultural expectations and safety measures. These expectations and agreements build on previous sets of regulations but take new technical possibilities and dangers into account. The rules are often created by those who are most intimately familiar with the technologies—often, the scientists who are performing the work at the leading edge of development.

In the biological sciences, the most well-known example of scientists calling attention to nascent dangers in their field and setting the standards for scientific practice occurred when the field of recombinant DNA biology was new. In a letter published in Science in 1974, leading scientists and Nobel laureates recommended that certain types of recombinant DNA experiments—those with toxins, oncogenic viruses, and antibiotic resistance—should be off limits until their safety could be evaluated and assessed in a conference held a year later.26 That conference, held at Asilomar, California, in February 1975 and attended by scientists, government officials, and members of the press, led to a lifting of the moratorium in 1976, as well as the creation of a new regulatory system for recombinant DNA work funded by the US government.26 Efforts of the scientists to self-govern may well have forestalled restrictive national legislation.27 Asilomar now symbolizes scientists' attention to the public's concerns, as well as the scientific community's capacity to self-govern.

A more recent example of self-governance can be found in a synthetic biology application: commercial DNA synthesis. Companies that sell DNA synthesis products now screen their orders to determine whether a customer is ordering genetic material for dangerous pathogens and to block orders if the customer is not authorized. This screening system was developed in large part through self-governance of the commercial suppliers and interested scientists, with funding from the Alfred P. Sloan Foundation, and was eventually put into formal guidance from the US Department of Health and Human Services in 2010.11,28

In the synthetic biology field, there are other applications at the leading edge of development that will require governance measures to be safely and ethically applied, and some scientists have already stepped in to propose self-governance measures to deal with them. One example is the development of gene drives, which are systems that can spread a particular gene throughout a population with non-Mendelian inheritance—that is, much faster than would occur naturally.29 These have become much easier to construct using a new gene-editing technique—clustered regularly interspaced short palindromic repeats (CRISPR/Cas9 or Cpf1)—which allows sections of DNA to be searched for and replaced in a matter roughly analogous to editing a document in Word. Some scientists have proposed using gene drives to change the DNA of mosquitoes to make them resistant to malaria. Such a project could decrease the prevalence of malaria, which currently kills more than 600,000 people—mostly children—per year. Yet, this technology could be misapplied or result in a consequential accident should the genes spread to other species or cause other unintended effects. Those scientists who have been leading the development of gene drive and gene editing technologies have also taken the lead in thinking about the safety consequences, and they have been developing a series of commonly agreed upon safeguards for laboratory research into gene drives, such as using a combination of multiple stringent confinement strategies, as any single confinement strategy could fail.29 Scientists have also put forward ideas for how to safely use them outside of the laboratory.30

Another contentious application of synthetic biology that will require careful planning and safety standards is human germline editing, wherein modifications to sperm or egg DNA would not be applied to just one person, but to all their progeny. A group of interested and involved scientists met in Napa, California, to consider the ethical and safety ramifications of this work; the meeting was convened by Jennifer Doudna, one of the molecular biologists credited with developing the CRISPR/Cas9 tool. The meeting was intended to discuss the “scientific, medical, legal, and ethical implications of these new prospects for genome biology,” and they identified steps so that this technology could be performed “safely and ethically.”31(p36) In their consensus paper, published in Science, they recommend that the practice of germ-line editing be strongly discouraged for now, that forums be held in which this application can be discussed more broadly, and that foundational research that does not cross the line into embryo modification be encouraged.31 The National Academies of Science also launched an initiative to recommend guidelines for the new genetic technology, to explore the scientific, ethical, and policy issues associated with human gene-editing research.32

Determining what the “red line” is for allowable, critical, or ethical applications of synthetic biology, as well as how much safety data are required before pressing ahead, will always be a challenging exercise, and not all scientists, experts, and observers will agree. Tension over what is acceptable to pursue has already come up for germline editing, after a Chinese research group reported that they used CRISPR techniques to modify human embryos.33 (And there are at least 4 additional research groups in China known to be pursuing gene editing in human embryos.34) While the standards or expectations set by the scientific community will be impossible to enforce in an international context, the scientific community does set boundaries; those who flout those standards have to justify their actions in the international practice of science, and those boundaries and expectations are set by the leaders in the field. In the case of germline editing, the Chinese research was rejected by top-tier scientific journals Nature and Science, in part because of ethical objections.35

Self-governance of science has its critics, who are justifiably skeptical that scientists can be trusted to govern their own research fairly and who question the effectiveness of this approach in an international context, as the embryo editing example illustrates. However, self-governance is not the sole mechanism of governance in this area, as many foundational aspects of biotechnology and laboratory practice are already tightly regulated, and also because in forming new rules there is often a complex interplay among scientists, journalists, and policymakers to bring about new guidelines. In the case of DNA synthesis guidance, while there was substantial work done by scientists and interested parties to prevent misuse of DNA synthesis and promote screening, the issue became more salient, requiring immediate action, after a journalist ordered a small segment of DNA that encoded the smallpox virus.36 Still, feasible alternatives to self-governance are limited when technologies are still in the early stages of development, particularly when the applications are of broad interest, generating funding from private companies and multiple national governments, when the work is pursued in many places internationally, and when the technologies have great potential for tangible benefits to health and medicine. In addition, the amount of technical knowledge required for understanding the implications of new research and what can be done to ameliorate negative consequences makes it challenging even for scientists in distinct disciplines to evaluate research outside their expertise, because understanding the technical details inherent in the technology are critical both for identifying problems as well as proposing solutions.

There are additional applications of synthetic biology that have already generated conversations about governance within the scientific community—such as rescuing a species on the path to extinction; or even using synthetic biology for “de-extinction,” to bring back a species that was lost because of human hunting or negligence; or brewing opiates by fermentation in a process not unlike brewing beer.37-39 These applications have already sparked scientific involvement in discussions of what is technically possible and what rules should be developed. In 5 to 10 years, the list of applications that will require expert opinion and involvement to set expectations, standards of practice, and self-governance may well be very different, just as consequential, and require technical experts to take the lead in setting norms and safety standards. If US scientists, policymakers, and institutions would like to have some say in what is decided, they will need to be at the forefront of those technologies.

#### Only optimizing on biodefense solves inevitable, short-term extinction

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MIT Technology Review, Emerging technology: Genetic Engineering Holds the Power to Save Humanity or Kill It, 19 September 2017, <https://www.technologyreview.com/s/608903/genetic-engineering-holds-the-power-to-save-humanity-or-kill-it/>

How likely is it that humanity will destroy itself? Various scientists have studied this probability, and the basic calculation is straightforward. The key parameters are the number of people capable of destroying the planet and the likelihood that they will do so. This likelihood has been hard to measure, since it depends on the psychological stability of the commanders in charge—how likely are they to trigger a nightmare scenario? The number of these individuals has been much easier to gauge. Throughout the second half of the 20th century and the early 21st century, this number has been the American and Soviet/Russian leaders in charge of massive nuclear arsenals. The projected lifetime of a civilization (LD50) depends inversely on the number of people, or entities, capable of destroying it (E) and the probability per year that one of them will (P). So perhaps as few as two people have truly civilization-destroying power. That may not be entirely reassuring, given the nature of those individuals, but it is a bed of roses compared to the future, says John Sotos, who is affiliated with the Joint Forces Headquarters of the California National Guard. Sotos says the calculus of civilization-ending technologies is about to change dramatically, and the consequences for humanity are devastating. Back in the 20th century, people all over the world became aware of an existential threat to civilization. Indeed, this possibility became an important part of the political strategies of the world’s two superpowers, the U.S. and the Soviet Union. The threat came from the technologies behind nuclear weapons, and the nightmare scenario was called mutually assured destruction. This involved both sides letting loose their nuclear arsenals in an attempt to destroy the other. The outcome of this process was intended to be so disastrous that neither side could benefit from triggering it and would therefore never start such a war. Whether by luck or judgment, this strategy has worked—so far. But the U.S. and Russia maintain their planet-destroying capabilities, and the threat of all-out nuclear war still hangs over the planet. A similar threat comes from climate change. And again the power to control or unleash it rests with the relatively small number of individuals who run the world’s major economies. Again, an important unknown is how likely they are to rein in the destructive power of greenhouse gas emissions. But the world looks to be moving toward a planet-saving strategy, although the efficacy of this approach is unknown. Now a new technology is posing a global threat. This is the ability to engineer organisms that can kill large numbers of people—perhaps almost everyone—in a global pandemic. Until recently, the development of bioweapons has required the kind of large-scale investment that only nation states can bring to bear. That has allowed this work to be carefully monitored on an international scale. Consequently, the use of bioweapons has been largely controlled by international agreement. But the ability to engineer lethal organisms is spreading. That’s because the same technology that allows researchers to design viruses and vaccines for specific genetic targets also allows them to design organisms that can spread and kill. Sotos points to the Cancer Moonshot project, which aims to accelerate the use of immunotherapies to treat cancer. The goal is to test this technology on 20,000 cancer patients in various trials by 2020. As a result, large numbers of individuals in hospitals and research facilities all over the world will have access to a technology that has a frightening dark side. To get a sense of the numbers of people involved. Sotos has searched the PubMed database of scientific papers for authors who have worked on “genetic techniques.” This search produced over 1.5 million unique names, of which 180,000 have authored more than five papers. If only a fraction of these have, or will soon have, the capability to engineer organisms that could end civilization, that represents a very significant increase in the threat level. Given this number, how likely are they to release a civilization-ending biotechnology? Sotos thinks of it as the likelihood per year that a person with this destructive technology will use it. There is no way of knowing what this probability is for humanity, so Sotos simply puts a few probabilities into his model to see how this influences the likely lifetime of our civilization. The results are sobering. If there is a one in 100 chance that somebody with the technology will release it, and there are a few hundred individuals like this, then our civilization is doomed on a timescale of 100 years or so. If there are 100,000 individuals with this technology, then the probability of them releasing it needs to be less than one in 109 for our civilization to last 1,000 years. But people are not all equally likely to behave in this way. A frightening scenario is the case of a person for whom the probability of releasing this technology is certain when they get hold of it. If people like this exist, the end of civilization is a certainty. Of course, Sotos’s model has some shortcomings. For example, it does not account for defensive strategies, such as the development of a treatment or cure. Humanity’s ability to detect and respond to global pandemics is in its infancy and certainly well behind our ability to create and release pandemics. Nevertheless, the chances of creating a timely treatment for billions of people seems remote. Another thought-provoking point is the nature of future advances in personalized medicine. “An especially concerning scenario arises if, someday, hospitals employ people who routinely write patient-specific molecular-genetic programs and package them into replicating viruses that are therapeutically administered to patients, especially cancer patients,” says Sotos. This technology allows these same people to create and release pandemics. And if this kind of health care spreads around the world, the number of people who have access to it will explode. “If the world attained the European Union’s per capita hospital density, this could mean 200,000 hospitals employing perhaps one million people who might genetically engineer viruses every workday,” says Sotos. That’s a stark warning with broader implications. One longstanding puzzle is that the universe is filled with stars like our own, presumably with the potential to evolve intelligent life, and yet we can see no sign of these civilizations. “Where is everybody?” said Enrico Fermi, the physicist who first posed this paradox. One line of thought is that there is some kind of filtering mechanism that prevents civilizations surviving indefinitely. During the Cold War, the obvious mechanism behind this “Great Filter” was nuclear war. Could humanity avoid blowing itself up? Now the question has morphed into whether humanity can prevent a catastrophic release of a lethal pandemic. If the answer is no, then Sotos’s numbers neatly solve the Fermi Paradox. He says there are 1024 stars and planets in the visible universe and yet only one civilization—our own. If civilizations destroy themselves with biotechnology, Sotos’s numbers suggest that there is likely to be only one intelligent civilization today. “Most remarkably, the present model supplies the quantitative 24 orders-of-magnitude winnowing required of a Great Filter,” he says. So what to do? Sotos has an answer, and his voice has some influence given that, in addition to his affiliation with the California National Guard, he is chief medical officer at Intel Health and Life Sciences. “I would advise advanced technical civilizations to optimize not on megascale computation nor engineering nor energetics, but on defense from individually possessable self-replicating existential threats, such as microbes or nanomachines,” he says.

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## Prices Adv

#### Most patents are weak – generics would win and enter the market sooner if they challenged the patents

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

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

Creating a full sweep, courts have also struggled with the question of what constitutes delay. The uncertainty centers on whether an agreement in which the generic enters before the patents expire should be considered delay. Supporters of pay-for-delay settlements routinely argue that such settlements can be procompetitive because they facilitate early entry of a generic before a branded drug’s patents have expired.166

In such instances, consumers would benefit from lower prices sooner than if the Paragraph IV challenge had never taken place. In Actavis, the Supreme Court recognized this procompetitive potential, commenting that early entry settlements, or settlements permitting the patent challenger to enter the market before the patent expires, could “bring about competition . . . to the consumer’s benefit.”167

That argument, however, assumes the patent is valid and infringed.168 Various studies suggest that assumption is unwarranted. For example, a 2002 Federal Trade Commission report found that considering all the patent infringement cases between generic and brand manufacturers between 1992 and 2000, generic applicants prevailed in a staggering 73 percent of cases.169 Similarly, an academic analysis of Federal Circuit decisions between 2002 and 2004 in which the court made a final ruling on the merits of a pharmaceutical patent claim found that generic challengers had a 70 percent success rate.170

In a more recent analysis, a study of patent lawsuits filed in a federal district court between 2008 and 2009 found that accused infringers won 74 percent of the definitive merits rulings while patentees won only 26 percent of the time.171

In fact, the FDA has gone so far as to provide a registry of disputed patent information in order to address inaccurate or extraneous patent listings on new drugs.172 As the author has previously written, “one can never assume that just because a company holds a patent that the patent is either valid or validly applied to the drug at issue.”173

A patent that is invalid or not infringed would have no power to stop entry. Thus, if the generic had pursued the litigation to conclusion, the result could easily have moved the patent barrier out of the way, allowing the generic to enter right away. As a result, it would be nonsensical to say that there is no delay if the parties agreed to stay out of the market until the expiration date of a noninfringed patent. Nevertheless, some courts have failed to contemplate that possibility in analyzing agreements.

Consider In re Humira. 174 Plaintiffs alleged that AbbVie’s settlement agreements with biosimilar manufacturers, in which the biologic company granted licenses for biosimilars to market the Humira biosimilar in Europe in 2018 while delaying entry into the U.S. market until 2023, constituted an unlawful pay-for-delay scheme.175

In dismissing the lawsuit, the district court found that the settlements were permissible because they allowed AbbVie’s rivals to enter the U.S. market before the patents on Humira (the latest of which expires in 2039) expired.176 The court failed to recognize, however, that the settlements eliminated the possibility that the biosimilars might have entered the U.S. market earlier than the stipulated date if they had pursued the litigation to conclusion and prevailed. As with many cases, the patents might not have been valid or validly applied.

## Innovation Adv

#### P4D shields weak patents from scrutiny – undermines transformative innovation

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Severin Frank and Wolfgang Kerber, “Patent Settlements in the Pharmaceutical Industry: What Can We Learn From Economic Analysis?” MAGKS Joint Discussion Paper Series in Economics, November 2015, <https://www.econstor.eu/bitstream/10419/129293/1/845189549.pdf>

The problem of patent settlements in the pharmaceutical industry stems from the fact that a large number of granted patents are found invalid in patent litigation, which gives patent holders large incentives to defend their weak patents through settlements with reverse payments to challenging generic firms. An important reason is that patent offices do not invest enough time and resources in patent examination (esp. in regard to "prior art") and therefore tend to grant too many patents which often would not survive a challenge in patent litigation ("weak patents"). Empirical studies show that litigated patents are found invalid in 50% (or more) of all cases (Lemley/Shapiro 2005, p. 76). This result could be interpreted as a defect of the patent system. However, Lemley (2001) argued from an economic perspective, that such a result might also be efficient, because it might not be worthwhile to make deep and costly examinations of all patent applications, because many of the granted patents turn out as not valuable (rationally ignorant patent offices). But both interpretations lead to the conclusion that it is necessary that the patent system has effective legal instruments for challenging and weeding out invalid patents. It is an open question in the patent literature, whether and to what extent the institutional design of the entire patent system (with all its rules about granting, opposing, and challenging patents in courts) leads to an efficient patent system or - as in the meantime most legal and economic scholars claim - that the existing patent systems are deeply flawed and suffer from serious problems (Shapiro 2004, pp. 1018, Hall/Harhoff 2004, pp.4). An economic perspective on this problem of weak patents has led to the development of the concept of "probabilistic" patents or “partial property rights” which has played a major role in the patent settlement discussion.13 The basic idea is simple: Whereas from a legal perspective a patent right is either valid or not, the economic value of a granted patent right before litigation depends also crucially on the expected probability of defending it in patent litigation. If this probability is, e.g., θ = 0.25, then the expected value of the patent for the patent owner is much lower than the value of a fully defendable (iron-clad) patent right. This probability θ is used for defining the strength of a patent. This "probabilistic" character of a patent has been used in the patent settlement discussion in two different ways: Since the patent strength θ reflects the winning probabilities of the settling parties in patent litigation, it influences the ranges of the settlements (in regard to agreed entry dates and/or the size of reverse payments). In the economic models but also in argumentations of legal scholars, this has led to conclusions that a 25% chance of defending a patent against a challenging generic firm would lead to a settlement on an agreed entry date without reverse payment of 25% of the remaining patent duration (e.g. Elhauge/Krüger 2012, pp. 295). However, it can also be used for the analysis of the innovation incentives that such a probabilistic patent offers (e.g. how large are the incentives for an innovation that allows for a patent with a patent strength of 25%). In their seminal paper "How Strong are Weak Patents?" Farrell/Shapiro (2008, p. 1348) assume that innovation incentives for probabilistic patents are optimal, if the proportionality principle is fulfilled, i.e. that incentives for an innovation from a probabilistic patent are proportional to its patent strength, i.e. that the rents from a patent with θ = 0.5 should be half of the rents of an iron-clad patent (θ = 1) and twice the rents for a patent with θ = 0.25. Farrell/Shapiro (2008) have suggested that profits from weak patents might be relatively too large in comparison to stronger patents, leading to a distortion of innovation incentives in favour of "innovations" that only with a small probability are true innovations that should be rewarded by patent protection (see below section 5). It is well known that the challenging of potentially invalid patents can suffer from serious incentive problems. Since all patent systems rely on private litigation for challenging patents, the private incentives for challenging patents suffer from a public good problem, because the costs and risks of patent litigation is borne by the challenging firm, whereas the benefits of having eliminated an invalid patent right accrues to everybody. This externality of challenging patents cannot only lead to too small incentives for challenging firms, but also implies that patent settlements between originator and generic firms can have negative (external) effects on third parties, because the settlement helps to maintain an unjustified exclusive right. Due to these third-party effects, the usual normative notion that private parties should be free how to settle their conflicts in private litigation is problematic in the case of patent litigation. Therefore rules for critically scrutinizing and limiting the scope of patent settlements are justified also from an economic perspective. However, this is not only a problem of patent settlements. Shapiro (2003) showed that patent owners can achieve the same result of defending their weak patents also through licensing agreements (with too low license fees), mergers, and patent pools leading him to the conclusion that all of these transactions should be put under antitrust scrutiny.

## T Exemption

#### We meet—aff eliminates immunity for agreements shielded by patents

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

Although all parties stated that these payments were intended to compensate for services the generic companies would perform for Solvay, the FTC contended that the services had little value. Arguing that the “true point of the payments was to compensate the generics for agreeing not to compete against Androgel until 2015,” the FTC filed a lawsuit against Solvay, Actavis, Paddock, and Par on January 29, 2009.44 The district court dismissed the complaint, a decision that was affirmed by the Court of Appeals for the Eleventh Circuit. Specifically, the Court of Appeals found that “absent sham litigation or fraud in obtaining the patent, a reverse payment settlement is immune from antitrust attack so long as its anticompetitive effects fall within the scope of the exclusionary potential of the patent.”45

#### CI—expand scope means making more conduct illegal than the squo

Kovacic et al. 03 – Professor at George Washington University Law School

William E. Kovacic, Theodore B. Olson, R. Hewitt Pate, Paul D. Clement, Jeffrey A. Lamken, Catherine G. O’Sullivan, Nancy C. Garrison, David Seidman, Brief for the United States and the Federal Trade Commission as Amici Curiae Supporting Petitioner, Verizon Communs. Inc. v. Law Offices of Curtis v. Trinko, 2003 U.S. S. Ct. Briefs LEXIS 513, Supreme Court of the United States, May 2003, LexisNexis

Conversely, the 1996 Act does not expand the scope of the antitrust laws to outlaw conduct that, but for the 1996 Act, would not violate the antitrust laws. Such an expansion of Sherman Act duties would "modify \* \* \* the applicability of \* \* \* the antitrust laws" in contravention of 47 U.S.C. 152 note. Violations of the duties imposed by the 1996 Act are just that--violations of the 1996 Act, subject to the sanctions and penalties imposed by that Act. They do not automatically amount to treble-damages antitrust claims. The courts of appeals are again in accord. Pet. App. 29a; Covad, 299 F.3d at 1283 ("We agree with Goldwasser that merely pleading violations of the 1996 Act alone will not suffice to plead Sherman Act violations."); Goldwasser, 222 F.3d at 400 (It is "both illogical and undesirable to equate a failure to comply with the 1996 Act with a failure to comply with the antitrust laws."); Cavalier Tel. Co., 2003 WL 21153305, at \*11-\*12 (similar).

#### “Increase” requires pre-existence.

Ortega 07 – Judge, Oregon Appeals Court, Oregon Supreme Court

Darleen Ortega, Papas v. Or. Liquor Control Comm'n, 213 Ore. App. 369, Court of Appeals of Oregon, June 2007, LexisNexis

We begin with whether OLCC's interpretation of the rule, as developed and applied in this case, is consistent with the rule's text. Certainly, OLCC's understanding that the rule applies to "competitions" is consistent with the rule's use of the term "contest." See Webster's Third New Int'l Dictionary 492 (unabridged ed 2002) (defining the noun "contest" as a "competition"). However, by its terms, the rule refers and applies to specific types of drinking contests: as pertinent here, ones that involve "increase[d] consumption \* \* \* in increased quantities" of alcoholic beverages. OLCC's interpretation and application in this case fail to account for that qualification or to yield any pertinent point of reference in that regard; that is, nothing in OLCC's interpretation or application of the rule here identifies the consumption or quantities against which the required "increase" is to be, or was, measured. See Webster's at 1145 (defining the transitive verb "increase" as "to make greater in some respect (as in bulk, quantity, extent, value, or amount) : add to : enhance" and defining the adjective "increased" as "made or become greater"). Thus, OLCC's proposed interpretation--that mere competition between participants constitutes conduct violating the rule--is inconsistent with the latter, qualifying aspects of the rule.

#### Arbitrary—the author thinks “scope” is meaningless

Sagers, James A. Thomas Distinguished Professor of Law and Faculty Director of the Cleveland-Marshall Solo Practice Incubator, ‘21

(Christopher, Antitrust Question, email exchange with Anthony Trufanov, December 7, https://nudebateadt.blogspot.com/2021/12/antitrust-question.html)

To me, the problem is that this idea of the "scope" of antitrust has no established legal meaning and very little practical significance. It isn't really used in actual practice and it would rarely have any legal significance in an actual antitrust case. It was a convenient shorthand that I came up with for organizing the materials in that book, and it also had one theoretical value to me, but that's pretty much it. Most antitrust lawyers I've worked with understand it what I meant by it, but it doesn't have any precise meaning or doctrinal significance. I don't think the term was even really used before that book. I almost literally made it up.

## T Prohibit

#### We meet— A] plan creates liability for activity not currently prohibited

Marmaro 21 – JD, Columbia

Morgan Marmaro, Editor-in-Chief, Colum. J.L. & Soc. Probs, Law Clerk, Freshfields Bruckhaus & Deringer LLP, JD-Columbia, 54 Colum. J.L. & Soc. Probs 169, <http://blogs2.law.columbia.edu/jlsp/wp-content/uploads/sites/8/2021/02/Volume-54-Marmaro.pdf>

A class action, In re Humira (Adalimumab) Antitrust Litiga-tion,46 alleges that AbbVie’s multiple agreements are actually mar-ket allocating agreements and settlements qualifying as reverse payments. As of this writing, the In re Humira litigation is under-going appeal after a district court ruled in favor of AbbVie, noting that while the behaviors seem unsavory, they were legal “exploited advantages” derived from the current regulatory system.47 The court went further astray, finding that the agreements were not anticompetitive, and in contradiction with Actavis’s rejection of the scope of the patent doctrine, did so by relying upon the alleged strength of AbbVie’s Humira patents.48 But neither the parties nor the Court in In re Humira questioned the basic application of Ac-tavis to the agreements in this case. Though the In re Humira district court dismissed the case in favor of defendants,49 this Note argues that the In re Humira district court was correct to engage in an Actavis analysis but did so incorrectly.

[FN 47]

47. Id. at 819 (“The legal and regulatory backdrop for patented biologic drugs, together with a well-resourced litigation strategy, gave AbbVie the ability to maintain control over Humira. Plaintiffs say that AbbVie’s plan to extend its power over Humira amounts to a scheme to violate federal and state antitrust laws. But what plaintiffs describe is not an antitrust violation. AbbVie has exploited advantages conferred on it through lawful practices and to the extent this has kept prices high for Humira, existing antitrust doctrine does not prohibit it.”).

[End FN]

#### Prohibitions are implemented via legal tests—the threshold of the test determines how much or how little conduct is prohibited

Mark S. Popofsky, Antitrust Partner at Ropes and Gray, Served as Senior Counsel to DOJ Antitrust Division, Adjunct Professor of Advanced Antitrust Law and Economics at Harvard Law School and the Georgetown University Law Center, 2016, Section 2 and the Rule of Reason: Report from the Front, CPI Antitrust Chronicle March 2016 (1)

Courts remain, in the words of one observer, mired in an “exclusionary conduct ‘definition’ war.”2 Applying Section 2’s broad prohibition on “monopolizing” conduct requires courts to select a governing legal test. Section 2 legal tests run the spectrum from rules of per se legality to rules of near per se illegality.3 Courts, nonetheless, largely apply two dominant paradigms. The first consists of legal tests based on bright-line rules or safe harbors. Familiar examples include the Brooke Group4 below-cost price test for analyzing predatory pricing claims and the Aspen/Trinko5 “profit sacrifice” test for refusals to deal. Developing bright-line rules for Section 2, proponents argue, promotes business certainty and reduces the risk of chilling otherwise procompetitive conduct. The second paradigm is rule of reason balancing. Arguably the default Section 2 legal test,6 courts and commentators have described Section 2’s rule of reason in various ways: as mandating a step-wise approach, as requiring a balancing of pro- and anticompetitive effects, or (to borrow from Section 1) a framework for generating the enquiry “meet for the case.”7 However the rule of reason is expressed, its champions contend, its flexibility and fact-intensive approach permits courts to identify anticompetitive conduct without the under-inclusion that is an admitted feature of safe harbors and other bright-line rules.

#### Aff ratchets up from rule of reason

Stucke, Associate Professor, University of Tennessee College of Law, ‘09

(Maurice, “Does the Rule of Reason Violate the Rule of Law?” https://lawreview.law.ucdavis.edu/issues/42/5/articles/42-5\_Stucke.pdf)

Although the Court’s 1977 decision in Sylvania represents its retreat from per se rules to the rule of reason, there appeared in the 1980s the prospect of a third standard that lay between the Court’s full-blown rule of reason and per se illegality: quick-look standards.154 The quick-look relieves an antitrust plaintiff from an extensive detailed market analysis in its prima facie case.155 “If, based upon economic learning and the experience of the market, it is obvious that a restraint of trade likely impairs competition, then the restraint is presumed unlawful.”156 The antitrust plaintiff need not prove as part of its prima facie case the relevant product and geographic market. Instead, the burden shifts to defendants to establish the restraint’s procompetitive benefits.157 Encouraged by the Court’s openness to a quick-look,158 the FTC and DOJ refined these standards,159 which sparked further discussion within antitrust circles.160

#### Precision—prohibition turns on whether something is anticompetitive or not

Light, Assistant Professor of Legal Studies and Business Ethics, The Wharton School, University of Pennsylvania, ‘19

(Sandra, “The Law of the Corporation as Environmental Law,” 71 Stan. L. Rev. 137)

The more fact-intensive inquiry under the rule of reason tests “whether the restraint imposed is such as merely regulates and perhaps thereby promotes competition or whether it is such as may suppress or even destroy competition.”196 While this extremely broad statement might suggest that any fact is relevant to the inquiry, the salient facts under the rule of reason are “those that tend to establish whether a restraint increases or decreases output, or decreases or increases prices.”197 If an anticompetitive effect is found, then the action is illegal and the rule of reason operates, like the per se rule, as a prohibition.198 The rule of reason can also operate as a disincentive, even if no court finds an anticompetitive effect, as uncertainty and litigation risk may discourage firms from undertaking legally permissible, environmentally positive industry collaborations.199

## FDA CP

#### Regulatory capture destroys solvency

Chilson, JD, Chief Technologist at the Federal Trade Commission, where he focused on the economics of privacy and blockchain-related issues. Previously, he was an attorney advisor to Acting FTC Chairman Maureen K. Ohlhausen, ‘20

(Neil, “Does Big Tech Need Its Own Regulator?” October 25, <https://gaidigitalreport.com/2020/08/25/does-big-tech-need-its-own-regulator/>)

A. A “Big Tech” Regulator Would be Captured by Big Tech

The biggest problem with creating a specialized agency is that such agencies are more vulnerable to regulatory capture. Instead of creating a new, separate agency to regulate big tech, Congress should assign any new authority and expertise to existing agencies, particularly to generalist agencies like the Federal Trade Commission, which—as even the Stigler Center report acknowledges—have proven relatively resistant to regulatory capture.[81]

1. All Agencies Tend Toward Capture

The basic idea of regulatory capture was explained by Nobel Memorial Prize-winning economist George Stigler, who argued that “regulation is acquired by the industry and is designed and operated primarily for its benefit.” In his foundational paper, “The Theory of Economic Regulation,” he warned that any regulated industry has strong incentives to form close connections with its regulators to seek favors. The inevitable result is that the industry disproportionately influences the agency’s agenda, shapes its rulemaking and even supplies it with personnel.[82] Captured agencies do not hold companies accountable; instead, they act to benefit the industry’s established players, disadvantaging newer firms and the public at large.

The forms and causes of regulatory capture vary, and regulatory capture is nearly always a question of degree.[83] The most egregious forms of regulatory capture are government “oversight” organizations occupied and controlled by the regulated entities themselves. For example, state boards responsible for setting the rules for the practice of dentistry should not be (but often are) dominated by practicing dentists.[84]

But regulatory capture occurs even when agencies are populated by government officials who are independent. Public choice scholars have explained how agency leaders will act in rational self-interest by seeking to keep their position and to expand the power and budget of the agency and to secure prestigious or profitable positions after leaving leadership.[85] This requires currying favor with influential politicians and powerful interest groups, usually by employing the tools of the regulator in favor of those groups’ interests.[86]

Capture can happen in less cynical and more subtle ways. Agency expertise requires experience or long-term interest in the regulated industry, and individuals with that background will tend to view issues from the perspective of that industry, want that industry to thrive, and draw information from industry sources. “Thus, even a benign, well-intentioned industry expert will be inclined to render decisions that favor the industry he regulates.”[87]

Regulatory capture undermines the agency’s oversight mission, shifting the benefit away from the public and toward the regulated industry. Perhaps most concerning, regulated incumbents can use the power of the captured agency to establish a significant barrier against competition. For example, industry participants might directly convince regulators to subsidize their businesses, giving them an advantage against would-be competitors. More subtly, large firms might support costly compliance regimes that disproportionally disadvantage smaller firms. In either case, this type of “public competition” is a particularly pernicious type of rent-seeking.[88]

Even absent overt acts by the regulated firms, regulation and incumbent business models will naturally co-evolve to fit each other. Disruptive business models that do not fit into the current regulatory boxes will face significant regulatory risks in this circumstance. Some have called this the “procrustean problem” of regulation after the ancient Greek myth in which a rogue blacksmith stretches or amputates human visitors to fit his iron guest bed.[89] Regulators need to fit and classify companies according to regulatory categories, and this naturally benefits incumbent business models while disadvantaging novel and experimental approaches.

This type of regulatory capture creates a status quo bias. The mismatch between existing regulation and a new business model can mean that innovative ways of accomplishing certain goals may be legally risky to pursue not because they are dangerous or harmful but because they were not contemplated when the regulation was developed. At best, innovators in this situation will have to educate regulators and potentially pursue regulatory changes. At worst, innovators will be warned off by their lawyers and investors, will choose to pursue less legally uncertain endeavors, and the agency will not even know the chilling effect its framework is having.

2. The Risk of Regulatory Capture is Higher for Specialized Agencies

Regulatory capture is a problem that all agencies face. However, a sector-specific regulator of big tech is more likely to be captured than are generalist agencies like the Federal Trade Commission.[90] Yale Law Professor Jonathan R. Macey examines this issue in depth in his article, “Organizational Design and Political Control of Administrative Agencies,” where he analyzes the outcomes from “the most fundamental choice of agency design: whether to create a single industry regulatory agency or a multi-industry agency.”[91] As he explains:

Where a regulatory agency represents a single ‘clientele,’ the rules it generates are far more likely to reflect the interests of that clientele than the rules of an agency that represents a number of clienteles with competing interests.[92]

That is, the smaller the number of companies under a regulator’s jurisdiction, the easier it is for those companies to capture the regulator. This is because the pressures toward regulatory capture are amplified for more specialized agencies. Although James Madison was comparing forms of national government rather than forms of agencies, his discussion of factions in Federalist 10 helps explain why narrowly specialized agencies face heightened risks of capture:

[T]he fewer the distinct parties and interests, the more frequently will a majority be found of the same party; and the smaller the number of individuals composing a majority, and the smaller the compass within which they are placed, the more easily will they concert and execute their plans of oppression.[93]

In other words, a small group with similar interests and perspectives can more easily bend government action to its benefit. When a small interest group has a dedicated regulator, the risk of regulatory capture is at its peak. “The interest group that is regulated by a single regulatory agency will be able to influence that agency to a far greater extent than the interest groups that must ‘share’ their agency with a variety of other interest group,” argues Professor Macey.[94] By contrast, government actors with jurisdiction over a wide range of conflicting interests are “beholden to many but captured by none.”[95]

Incumbents regulated by a specialized agency can more easily weaponize regulation against new competitors, often with the regulator’s help. Competitive threats to a sector also threaten the sector-specific regulator. In fact, “[t]he creation of administrative agencies helps insure against an industry’s obsolescence by creating a regulatory body with incentives to pass rules that increase the probability of the industry’s survival,” Macey explains.[96] For instance,

[L]ong after there was any economic need for a savings and loan industry, thrift regulators took extraordinary steps to ensure the industry’s survival. The regulators acted as they did, not to further the public interest, but because they understood that the survival of the industry was crucial to their own professional survival.[97]

In such situations, outside innovators can face a unified front of incumbents and regulators seeking to control disruption in their own interest, not in the public interest. This weaponization of a regulatory agency by incumbents is particularly harmful in industries with the potential for rapid and disruptive innovation, where the existential threat is heightened.[98]

For these reasons, the decision to create a new, sector-specific agency should not be taken lightly. “[T]he ability to structure the initial design of an agency,” Macey argues, “may well be the most powerful device available to politicians and interest groups” to shape the future path of an agency after its creation.[99] Specifically, when Congress chooses between a “single-interest” or “multi-interest” design for an agency, it affects which groups will be influential repeat dealers and which will be infrequent and thus less influential.[100] Macey compares single interest agencies like the Securities and Exchange Commission with multi-interest agencies like the Occupational Safety and Health Administration. He provides example after example of the SEC, the Commodities Futures Trading Commission and other sector-specific agencies serving the interests of the firms they regulate.[101]

Establishing a sector-specific agency comes with significant risks that the agency will serve the interests of the regulated industry rather than the public interest. In contrast, “[t]he FTC, unlike industry specific regulatory bodies, deals with industry in general. Perhaps this explains why, at least to date, we are unaware of claims that the FTC has been captured by any industry or special interest group.”[102]

#### Califf won’t be confirmed as FDA head now, but the CP flips it – Dems see the CP as a signal that the FDA will crack down on pharma

Jewett and Cochrane 2/3 – Christina Jewett covers the FDA for the New York Times. Emily Cochrane is a reporter covering Congress for the New York Times.

Christina Jewett and Emily Cochrane, “F.D.A. Nominee Faces Steep Climb to Senate Confirmation,” *The New York Times*, 3 February 2022, https://www.nytimes.com/2022/02/03/health/fda-califf-senate.html.

The White House is facing pressure from prominent lawmakers over its pick to lead the Food and Drug Administration, with abortion foes urging Republican senators to reject the nominee, Dr. Robert Califf, and with key Democrats withholding support over opioid policies and his industry ties.

Nearly six years after Dr. Califf received overwhelming bipartisan support to lead the agency in the final year of the Obama administration, lawmakers and aides are struggling to lock up the votes he needs to clear an evenly divided Senate, where Vice President Kamala Harris serves as the tiebreaking vote.

Few, if any, nominees to the F.D.A. have faced as much opposition on both sides of the aisle, and the agency has been without a permanent commissioner for more than a year. The agency’s agenda includes a series of significant issues: oversight of drugs, tests and devices related to Covid-19; the pandemic-related decline in inspections of drug and device manufacturers; and the popularity of flavored e-cigarette products among teenagers.

Administration officials have been trying to rally support for Dr. Califf and say he continues to have the support of President Biden and top health officials. Senate Democratic leaders also continue to back him publicly. But a date has not been set for his confirmation vote before the full Senate. At least five Democrats are publicly opposing his nomination, so Dr. Califf needs at least five Republicans to support him.

“We are confident Dr. Califf will be confirmed with bipartisan support, and it is critical to have confirmed leadership at the F.D.A. in the midst of a pandemic,” Chris Meagher, a White House spokesman, said. Dr. Califf has declined interview requests while his nomination is pending.

This week, some senators seemed uncertain that Dr. Califf could survive the divisions over his candidacy. “I’m not sure that’s going to come to a vote, and I’ll make a final decision then,” said Senator Roy Blunt, Republican of Missouri. “I like him as a person, I think he can do the job and let’s see what else develops between now and the vote.”

Prospects for a quick vote may be further complicated by the absence of Senator Ben Ray Luján, Democrat of New Mexico, who is recovering from a stroke. A senior aide to Mr. Luján said on Wednesday that he remained in the hospital and would return in four to six weeks unless there are complications. Mr. Luján voted in favor of Dr. Califf at the committee stage.

Notable Democrats — including Senators Joe Manchin III of West Virginia, a key centrist, and Bernie Sanders of Vermont, the independent — have publicly announced that they will oppose the nominee over his ties to the pharmaceutical industry and his handling of the opioid crisis during the Obama administration.

“In terms of health care, in terms of the F.D.A., we need aggressive leadership who are prepared to take on the greed of the pharmaceutical industry,” Mr. Sanders said. “Unfortunately, I don’t think Dr. Califf is that person.”

Dr. Califf cleared a vote in the Senate Committee on Health, Education, Labor and Pensions in January with Republican support. Four senators crossed the aisle to advance the nomination: Richard Burr of North Carolina, the committee’s ranking member; Susan Collins of Maine; Lisa Murkowski of Alaska; and Mitt Romney of Utah.

Senator John Thune of South Dakota, the second-ranking Senate Republican, said on Wednesday that Dr. Califf’s experience and competence boded well for his prospects with many in his party, though concerns over his role in abortion decisions were driving others away.

“It’s hard for me to say at this point kind of where our members are going to be,” Mr. Thune said, “but I know that there are mixed views.”

Two Democrats — Mr. Sanders and Senator Maggie Hassan of New Hampshire, facing a tough re-election in a state hit hard by opioids — opposed the choice, and more Democrats are said to be leaning against his nomination. All three Democrats who voted against Dr. Califf’s first confirmation to the post in 2016, Mr. Manchin and Senators Ed Markey of Massachusetts and Richard Blumenthal of Connecticut, remain in office.

Mr. Markey’s office confirmed that he would again vote against Dr. Califf. Mr. Blumenthal said on Tuesday that if the vote were held that day, he would do the same.

“I still strongly believe that there’s a need for a new era and leadership that will separate the F.D.A. from the pharmaceutical industry in a very public and important way,” Mr. Blumenthal said, adding that he had lingering concerns after speaking with Dr. Califf. On Wednesday, he made a point of reiterating his opposition.

Dr. Califf has been making the rounds of the Senate, meeting with an estimated 45 members, among the most scheduled for any Biden nominee. Aides privately indicated that they believed they could rally the necessary support for his appointment. This week, Mr. Burr predicted: “I think Dr. Califf will be the next F.D.A. commissioner.”

Despite concerns from Mr. Manchin and other Democrats, Dr. Califf was named for the position in November. Mr. Manchin, whose state has been devastated by the opioid epidemic, has outlined numerous changes he would like to see at the F.D.A., including mandatory education for opioid prescribers similar to the education required of those prescribing addiction medication.

The senator’s concerns about the crisis have hampered negotiations over Mr. Biden’s marquee $2.2 trillion domestic policy bill, as Mr. Manchin rejected plans to extend the child tax credit over concerns that those monthly payments to families with children were being used to purchase opioids.

“I strongly opposed his nomination, which is an insult to those who have been impacted by the drug epidemic,” Mr. Manchin said on Twitter on the day of the panel’s vote, adding: “It’s time the F.D.A. had leadership willing to step forward to protect Americans from the drug epidemic that continues to ravage our nation. Dr. Califf is not that leader.”

Several senators, pressed this week on their support for Dr. Califf, said they had not yet made a decision.

Senator Shelley Moore Capito, Republican of West Virginia, said she was still undecided: “I know there’s some issues that have come up, but he has been to West Virginia — he has seen firsthand some of the issues that we have. That’s important to me.”

The F.D.A. commissioner role has been subject to Senate confirmation since 1988, unlike the director of the Centers for Disease Control and Prevention, who is a presidential appointee. The nominee tends to be subject to sharp questioning, but observers say the decision has never been so wrapped up in national politics unrelated to the nominee’s qualifications.

With no confirmed leader, Dr. Janet Woodcock, the interim commissioner, can serve while the nomination is pending. If Dr. Califf’s nomination is voted down, she could lead the agency for 210 more days, according to Charles Young, a spokesman for the Government Accountability Office.

Dr. Califf spent much of his career running cardiology trials at Duke University medical school, where he earned a reputation as an evenhanded expert. In 2017, he joined Verily, the life sciences arm of Alphabet, the parent company of Google.

As head of clinical policy and strategy there, he earned $2.7 million in income and between $1 million and $5 million in stock, according to his ethics disclosure. He also held lucrative leadership roles at pharmaceutical and biotech companies developing drugs for patients with hemophilia and impaired muscle function. In an effort to shore up more support, he committed to Senator Elizabeth Warren, Democrat of Massachusetts, that he would adhere to additional restrictions to separate any administration decisions from his prior work.

“The F.D.A. nominee has agreed to go beyond the current legal requirement to cut himself off from participating in the revolving door after his government service and insulate himself from interactions with former employers during his time in office,” Ms. Warren said. “Because he was willing to make a public commitment to stop the revolving door, I will support him.”

Some critics of Dr. Califf cite his track record at the F.D.A., where he was deputy commissioner for medical products and tobacco starting in 2015 and the Senate-confirmed agency commissioner in 2016 and 2017.

The anti-abortion group Susan B. Anthony List is leading a coalition that is pressuring Republican senators to vote against Dr. Califf. The group criticized changes to medication abortion policies, which became less restrictive in 2016 when Dr. Califf was leading the agency. “In 2016, he was a nominee without a record; now he is a nominee with a track record of disregarding life,” the group wrote.

The group also is opposing Dr. Califf over his responses to questions during the Dec. 14 committee hearing on the agency’s imminent decision about the medical abortion drug mifepristone. Dr. Califf said he trusted the agency to make the right decision with the evidence at hand.

Two days later, the F.D.A. announced that it would permanently allow telehealth providers to prescribe at-home abortion medications.

Tommy Tuberville of Alabama, Mike Braun of Indiana and Roger Marshall of Kansas, all Republicans, voted against Dr. Califf in committee partly over abortion-related issues, staff members confirmed.

The advocacy group is also pressing Mr. Romney, who was one of the four Republicans on the Senate Committee on Health, Education, Labor and Pensions who voted in favor of Dr. Califf on Jan. 13.

Some of the lawmakers’ concern over opioid policy is also based on Dr. Califf’s brief tenure as commissioner in 2016. Three months into his term, the Centers for Disease Control and Prevention issued new guidelines and a searing commentary decrying the often-fatal risks of opioid medications amid “unproven and transient benefits.”

Instead of following up with policy changes, Dr. Califf commissioned another study, said Dr. Andrew Kolodny, a critic of the F.D.A.’s opioid policies who has advised Mr. Manchin, Mr. Markey and Ms. Hassan.

#### Califf confirmation worsens the opioid crisis

Castronuovo and Ruoff 1/24 – Celine Castronuovo is a reporter for Bloomberg Law covering the FDA and drug pricing laws. Alex Ruoff is a health reporter for Bloomberg Government.

Celine Castronuovo and Alex Ruoff, “Califf on Path to Win FDA Chief Role Despite Expected ‘No’ Votes,” *Bloomberg Law*, 24 January 2022, https://news.bloomberglaw.com/health-law-and-business/califf-on-path-to-win-fda-chief-role-despite-expected-no-votes.

Opioid Concerns

Sen. Ed Markey (D-Mass.) is one of several Democrats who have expressed concerns over Califf’s nomination and the FDA’s role in addressing the opioid crisis. The FDA has faced repeated criticism over its prior approvals of Purdue’s OxyContin and other addictive drugs without requiring more thorough warning labels to help combat misuse.

“Dr. Califf did not commit to the decisive and comprehensive action necessary to ensure reforms that the FDA, under his leadership, would implement on opioid regulation,” when they met in December 2020, Markey said in a Jan. 13 letter to acting Commissioner Janet Woodcock.

Hassan said Jan. 11 that she didn’t believe Califf fit the bill of “a strong FDA Commissioner” who “recognizes the role that the agency’s decisions played in fueling” the nation’s opioid epidemic. Sens. Joe Manchin (D-W.Va.) and Richard Blumenthal (D-Conn.) have previously said they wouldn’t support Califf due to his extensive work with the drug industry.

#### Opioid deaths will increase exponentially absent strong action – kills over a million, and limiting pharma influence is key

Glenza 2/2 – Health reporter for the Guardian, citing a new study published in the Lancet.

Jessica Glenza, “Opioid overdose deaths to ‘grow exponentially’ without action – study,” *The Guardian*, 2 February 2022, https://www.theguardian.com/us-news/2022/feb/02/doubling-opioid-overdose-deaths-global-growth-lancet-stanford-study.

More than 1.2 million additional people across North America are expected to die of opioid overdoses by 2029 if dramatic interventions are not taken to prevent it, according to a new study published in the Lancet.

Overdose deaths from all drugs, including opioids, have increased dramatically in the US and Canada during the Covid-19 pandemic.

The Lancet report, prepared by the Stanford-Lancet commission on the North American Opioid Crisis, is a wide-ranging analysis which seeks to highlight evidence-based recommendations to the opioid crisis.

The report predicts that the number of overdoses will “grow exponentially” in the next seven years, killing an additional 1.2 million people. Such a figure would represent a doubling of the number of deaths seen over the last two decades.

As long as the status quo stands, “We will continue to have these kinds of addiction outbreaks in our healthcare system,” said Keith Humphreys, chair of the commission and a professor of psychiatry at Stanford University, which financed the commission’s research.

The commission emphasized that while specific vulnerabilities in American regulations accelerated the current problem, there was also evidence the opioid crisis had “got a good chance of spreading globally,” Humphreys added.

“As we show in [the report], Australia has a 15-fold increase in opioid prescribing. England has doubled. Finland has gone up by a factor of seven. Brazil by 465%,” he said.

Provisional data released by the Centers for Disease Control and Prevention (CDC) showed that during the 12-month period ending in April 2021, more than 100,000 people died in the US of drug overdoses, including more than 75,000 people whose deaths involved opioids.

Opioids, a broad class of drugs including prescription painkillers and illicit drugs such as fentanyl and heroin, are involved in about three-quarters of overdose deaths in the US. The number of overdose deaths involving fentanyl has risen sharply since 2015.

In North America, more than 600,000 people have died of opioid overdoses since 1999. The opioid epidemic is broadly recognized to have started when drug companies, such as Purdue Pharma, aggressively and fraudulently marketed opioids despite evidence they were being abused and diverted.

Humphreys argued that weak regulation, poor addiction treatment services and disinvestment in preventive measures make the US particularly vulnerable to future waves of addiction epidemics involving other drugs.

“It may not be opioids, but it may be tranquilizers or stimulants,” said Humphreys. Regardless of the class, he warned, all would cause unnecessary injury and death.

In North America, the opioid crisis is largely seen to have occurred in three waves. Widespread prescribing of opioid painkillers in the 1990s led millions, particularly white and Indigenous people living in rural areas, to become addicted.

Insufficient addiction treatment resources expanded markets for illicit heroin, and also moved the opioid epidemic into urban centers, expanding their use among Black Americans. Those markets were then flooded with fentanyl, a synthetic opioid 50 to 100 times more potent than morphine, leading to recent peaks in opioid overdose deaths.

To try to “unwind” the opioid epidemic in the US over the coming years, the commission argued efforts should start by curbing pharmaceutical industry influence on doctors, politicians, regulatory agencies, medical students and the public through industry-supported patient advocacy groups.

The commission then calls for opioid stewardship that takes into account both benefits and risks of painkillers; addiction treatment that is part of core public health services; criminal justice reform; investment in healthier communities and childhood education; innovations in biomedical research to find non-addictive painkillers; and lastly a commitment from wealthy nations to enact policies to avoid exporting the opioid crisis to developing countries.

Even if lawmakers only tackled the influence of pharmaceutical companies, such a change would represent a dramatic realignment of power in the US. The pharmaceutical and health industry spent more than $352m lobbying members of Congress in 2021. In 2020, the pharmaceutical industry alone donated to two-thirds of sitting members of Congress, or 356 lawmakers, according to the health publication Stat.

#### Circumvention – absent changing the burden of proof, regulatory agencies can’t identify deals

Anderson 20 – Professor of Public Health & Professor of Medicine, Johns Hopkins; Director, JHU Center for Hospital Mgmt.

Gerard F. Anderson, PhD; Laura Karas, MD, MPH, Dept. of Health Policy & Mgmt. in the JHU Bloomberg School of Public Health; and Robin Feldman, Arthur J. Goldberg Distinguished Professor of Law and Director of the Center for Innovation at UC Hastings Law, Visiting Professor at UCLA Law, Pharmaceutical “Pay-for-Delay” Reexamined: A Dwindling Practice or a Persistent Problem?, 71 Hastings L. J. 959 (May 2020), <https://hastingslawjournal.org/wp-content/uploads/Karas-et-al.-71.4.pdf>

Hence, there is good reason to believe that anticompetitive pay-for-delay agreements continue to be reached in the United States post-Actavis. A reduction in explicit payments to figures below $7 million can likely be attributed to Justice Breyer’s emphasis on the size of the reverse payment in Actavis. 43 However, payments below litigation costs can still present anticompetitive harm. A small reverse payment should not immunize anticompetitive behavior any more than does allowing generic entry prior to expiration of the patent in question. The “scope of the patent” test has effectively been replaced by a “size of the payment” test, permitting brand companies with more complex deals but modest explicit payments to stay under the radar. Moreover, modern deals now provide potential vehicles for transferring value other than cash in a convoluted manner.

In the view of the authors, less attention should be paid to the form or even the size of the value transfer, and the primary focus of antitrust scrutiny should be any restriction on generic entry together with a category of patent less likely to survive a challenge. The strength of the category of patent in question must necessarily be part of a proper pay-for-delay evaluation by the courts or the FTC because, following Actavis, the size of the reverse payment can no longer be presumed a reliable indicator of patent strength or weakness. Nor can reporting requirements alone provide a complete safeguard. Given the complexity of modern pay-for-delay deals, the actual transfer of value can be deeply camouflaged, hidden among the folds of layers of interactions between the brand-name and generic company. Regulatory agencies examining the deal paperwork on its face are unlikely to stay ahead of the game.

#### Per se ban wrecks access and innovation

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

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

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

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

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

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

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

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

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

## FTC Tradeoff DA

#### Fiat solves – new authority comes with new funding authorization

Bannan is policy counsel at New America’s Open Technology Institute, focusing on platform accountability and privacy, and Gambhir, New America's Open Technology Institute, ‘21

(Christine and Raj, “Does Data Privacy Need its Own Agency?” <https://d1y8sb8igg2f8e.cloudfront.net/documents/Does_Data_Privacy_Need_its_Own_Agency.pdf>)

Proposals delegating privacy law enforcement to the FTC generally bolster an existing bureau or establish a new bureau within the agency. Senator Wyden’s Mind Your Own Business Act of 2019 would create a new 50-person Bureau of Technology within the FTC and add 125 employees to the Bureau of Consumer Protection—100 of whom would do privacy enforcement work.102 This would bring the total number of FTC employees doing privacy enforcement work up to about 190. While the Wyden bill does not provide figures for how much adding 175 new employees would cost, former FTC Chairman Joseph Simons estimated that a $50 million budget increase from Congress would enable the FTC to hire 160 new staff.103 Under this proposal, the number of employees working on privacy would more than triple. However, it would still only be about one-tenth the size of the Eshoo-Lofgren DPA proposal.

#### Enforcement now – already taking an aggressive approach in HC

Cornell 9/16 – Head of the U.S. antitrust practice at global antitrust powerhouse Clifford Chance LLP

Tim Cornell, 20 years of antitrust experience, has advocated on behalf of dozens of clients before the US Federal Trade Commission, the US Department of Justice, and the federal courts, with Robert Houck, Peter Mucchetti, and Brian Yin, Antitrust Litigation 2021, Last Updated September 16, 2021, <https://practiceguides.chambers.com/practice-guides/antitrust-litigation-2021/usa/trends-and-developments>

After an eventful year of antitrust litigation related to healthcare in 2020, all indications are that 2021 will be just as action-packed.

In October 2020, subscriber plaintiffs and defendants in the Blue Cross Blue Shield (BCBS) multi-district litigation (MDL) in Alabama reached a preliminary agreement on a USD 2.67 billion settlement fund, along with sweeping reforms aimed at restoring competition in the healthcare insurance industry. The litigation is an amalgamation of claims going back to 2012 accusing dozens of local insurers (so-called "Blues") of using restrictive practices to suppress competition.

Then in January 2021, President Trump signed the Competitive Health Insurance Reform Act, eliminating certain antitrust exemptions health insurers had previously enjoyed under the McCarran Ferguson Act. While these exemptions were limited, commentators have suggested that the availability of the defense may have had a chilling effect on antitrust litigation in healthcare. The plaintiffs' success in the BCBS cases and the elimination of these antitrust protections for health insurers may result in more antitrust cases against health insurers in the next few years.

Meanwhile, the multitude of suits in the long-running generic drug price fixing matters has continued to progress. In July 2020, the federal judge overseeing the multidistrict litigation initially selected the complaint filed by a coalition of 44 state attorneys general against Teva to act as a "bellwether" case (a procedure whereby a representative action among many lawsuits proceeds first to trial to help shape subsequent litigation). But in August 2020, a grand jury indicted Teva on criminal price-fixing charges, as part of the DOJ's ongoing antitrust investigation of the generic drug industry. Concerned for the complications the civil and criminal matters could pose to one another, the court vacated its bellwether selection. In May 2021, the judge instead chose the states' complaint asserting a price fixing conspiracy affecting various dermatology treatments and other drugs. Meanwhile, the DOJ has continued to pursue its own generic drugs investigations, having criminally charged at least seven companies and a number of executives, while indicating that more indictments are expected.

The FTC also has continued to make healthcare a priority for antitrust enforcement. In the Spring of 2020, the FTC announced that it would increase resources it put towards the review of previously consummated healthcare deals, sending requests for information to a number of health insurers that had recently merged. Around the same time, the FTC initiated a challenge of Jefferson Health's proposed acquisition of Albert Einstein Healthcare Network in Philadelphia. In a rare defeat for the agency, a federal court rejected the challenge in December 2020. Seemingly undeterred, however, the FTC has continued to challenge hospital mergers, including in Memphis [In re: Methodist Le Bonheur Healthcare and Tenet Healthcare Corporation, FTC No. 9396] and New Jersey [In re: Hackensack Meridian Health, Inc. and Englewood Healthcare Foundation, FTC No. 9399].

In his 9 July 2021 Executive Order, President Biden continued his administration's focus on antitrust and healthcare issues. The order directs federal agencies to seek solutions to address anticompetitive conditions affecting the US economy, including the high cost of prescription medication and healthcare services, increasing hospital consolidation, and other areas related to healthcare.

#### Plan reverses current tradeoffs

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

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

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

A presumption offers a variety of advantages to the judiciary and regulatory systems. It would ease the burdens on regulators such as the FTC, which tend to lack the resources needed to scrutinize and, if necessary, litigate each of the dozens of brand-generic settlements that occur annually. 183 [FN 183] 183 See Feldman & Misra, Fatal Attraction, supra note 8, at 260–261 (noting that, although all brand-generic agreements under the Hatch-Waxman Act must be filed with the FTC, the agency’s delays in publishing pay-for-delay reports, and the reports’ relative lack of specificity, suggests limited resources to address the problem of pay-for-delay). [End FN] In addition, by shifting the burden to the companies themselves, a presumption avoids rewarding those who concoct increasingly elaborate schemes. The company would have to establish how a complex and convoluted scheme works and why it is procompetitive.

#### Scenario fails—no privacy rule uq, legal challenges kill it

David Uberti, WSJ, FTC’s Effort to Strengthen Online Privacy Protections Faces Hurdles, 11/1/21, <https://www.wsj.com/articles/ftcs-effort-to-strengthen-online-privacy-protections-faces-hurdles-11635845401>

The Federal Trade *C*ommission has outlined *a* far-reaching vision for protecting consumers’ privacy online, but the plan faces challenges including budget constraints, personnel changes and potential legal pushback.

Critics of big technology companies have praised the FTC’s effort, which comes after years of inaction in Congress on the issue, even as businesses have ramped up data collection. The FTC has pledged to go it alone by intensifying scrutiny of digital advertising and exploring new rules for how companies can collect and use consumers’ information.

The agency hasn’t announced the start of any broad rule-making process. But its new chairwoman, Lina Khan, a Democrat who has criticized big business, said in an October statement on the FTC’s data strategy that she intends to explore privacy standards as she probes emerging technologies, discriminatory data practices and companies’ amassing of consumer information to cement their market power.

Current and former FTC officials say budgetary wrangling in Congress will shape the agency’s ultimate impact on data privacy. Some observers also caution that writing broadly defined privacy rules under a rarely used authority known as Magnuson-Moss might lead the agency into legal gray areas that could result in successful industry lawsuits.

“For those who say that Congress hasn’t acted, so let’s have the FTC do it, it’s an uphill climb,” said Jessica Rich, who stepped down as director of the FTC’s Bureau of Consumer Protection in 2017 and now works for law firm Kelley Drye & Warren LLP.

The agency is reviewing piecemeal data regulations authorized in specific laws, issuing an update last week to a rule requiring financial institutions to secure customer data.

Some Democratic lawmakers have also urged the FTC to use its Magnuson-Moss authority, established in 1975, to write more general rules for data usage. Under that authority, the FTC could prohibit certain activity and potentially fine companies on the first offense.

To restrict a behavior under a rule created through Magnuson-Moss, the agency would have to argue it constitutes an unfair or deceptive practice that harms consumers, said Justin Brookman, a former FTC official who is now director of consumer privacy and technology policy for advocacy group Consumer Reports. There is little precedent for such arguments about privacy and they could be challenged in court, Mr. Brookman said: “We’re off the map here.”

Consumer advocates say the agency could use such power to restrict digital advertising, which relies on an opaque exchange of data among businesses to target users with content. Representatives for Facebook parent Meta Platforms Inc., Alphabet Inc.’s Google and Amazon.com Inc., which together control about 90% of the digital advertising market, didn’t respond to requests for comment.

Julie Brill, Microsoft Corp.’s chief privacy officer, said new privacy standards could improve trust in the technology sector by zeroing in on data brokers or “gatekeepers” that take potentially anticompetitive actions through measures aimed at security or privacy.

Ms. Brill, a former FTC commissioner, didn’t name particular companies. Google has drawn such criticism over its decision to end third-party cookies that rival companies use to target ads. Apple Inc.’s recent move to restrict how users are tracked on mobile devices has also come under fire from companies that say they have to spend a lot more money to find new customers. A representative for Apple didn’t respond to a request for comment.

While the Biden administration has promised to hold big tech companies accountable, broad rules could prevent businesses from making innovative use of consumer data in the future, said James Cooper, a former official in the FTC’s Bureau of Consumer Protection who is now an associate professor at the Antonin Scalia Law School at George Mason University. Such regulations could take several years to complete despite Democratic commissioners voting in July to streamline the Magnuson-Moss process, Mr. Cooper added.

Ms. Khan, who became FTC chairwoman in June, in her recent statement on the agency’s data strategy called for a shift away from the “notice-and-consent” framework for privacy, in which companies explain their data practices and ask for consumers’ permission to collect and use their information. Ms. Khan wrote that policing unfair or deceptive practices through that lens can sidestep “more fundamental questions about whether certain types of data collection and processing should be permitted in the first place.”

The agency told Congress that its inquiries into such behaviors would include more aggressive probes of digital platforms and enforcement of existing settlements with companies such as Facebook, now called Meta.

The FTC said the expansion would hinge on at least tripling the size of its Division of Privacy and Identity Protection, which has about 40 staffers.

Democratic lawmakers in September suggested creating a new FTC privacy bureau with $1 billion in funding from President Biden’s social-policy plan. But the administration last week pared down the sum to $500 million in its latest blueprint for the package.

Ms. Khan has introduced her approach amid a personnel shake-up that could influence potential rule-making, current and former officials said.

Two staffers who have overseen the FTC’s privacy work in recent years, the deputy director of the Consumer Protection Bureau and the associate director of the Division of Privacy and Identity Protection, left in October to join law firms. An agency spokeswoman didn’t respond to a request for comment on the departures.

Separately, President Biden nominated Alvaro Bedoya, a privacy scholar at Georgetown University, to an open seat on the commission. If approved by the Senate, Mr. Bedoya’s appointment would return Democrats to the majority of the five-member panel. The commission currently has two Democrats and two Republicans.

Noah Phillips, a GOP commissioner, said that differing views on FTC rules illustrate why Congress is best suited to define guardrails, rather than the panel on which he could soon be in the minority.

“The resolution of that question is much better had by elected officials than by, potentially, just three people,” he said.

## Court Ptx DA

#### Antitrust doesn’t affect legitimacy – no one cares

Baum and Devins 10 – Lawrence Baum is a professor emeritus in the Department of Political Science at Ohio State University; his primary research focus is judges’ behavior in decision making. Neal Devins is Sandra Day O’Connor Professor of Law and Professor of Government at William and Mary Law School.

Lawrence Baum and Neal Devins, “Why the Supreme Court Cares About Elites, Not the American People,” *The Georgetown Law Journal*, vol. 98, 2010, pp. 1549-1550, https://scholarship.law.wm.edu/cgi/viewcontent.cgi?article=2149&context=facpubs.

It is worth underlining the point that a great deal of the

Court’s work is essentially invisible to the public. Decisions in fields such as antitrust and patent law may be highly consequential, but it seems unlikely that there are strong public feelings about those decisions. Even if Justices seek to maintain the Court’s legitimacy, they have no reason to worry that public outrage in decisions in those fields will damage this legitimacy.170 More telling, the Rehnquist Court’s federalism revival was unnoticed by most of the mass public. During the period from 1992 to 2006, the Court invalidated eleven federal statutes on federalism grounds,171 thereby shifting the balance between the federal government and the states substantially. Nevertheless, these decisions (although prompting significant law review commentary) appeared to have low political salience.172 Of 229 Gallup Poll questions that explicitly referenced the Supreme Court during this period, there was not a single question concerning these decisions or any other Supreme Court invalidations of federal statutes.173

#### Court isn’t moderating its decisions – their evidence cherry-picks cases – VRA and campaign finance cases prove

Litman and Murray 7/1 – Leah Litman is an assistant professor of law at the University of Michigan Law School. Melissa Murray is a professor of law at the New York University School of Law.

Leah Litman and Melissa Murray, “Don’t be fooled: This is not a moderate Supreme Court,” *The Washington Post*, 1 July 2021, https://www.washingtonpost.com/opinions/2021/07/01/make-no-mistake-this-is-conservative-supreme-court-it-just-sometimes-acts-slowly/.

This Supreme Court term was significant mostly because of what the court did not do: The newly constituted 6-3 conservative supermajority did not use every case to openly and dramatically move the law rightward. Rather, in several important cases — including those involving the fate of the Affordable Care Act and the tension between religious liberty and gay rights — the court managed to resolve matters on seemingly narrow grounds and with broad majorities that transcended ideological differences.

But to call this term a model of judicial restraint — or even nonpartisanship — would be misleading. This is not a moderate or apolitical court. It is a reliably conservative court that, on occasion, chooses to act incrementally.

Characterizing this term as moderate would also overlook the profound impact of the court’s final two decisions, a pair of 6-to-3 rulings — one that hobbled what remains of the Voting Rights Act and another that lays a foundation for a seismic shift in campaign finance rules.

In some cases where there was cross-ideological agreement, the court achieved that result by deciding very little. In its 8-to-1 ruling on the case of the cheerleader disciplined for vulgar speech, the court declined to impose a broad rule letting schools regulate students’ off-campus speech in all circumstances. But meaningfully, the court did not say off-campus speech was never subject to oversight by school authorities. As its reasoning suggests, cross-ideological agreement is possible, as long as you agree to not say very much.

Technical legal doctrines also gave the court a way to appear less ideological. In the Affordable Care Act case, the court, voting 7 to 2, turned aside a third challenge to the law on the narrow grounds that the states and private parties challenging the law didn’t have standing to sue because they couldn’t show they were injured by the unenforceable requirement to obtain insurance.

Cross-ideological agreement also prevailed in the case involving whether Catholic Social Services could decline to certify same-safe couples as foster parents. In Fulton v. City of Philadelphia, the court ruled unanimously in favor of Catholic Social Services’ challenge to Philadelphia’s policy requiring city contractors not to discriminate on the basis of race, sex or sexual orientation. But the court’s fragile unanimity only warded off the more aggressive approach to religious liberty favored by some of the court’s Republican-appointed justices.

Much to the chagrin of some of the court’s most stalwart conservatives, the decision avoided overruling a major religious liberty precedent. But even in its so-called restraint, the majority changed the law. By invalidating a nondiscrimination requirement on the ground that it includes some system for exercising discretion — even if that discretion is never exercised — the court’s ruling opens the door to religious liberty challenges to a wide range of laws and policies.

In lower-profile cases, the court behaved in more obviously ideological ways — with conservatives banding together to aggressively move the law sharply to the right. In a major labor case that continues the conservatives’ hostility toward unions and worker organizing, the six conservative justices voted to invalidate a California regulation that facilitated agricultural workers’ ability to unionize.

The ruling could affect other private-sector unions’ ability to enter employers’ property if organizers cannot easily contact workers off-site. But the potential impact goes far beyond labor organizing. The court concluded that a California law that allowed union organizers to enter a workplace for a few hours a day constituted a taking of private property. This finding could call into question all manner of laws and regulations that require businesses to allow certain people onto their property — including for health and safety inspections, for child welfare or to prevent discrimination in the provision of goods and services.

In another case that will insulate corporations from regulation, five conservative justices held that a major credit reporting agency could not be sued for wrongly labeling its customers as possible terrorists or drug traffickers on a Treasury Department watch list. The decision accelerates a trend toward blocking the courthouse doors to persons seeking to enforce federal consumer protection laws.

As the term reached its conclusion, the muscular conservatism of the Roberts court was in full flower. In a major Voting Rights Act challenge, the justices sharply divided along ideological lines, weakening what remained of the act’s protections for our multiracial democracy. Likewise, in a challenge to a California public disclosure law, the court determined that states cannot require charities to report the identity of their donors to state authorities — a decision that will likely have sweeping repercussions for state and federal laws that require disclosure of campaign donations.

Instead of viewing this term as a triumph of restraint and moderation, we should see it for what it was — table-setting for the term to come. When the court resumes its work in October, it will have even more opportunities to reshape the landscape of American law, including on abortion rights and gun regulation. The question is whether the justices will do so explicitly, or in this term’s more slow and subtle fashion.

#### They’ll overturn Roe now – Texas abortion decision proves

Sarat and Aftergut 9/6 – Austin Sarat is the William Nelson Cromwell Professor of Jurisprudence and Political Science at Amherst College. Dennis Aftergut is a former federal prosecutor who has successfully argued before the Supreme Court.

Austin Sarat and Dennis Aftergut, “Supreme Court trashed its own authority in a rush to gut Roe v. Wade,” *The Hill*, 6 September 2021, https://thehill.com/opinion/judiciary/570958-supreme-court-trashed-its-own-authority-in-a-rush-to-gut-roe-v-wade?rl=1.

But in addition to the harms to women’s rights in this law, the court’s Sept. 1 decision in Whole Women’s Health v. Jackson reveals something dangerous to lawful society writ large: the 5-4 ultra-partisan, conservative majority has, in its haste to gut Roe, eviscerated the rule of law it is supposed to stand for and diminished the court’s own authority.

The decision adds fuel to the already strong arguments for reforming the Supreme Court and urgency to the work of President Biden’s Commission on the Supreme Court.

It concedes, perhaps even celebrates, the fact that states, and individuals, can engage in legally questionable action and evade judicial scrutiny. By allowing Texas to flout Roe’s clear meaning, the court undermines an ordered society and may be paving the way for authoritarian rule.

The decision is a radical departure from the institutional history of the Supreme Court, which previously has been marked by efforts to assert and preserve the court’s exclusive prerogative to “say what the law is.” That was the crux of Chief Justice John Marshall’s famous 1803 opinion in Marbury vs. Madison, the case that established the Supreme Court as the ultimate arbiter of the Constitution’s meaning.

Over time, the court has jealously guarded its authority against those who have challenged it. It is the court’s right to have the last word on constitutional questions that has secured for it a central place in our system of government. As Supreme Court Justice Robert Jackson once explained, “We are not final because we are infallible. We are infallible only because we are final.”

And the court has time and again insisted that everyone abide by its rulings no matter how much they might disagree with them.

This was vividly demonstrated in the civil rights era during the middle of the last century when southern states refused to respect the court’s constitutional decisions and when demonstrators took to the streets to promote racial integration in defiance of court orders. The court responded by insisting to both sides: obey the laws first, and only then can you challenge our views of what the Constitution means.

When Dr. Martin Luther King and other civil rights activists ignored an Alabama state court injunction in the belief that the order to desist from a planned protest was unconstitutional, the Supreme Court upheld their arrest and conviction.

In his majority opinion in the 1967 case of Walker v. Birmingham, Supreme Court Justice Potter Stewart recognized the “substantial constitutional questions” that a challenge to that injunction would have raised. But he firmly rejected the marchers’ contention that they were free to ignore a law they believed to be unconstitutional and condemned their decision to take the law into their own hands:

“This Court cannot hold that the petitioners were constitutionally free to ignore all the procedures of the law…. [I]n the fair administration of justice, no man can be [the] judge in his own case, however exalted his station, however righteous his motives, and irrespective of his race, color, politics, or religion.”

And the U.S. Supreme Court has not been alone in that view nor has it been alone in striking down attempts by citizens or governments to disobey existing law.

In 2004, the California Supreme Court invalidated then-San Francisco Mayor Gavin Newsom’s declaration that the city would marry same sex couples in defiance of an existing voter-approved law that declared “Marriage shall be restricted to a man and a woman.”

Justice Sotomayor’s dissent in Whole Women’s Health makes precisely the same point about courts’ exclusive role in deciding on the law’s meaning. Calling the Texas anti-abortion law a “breathtaking act of defiance,” she labelled the court’s failure to act “stunning.” In her view, it “rewards tactics designed to avoid judicial review and inflicts significant harm on the applicants and on women seeking abortions in Texas.”

Until last week, defense of the judiciary’s role in saying what the law is and insisting that others defer to its judgments has united conservative and liberal justices.

But, in Whole Women’s Health, only one conservative, Chief Justice Roberts, joined with the court’s three liberal justices in standing up for such nonpartisan jurisprudential principles. His five conservative colleagues seem so eager to gut Roe that they are willing to disembowel the judiciary’s own authority.

The risk of legal chaos from the Supreme Court’s inaction on Sept. 1 may soon be realized in a kind of Cold War between the states.

Imagine blue states reacting to Whole Women’s Health with laws permitting private lawsuits against anti-vaxxers who help someone evade a business’s COVID vaccination mandate, or against owners of banned guns whose prohibition is the subject of federal court challenges.

When the current conservative majority on the Supreme Court trashes its own authority to tilt the scales in the current culture wars, it endangers the liberty of all, no matter which side of the cultural wars they are on.

#### No swing vote

Peter W. Stevenson, Washington Post, Chief Justice John Roberts: From key swing vote to potential bystander?” May 20, 2021, <https://www.washingtonpost.com/politics/2021/05/20/chief-justice-john-roberts-key-swing-vote-potential-bystander/>

The Supreme Court has long declined to take on such cases, often falling back on the precedent set by previous decisions. Under Roberts, even with a 5-4 conservative majority after Trump’s first two nominees, Neil M. Gorsuch and Brett M. Kavanaugh, were confirmed, the court seemed reluctant to take on big, landmark cases — and certainly to challenge precedent on politically sensitive issues. It has been suggested that Roberts aimed to make the court appear less political by avoiding those sensitive issues. Some conservatives have even said he lacks the will to address issues such as abortion at all. But such things could increasingly be out of his hands.

Roberts’s status as a key swing vote was solidified by the 2012 decision he wrote upholding the Affordable Care Act’s constitutionality, in which the individual care mandate was preserved as a tax, a decision that infuriated conservatives.

But his supposed efforts to depoliticize the court were blunted by Barrett’s appointment. In a 6-3 court, Roberts is no longer a swing vote. Even if he were to side with the liberal-leaning justices, they could be outvoted 5-4.

This isn’t the first case that has seemingly made Roberts’s vote potentially less potent — but it has the potential to be the most high-profile (though we have no idea what the court will do with it).

# 1AR

## Prices Adv

Kicked

## Innovation Adv

#### U.S. commitments abroad k2 deterrence

Paolo Von **Schirach 16** --- Resident. of the Global Policy Institute. Chair of the International Relations and Political Science Programs at Bay Atlantic University.

[Published: 7-24-16. "Trump's Remarks On NATO.” Schirach Report. Accessible: http://schirachreport.com/2016/07/24/trumps-remarks-nato/]

NATO’s credibility rests mostly on the U.S. unconditional commitment to defend Europe. If future U.S. policy indicates that this blanket commitment is subject to conditions, this may encourage aggression, or at least unfriendly actions on the part of Russia, always keen to exploit divisions between the U.S. and its European allies.

Here is what Article 5 of the NATO Treaty says: The Parties agree that an armed attack against one or more of them in Europe or North America shall be considered an attack against them all and consequently they agree that, if such an armed attack occurs, each of them, in exercise of the right of individual or collective self-defence recognised by Article 51 of the Charter of the United Nations, will assist the Party or Parties so attacked by taking forthwith, individually and in concert with the other Parties, such action as it deems necessary, including the use of armed force, to restore and maintain the security of the North Atlantic area. [Emphasis added].

Unconditional pledge

It is clear that the NATO Treaty makes no mention of added conditionalities. It clearly stipulates that an attack against one NATO member shall be considered by all the others as an attack against all. Therefore, technically speaking, Trump’s remarks are wrong, and frankly ill-advised. Indeed, Trump’s glib remarks about circumstances that he would look at as president before deciding whether or not to come to the help of a European NATO country in peril are most inappropriate. The U.S. is bound to help a fellow NATO member because of a Treaty obligation. There is no gray area.

#### It's the key part

[Stanley **Sloan**](https://www.linkedin.com/in/stanley-sloan-4973ba?authType=NAME_SEARCH&authToken=FC1z&locale=en_US&srchid=174826001448403803714&srchindex=1&srchtotal=24&trk=vsrp_people_res_name&trkInfo=VSRPsearchId%3A174826001448403803714%2CVSRPtargetId%3A992563%2CVSRPcmpt%3Aprimary%2CVSRPnm%3Atrue%2CauthType%3ANAME_SEARCH) **17** --- Nonresident Senior Fellow, Atlantic Council of the United States, Member, Duco Experts, Visiting Scholar in Political Science, Middlebury College.

[Published: 2-16-17. “[US may moderate its commitment to NATO. What does it mean?](https://matisak.wordpress.com/2017/02/16/us-may-moderate-its-commitment-to-nato-what-does-it-mean/)” Matisak’s Blog. Accessible: <https://matisak.wordpress.com/2017/02/16/us-may-moderate-its-commitment-to-nato-what-does-it-mean/>]

Is this a different form of President Trump’s suggestion that the United States might not honor the Article 5 collective defense provision of the North Atlantic Treaty in the case of allies that were not taking on their “fair share” of the burden? Or does it mean that the United States would start pulling back forces from Europe, now that it had just started to build them back up again as a response a more aggressive Russia?

In any case, it is clear the allies need to make an enhanced commitment to the 2% spending goal by the end of 2017.  Just prior to the Mattis visit, NATO Secretary General Stoltenberg had praised the allies for defense spending increases in 2016 and called for more. That was useful guidance but, at least for the next four years, the allies apparently will not know what Washington’s commitment to NATO really means. Uncertainty now rules the roost.

As any strategic thinker knows, uncertainty can play more than one way in deterrence policy. NATO’s deterrence policy is intended to deter the Russian bear from thinking it can gain political influence or, in the extreme, battlefield victories against any NATO ally. It is good for this policy if Vladimir Putin doesn’t know exactly what kind of response NATO might mount to one case or another of Russian aggression, but knows that a response of some sort is guaranteed. That’s constructive uncertainty. However, if Putin sees that it is uncertain whether the United States would come to the aid of any one of its NATO allies to defend against threats ranging from political pressure, to invasions of little green men, or to nuclear blackmail, deterrence becomes less certain and the temptations for Moscow more inviting.

The point is that deterrence is a precious commodity; it can under some circumstances be purchased for a relatively small price if the political commitment behind it is credible. The focus of strategic discussions very often is on the need for capabilities to ensure that deterrence reassures allies and deters adversaries. But if the commitment is not politically sound, the actual cost could be a miscalculation by the adversary with potentially devastating consequences.”

#### Carve-outs undermine our deterrent credibly broadly---risks WWIII.

Richard C. **Longworth 16** --- Distinguished fellow at the Chicago Council on Global Affairs and former chief European correspondent for the Tribune.

[Published: 10-06-16. “Trump's poor grasp of NATO is dangerous.” Chicago Tribune. Accessible: <https://www.chicagotribune.com/opinion/commentary/ct-nato-trump-europe-russia-perspec-1005-md-20161004-story.html>]

For one thing, as the biggest contributor, we have the most clout. Through decades, NATO has been a useful arm of American foreign policy. We have 27 allies sheltering under the American nuclear umbrella. In return, these allies have helped us do things that without them we'd have to do ourselves.

More important, NATO is the difference between war and peace. In the two great European wars of the 20th century, 300,000 Americans died. In the 71 years since then, no American has died in European combat. What price tag do we put on seven decades of peace?

This is what Trump really doesn't get. NATO has turned the Western world, and especially blood-soaked Europe, into a zone of peace. It won the Cold War, virtually without a shot being fired. Early on it provided the security framework within which the West Europeans rebuilt their shattered societies. And then, in the 1990s, it did the same for the post-Communist East Europeans.

All this was, and is, enforced by NATO behind American leadership. Crucially, it is based on Article 5 of the NATO treaty, which says flatly that an attack on any NATO member is an attack on all members, which will respond immediately.

This promise deterred the Soviet Union for the 46 years of the Cold War. Would we really have gone to war if the Soviets had attacked Germany, or Norway or Turkey? Who knows. The point is that Moscow didn't know either but thought we would and wasn't willing to take the chance.

In other words, peace in Europe rests totally on trust in the credibility of NATO and the United States. Now comes Trump saying that we may or may not defend our allies, depending on whether they've paid their dues.

This rips up Article 5. It undermines the trust and credibility of America's word. Trump has given Russian President Vladimir Putin reason to believe that, if he wants to attack Poland or Lithuania, a President Trump will let him get by with it.

When Trump the businessman broke his word, the result was bankruptcies. If Trump the president breaks his word, the result could be World War III.

## FDA CP

#### Antitrust is comparatively better – narrower objectives

Lambert, Wall Family Chair in Corporate Law and Governance Professor of Law, University of Missouri Law School, November, ‘11/1/21

(Thomas, “Tech Platforms and Market Power: What’s the Optimal Policy Response?” Mercatus Working Paper)

The agency oversight approach, however, is not simply “faster antitrust with expert adjudicators.” While standards-based and flexible, the approach differs from antitrust along three significant dimensions: focus, political susceptibility, and duration of control. Taken together, antitrust courts’ more narrowly focused objectives, greater insulation from political influences, and limited jurisdiction over their subjects render them far less susceptible to adverse public choice concerns than agencies like the UK’s DMU.

In crafting remedies for anticompetitive harm, antitrust courts have a tremendous reservoir of authority.174 But antitrust’s focus—and the objective of any court-ordered remedy—is narrow: the restoration of market output to competitive levels for the benefit of consumers.175 This precludes successful claims by, and remedies in favor of, parties seeking some private benefit apart from the enhancement of market output. A digital markets regulator is unlikely to be as laser-focused on output effects as an antitrust court and will therefore be a more attractive target to rentseeking firms. The DMU’s “open choices” objective, for example, invites a laggard competitor that might otherwise be driven out of business to seek some rule hindering its more efficient rivals, on the ground that preserving its own offering will create a broader range of options for consumers.

#### Even if antitrust enforcers are politicized, adjudication is by judges, who are politically insulated

Lambert, Wall Family Chair in Corporate Law and Governance Professor of Law, University of Missouri Law School, November, ‘11/1/21

(Thomas, “Tech Platforms and Market Power: What’s the Optimal Policy Response?” Mercatus Working Paper)

A second important difference between antitrust courts and agencies relates to the decision makers’ incentives. The federal judges determining liability and imposing remedies in antitrust cases have little reason to please the parties before them. Possessing life tenure and fearing no retribution save possible reversal, they are insulated from outside pressure and motivated to make decisions calculated to enhance market output and thereby benefit consumers. The bureaucrats staffing agencies, by contrast, do not enjoy this level of political insulation. Many will have been appointed by or have ties to a political leader, whom they will wish to please. They may also contemplate future employment at one of their regulatees or at a regulatee’s rival. Even absent contemplation of a job change, they may have a stake in one regulatory outcome over another, as the budget or prestige of their agency may be affected by the regulatory choices they make. Their personal interests are therefore less aligned with the public’s interest in maximizing overall market output.

#### The deciding factor is ties to big pharma – senators are directly asking Califf for assurance that he’ll stand up to big pharma

Firth 12/14 – Health policy reporter and Washington correspondent for MedPage Today since 2014.

Shannon Firth, “Senators Grill Califf On Role in Opioid Crisis, Abortion Pill Restrictions,” *MedPage Today*, 14 December 2021, https://www.medpagetoday.com/publichealthpolicy/fdageneral/96199.

Ties to Big Pharma

Sen. Bernie Sanders (I-Vt.) raised concerns over the revolving door between the FDA and pharmaceutical industry. He flagged one person in particular, Curtis Wright, who served as a "high-ranking official." After leaving the agency in the mid-1990s, he received a $400,000 compensation package from Purdue Pharma "less than a year after [the FDA] approved Oxycontin with a label that said it was, quote, very rare, end quote, for patients to become addicted to that opioid."

Since leaving the FDA, Califf has made "several hundred thousand dollars" from pharmaceutical companies, Sanders noted, and according to his own financial disclosure statements, currently owns "up to $8 million in stock of major pharmaceutical companies."

Given these close industry ties, Sanders asked what reassurance Califf could offer Americans that he will be "an independent and strong voice" for the agency?

"I am a physician first and foremost," Califf said, citing his work in intensive care units in the early part of his career.

But Sanders persisted, calling out Califf's work as a consultant in the pharmaceutical industry. "How can the American people feel comfortable you're going to stand up to this powerful special interest?" he asked.

#### Key senators are winnable – he can convince them he’s willing to crack down on big pharma – Warren vote proves

Barrón-López and Cancryn 1/31 – Laura Barrón-López is a White House Correspondent for POLITICO. Adam Cancryn is a health care reporter for POLITICO Pro.

Laura Barrón-López and Adam Cancryn, “Biden’s FDA pick makes major ethics pledges to win over Elizabeth Warren,” *POLITICO*, 31 January 2022, https://www.politico.com/news/2022/01/31/bidens-fda-pick-ethics-pledges-elizabeth-warren-00003529.

President Joe Biden’s nominee to lead the Food and Drug Administration is making major ethics concessions to Sen. Elizabeth Warren as he tries to lock down critical confirmation votes.

Robert Califf, who was first nominated more than two months ago, is agreeing to not seek employment or compensation from any pharmaceutical or medical device company that he interacts with “for four years” following his time in government, according to a letter he sent to the Massachusetts Democrat and obtained by POLITICO.

A spokesperson for Warren said that, should Califf’s nomination ultimately come to a vote, the Massachusetts Democrat plans to support him.

In the letter, Califf also agreed to a four-year period in which he will recuse himself from decisions before the agency related to companies with which he had relationships. Originally, the recusal period was two years.

“The Biden-Harris Administration has set the highest ethical standards of any Administration for its political appointees,” Califf wrote to Warren last week. “However, in response to your letter, I am willing to voluntarily extend the recusal period from two years to four years for all particular matters involving companies with which I have a previous working relationship.”

A spokesperson for the Health and Human Services Department declined to comment. Califf did not respond to a request for comment. But an administration official defended Califf’s ethical track record, noting that he was confirmed by an 89-to-4 vote to lead the FDA during the Obama administration. At that time, Warren requested to see all research contracts between pharmaceutical companies and the Duke Clinical Research Institute founded by Califf. She subsequently voted for Califf.

Califf’s commitments come after Warren met with him privately earlier this month to discuss his nomination. The administration official said that Warren had asked Califf to “sign on to ethical standards that go beyond the Administration’s high standards and he agreed” during that meeting.

The Massachusetts Democrat, who has pushed other Biden appointees to adopt stronger ethical standards, was among a handful of Democrats concerned by Califf’s $2.7 million paycheck for advising the Alphabet-owned Verily Life Sciences. That work, along with board seats Califf held on two other pharmaceutical companies, came after he served as FDA commissioner in the Obama administration.

#### Even if Califf isn’t in charge yet, the FDA’s decisions still reflect on him – abortion pill proves

Weixel 2/3 – Healthcare reporter for The Hill.

Nathaniel Weixel, “FDA nominee meets unexpected hurdles,” *The Hill*, 3 February 2022, https://thehill.com/policy/healthcare/592591-fda-nominee-meets-unexpected-hurdles?rl=1.

On the Republican side, anti-abortion groups have been lobbying hard against Califf. The Susan B. Anthony List said it would “key vote” Califf’s nomination as a result of his work on the abortion drug mifepristone during the Obama administration.

Nearly all Republican senators have an A+ from the organization, with the exceptions of Sens. Susan Collins (Maine) and Lisa Murkowski (Alaska). Collins and Murkowski joined with Sens. Mitt Romney (Utah) and Richard Burr (N.C.) as the only Republicans to vote for Califf in committee.

Burr, who is the top Republican on the Senate Health Committee, said he knows his colleagues are feeling pressure from anti-abortion groups worried about increased access to mifepristone.

“I like him,” Burr said of Califf. “I think he’ll be confirmed. The overall concern is from the pro-life community, which Dr. Califf wasn’t there when this decision was made, so I’m not sure why they’re so irate.”

## Court Ptx DA

#### Moderate trends won’t hold – the world ends next term

Robinson 6/18 – Supreme Court reporter for Bloomberg Law.

Kimberly Strawbridge Robinson, “Barrett Channels Roberts’ ‘Go-Slow’ Approach in Landmark Cases,” *Bloomberg Law*, 18 June 2021, https://news.bloomberglaw.com/us-law-week/barrett-channels-roberts-go-slow-approach-in-landmark-cases.

End of the World

But the ACA and LGBT cases, along with the extraordinary agreement all term, suggests a majority of the justices don’t think it’s the right time to make major changes in the law.

“In the throes of everything"—the pandemic, Barrett’s first term, Kavanaugh’s biting confirmation, calls for Breyer to retire, and the caustic 2020 presidential election—"they didn’t want to shock the world this year,” Segall said.

“Preserving the court’s own political capital is incredibly important to the justices because they know their only capital is the confidence of the American people,” he added.

Adler said the court has developed a sort of 3-3-3 split—that is, three liberals, three conservative justices willing to chuck precedents they don’t agree with, and three conservative justices hesitant to overturn cases they may disagree with. Roberts, Kavanaugh, and now, apparently, Barrett make up that last group.

Adler said that split will create some interesting pressures for the three justices in the middle next term, when—as Segall said—"the world will end.”

The end of the world was a reference—in part—to the court’s abortion case, which could call into question the landmark ruling in Roe v. Wade and later cases.

Incomplete Story

The ACA and LGBT rulings are, however, not the complete story on Barrett, who isn’t even a full year into what’s likely to be a decades-long tenure.

Barrett’s nomination raised questions about her personal views on abortion and whether they would influence her decisions. In a 1998 law review article, she wrote that abortion and euthanasia “take away innocent life” and that abortion is “always immoral.”

On guns, some have seen a willingness in Barrett to go further even than the late Justice Antonin Scalia in protecting Second Amendment rights.

And along with the blockbuster issues the justices are set to tackle next term, the court still has some consequential cases to decide, including a free speech case dealing with corporate disclosures and a property dispute involving labor organizing.

Adler said he’d expect to see some splintered rulings this term.

Moreover, “we have seen important 6-3 decisions” in cases like Jones v. Mississippi and Edwards v. Vannoy, Chemerinsky said, referring to cases on life sentences for juvenile defendants and unanimous jury verdicts for criminal trials.

Both divided the justices ideological, with Barrett siding with her conservative colleagues.

#### Statistical analysis proves the court is moving rightward – conservatives disagree about the speed of shift, not the direction

Bronner and Mejía 7/2 – Laura Bronner is FiveThirtyEight’s quantitative editor. Elena Mejía is an associate visual journalist at FiveThirtyEight.

Laura Bronner and Elena Mejía, “The Supreme Court’s Conservative Supermajority is Just Beginning to Flex Its Muscles,” *FiveThirtyEight*, 2 July 2021, https://fivethirtyeight.com/features/the-supreme-courts-conservative-supermajority-is-just-beginning-to-flex-its-muscles/.

Understanding the full impact of former President Donald Trump’s 6-3 conservative supermajority is challenging at this point, though. On the one hand, this term saw the highest share of unanimous rulings in the last three years. On the other hand, the court’s last two major rulings broke down along 6-3 ideological lines. But that seeming inconsistency may have more to do with divisions among the court’s conservatives over how fast to move — not in what direction. Make no mistake, the court is moving in a conservative direction, and the conservative justices are in the driver’s seat.

To understand the court’s rightward shift, look no farther than the justice now at the center of the court: Justice Brett Kavanaugh. A position once held by Chief Justice John Roberts, this year’s preliminary Martin-Quinn scores, a prominent measure of the justices’ ideology, suggest Kavanaugh, not Roberts, was this term’s median justice. What’s most striking here, though, is not that Kavanuagh is at the center of the court, but the lack of daylight between where Roberts, Kavanaugh and even Justices Amy Coney Barrett and Neil Gorsuch are estimated to fall on the court.

One way to interpret the justices’ ideological scores this term is that there are actually multiple “median” justices on this court, as any split decision in which the liberal justices are part of the majority involves at least two conservative justices voting with the liberals. At the very least, Kavanaugh’s position at the center of the court doesn’t suggest he’s getting more liberal: Neither Kavanaugh nor Roberts are estimated to have moved to the left at all compared to where they fell last year. Rather, the replacement of the late Justice Ruth Bader Ginsburg by Barrett, whose ideological score this term is estimated to fall to the right of that of Roberts and Kavanaugh, has shifted the center of the court — and shifted it in a more conservative direction.

Of course, the Martin-Quinn scores are not a perfect measure of the justices’ ideology. Other work has shown that there is no single median justice on the court. Instead, different issues before the court often attract different “median” justices.

“The Supreme Court isn’t quite as one-dimensional as everyone says it is,” Josh Fischman, a law professor at the University of Virginia, told us.

That said, a conservative quad made up of Roberts, Kavanaugh, Barrett and Gorsuch has dominated the court’s decisions this term. Kavanaugh was in the majority in 97 percent of all cases this term — and in the majority in a whopping 95 percent of divided cases. Roberts wasn’t that far behind. He was in the majority in 91 percent of all cases and 84 percent of divided cases.1 Barrett and Gorsuch also were in the majority in more than 80 percent of divided cases. And in another sign that the court is moving in a rightward direction: Justices Thomas and Alito were in the majority 80 and 83 percent of the time, respectively, despite their images as the perennial dissenters. In fact, it was the three liberal justices who dissented most this term, perhaps unsurprisingly given the makeup of the court.

There was a lot of hype this term around the number of unanimous decisions issued — 44 percent in all — but that wasn’t actually all that unusual. In the previous 10 terms (2010-19), an average of 47 percent of cases were decided unanimously. And as you can see in the chart below, the rate at which the justices agreed with each other is still telling. The three liberal justices agreed with each other far more than with any of the other justices; the same was true of the five conservative justices. In fact, the two justices who are the most in lockstep are Roberts and Kavanaugh (they went the same way in 94 percent of all cases).

Barrett also was often lockstep with Gorsuch and Kavanaugh (she agreed with each of them in 91 percent of the cases in which she participated).2 It’s worth noting, though, that justices’ first years can be a bit misleading — in Kavanaugh’s first term on the court, for instance, he agreed as much with Justice Elena Kagan as he did with Gorsuch (70 percent), but in his second term he agreed far more with Gorsuch (88 percent) than with Kagan (72 percent), a pattern that has held true this past year as well.

Here, though, is where we can see Thomas and Alito earn their reputations as the two justices least likely to agree with the other justices. This term, they both agreed with Gorsuch the most (88 percent of the time), and although Alito voted in line with the other conservative justices (at least more so than Thomas), both conservative justices stand out for just how infrequently they agreed with the liberal justices — underscoring how intractable some members of the court’s conservative majority are.

So, what does this tell us about the court overall? As we said at the outset, it’s too early to evaluate just how far Trump’s conservative majority will fundamentally shift law in this country to the right. But we would caution that it’s important not to confuse disagreement among the conservative justices — which evidently exists — with disagreement over the direction the court is moving. Alito’s dissents, for instance, show impatience with the speed the court is moving at, but a closer look at some of the conservatives’ opinions reveal that even when they find themselves on opposite sides of Alito and Thomas, they still largely agree with them on the merits. Take Kavanaugh on the court’s decision to uphold the Centers for Disease Control and Prevention’s nationwide moratorium on evictions because of the COVID-19 pandemic. He joined the majority opinion, even though he thinks the CDC exceeded its authority in issuing the moratorium, saying he ultimately didn’t think it was worth overturning the moratorium because it ends July 31 anyway — hardly a ringing endorsement of the merits of the case. Or take Barrett on Fulton: She joined the majority opinion, but issued a separate concurrence with Kavanaugh, where both suggested they remain open to overturning the ruling in Employment Division v. Smith, which would dramatically change how courts evaluate laws that impose restrictions on religious groups.

Additionally, one caveat of the data we’ve looked at is that the justices’ ideology scores or how much they agree with each other don’t account for the types of cases the justices hear. For instance, this term, several of the highest-profile cases still resulted in the expected 6-3 ideological split. The Voting Rights Act of 1965 will now be less enforceable. Union access to workplaces will be restricted. Disclosure requirements for some political donations will have less oversight. And there won’t be any constraints on life sentences for juvenile offenders.

In other words, the conservative supermajority on the court has really just begun to flex its capabilities. What kinds of cases the justices decide to take on is as important as how they rule, and many of the cases decided this term were taken while Ginsburg was still on the court. The current court has already decided to take up cases on abortion and gun rights next term — two hot-button issues that might give us better insight into just how far, and quickly, the court is willing to move law to the right.

#### “Moderate” decisions won’t persist – conservative justices reliably vote as a bloc

Ford 6/30 – Staff writer for The New Republic.

Matt Ford, “Yes, It’s Still a Conservative Supreme Court,” *The New Republic*, 30 June, 2021, https://newrepublic.com/article/162878/barrett-roberts-moderate-supreme-court-term.

The Supreme Court’s October 2020 term wraps up this week, and it wasn’t as bad as some liberals may have had reason to fear. This has led some observers to question if the court is as conservative as previously assumed. Conservative and liberal are hazy, elastic terms in everyday politics, so some allowances can be made. These terms are even less useful in the context of the Supreme Court, where the justices’ judicial philosophies don’t always reflect America’s partisan divides. But by any defensible standard, the Supreme Court’s conservative majority is secure, if not fully operational.

According to preliminary statistics by SCOTUSblog, all six of the court’s conservative justices were part of majority rulings more often than their liberal colleagues. Leading the pack was Justice Brett Kavanaugh, who found himself in 97 percent of the court’s majorities this term. On the liberal side, Justices Elena Kagan and Stephen Breyer each found themselves in the majority 80 percent of the time, and Justice Sonia Sotomayor trailed at 72 percent. (All statistics in this article exclude Brnovich v. Democratic National Committee and Americans for Prosperity Foundation v. Bonta, which haven’t yet been released.)

Though some of the rulings had unpredictable coalitions, there is still evidence of a strong ideological split among the justices. Justice Amy Coney Barrett voted with her conservative colleagues between 94 percent (Kavanaugh) and 84 percent (Justice Samuel Alito) of the time. By comparison, she voted with Elena Kagan 76 percent of the time, with Stephen Breyer 71 percent of the time, and with Sonia Sotomayor just 65 percent of the time. Barrett and Kavanaugh were the closest pair of justices on the court this term, followed closely by Chief Justice John Roberts and Kavanaugh at 93 percent.

In recent weeks, these shifting coalitions have given rise to the notion that the 6–3 split is really a 3–3–3 split, with Roberts, Kavanaugh, and Barrett at the court’s center and the court’s liberals and conservatives revolving around them. It’s an elegant model—and a flawed one. For one, a justice’s first year is an imperfect indicator of their long-term voting patterns. It’s exceedingly unlikely that Barrett will end up like Justice David Souter, who drifted away from the conservatives to become a reliable member of the court’s liberal wing. But as she becomes more familiar with the court’s dynamics, and as Supreme Court litigants become more familiar with how she approaches cases, some drift could happen in either direction.

Another problem with the 3–3–3 model is that it doesn’t accurately capture the relationships on the court’s right wing. Alito voted with Roberts (83 percent) roughly as often as he voted with Clarence Thomas (82 percent). Justice Neil Gorsuch would almost qualify as a member of the center as well, since he voted with Kavanaugh and Barrett more often than anyone else, at 89 and 90 percent respectively. But he voted with Roberts only 82 percent of the time, far less often than with any of his other conservative colleagues. Half of the court’s conservative bloc has only joined the court in the last five years, and to a certain degree, they’re still figuring each other out.

Last term, it was Roberts who firmly controlled the court’s direction and the outcome of cases. The chief justice was in the majority in 97 percent of cases at the time and cast the deciding vote in 13 of the court’s fourteen 5–4 decisions that term. That figure dropped to a slightly more humble 90 percent this term. But there are signs that Roberts’s influence and moderation continues to shape the court’s results. Among the most striking figures of the court’s most recent term is that Roberts voted with Breyer and Kagan slightly more often than he voted with Clarence Thomas, the dean of the court’s conservative wing.

Some of the justices publicly reject the idea that they’re divided into neat ideological blocs. “We agree more than you think,” Breyer explained in a National Constitution Center podcast earlier this month. “I mean, we agree almost half the time, we’re unanimous and the five-fours are about, I don’t know, 20 percent, 25 percent, 15 percent, depending on the year. And it’s not the same five and the same four.” In literal terms, Breyer’s analysis is correct. A unanimous Supreme Court decided a plurality of cases in the 2019 term, and even the most divided justices of the 2020 term—Sotomayor and Alito—still found themselves voting together 57 percent of the time.

But in a more practical sense, his depiction is flat-out wrong. Occasionally there are major cases that result in 9–0 rulings: This term’s cross-ideological antitrust ruling against the NCAA is a classic example. But many of the court’s unanimous decisions involve arcane legal issues or simply don’t affect most Americans’ day-to-day lives. The public generally won’t notice rulings on how ERISA plans interact with some state laws or whether a plaintiff has standing to challenge Delaware’s judicial-balance requirement. But they do feel the effects of 5–4 decisions on abortion rights, gun ownership, and other major political issues. And while not all of those decisions fall along the expected ideological lines, enough of them do to make it a valid framework for understanding the court’s actions.

That said, describing a case as a “conservative victory” or a “liberal victory” can often oversimplify things. There are clear conservative victories: the 6–3 ruling in Cedar Point Nursery v. Hassid earlier this month that made it easier for farm owners in California to obstruct union organizing efforts on their property. And there are clear liberal victories, such as the Obergefell v. Hodges decision six years ago that found a constitutional right to marriage equality. But not every case or outcome falls so neatly along the prevailing political lines.

Consider this year’s two most high-profile rulings. In California v. Texas, the Supreme Court rejected a GOP-led bid to strike down the entire Affordable Care Act on a bad-faith technicality. Most observers expect this to be the last existential legal fight over the landmark health care law. In Fulton v. City of Philadelphia, the justices sided with a Catholic foster agency on exceedingly narrow grounds, once again avoiding the broader question of whether religious freedom claims outweigh laws that protect gay and transgender Americans from discrimination. On paper, both seem like clear victories for liberal causes and interests.

But the reality is less straightforward. California v. Texas was the product of aggressive jurisdiction-shopping by right-wing legal activists who managed to get an extremely dubious legal argument heard by a highly sympathetic federal judge in Texas. A 7–2 majority brushed it aside on standing grounds. In Fulton, the plaintiffs sought not only to prevail against the city but also to overturn Employment Division v. Smith, a landmark Supreme Court ruling that limits Free Exercise Clause claims. The court only gave them some of what they wanted. These are not cases where liberals started a fight and won, but rather cases where conservatives started a fight and (mostly) lost.

Conservative overreach is a persistent theme behind most of the major liberal “victories” at the high court in recent years. In the court’s two most recent abortion-related rulings, in 2016 and 2020, four liberals and one conservative justice—Anthony Kennedy and John Roberts, respectively—narrowly preserved the legal status quo for abortion clinics in states that sought to shut them down. In 2016, Kennedy also joined with the court’s liberals to rule in favor of the University of Texas’s race-conscious admissions program in a case brought by right-wing legal groups. In both cases, liberals fended off conservative bids to upend settled law.

That brings us to one of the most underappreciated factors behind a court’s ideological makeup: the kinds of cases that the justices decide to hear in the first place. Advocates from across the ideological spectrum closely follow how the justices decide certain cases and try to anticipate how they would rule on certain issues. When those expectations line up, as they did with gay rights activists and Kennedy over the last decade, major changes in constitutional law can occur.

Fulton, by comparison, is a classic example of when those expectations don’t line up with the Supreme Court’s reality. As I noted last year, there was good reason to believe the court would overturn Smith. Four of the court’s conservatives had effectively signaled that they would vote to do so in a minor written opinion, and even if Roberts wasn’t on board, Barrett’s addition was seen as a promising sign. But she instead voted not to do so this time, writing in a concurring opinion with Kavanaugh that she was unpersuaded by the constitutional and practical arguments and didn’t have a clear sense of what should replace it. Conservative legal activists will spend the summer deciding how best to answer those concerns in future litigation.

To reduce the justices to their labels can also flatten their individual quirks. In his time, Scalia took a more expansive approach to the Fourth Amendment than some of his colleagues on the right. Gorsuch has written multiple times about America’s duty to live up to its promises to Native American tribes, setting him apart on an underappreciated area of the law at the high court. (His ruling in Bostock v. Clayton County last term suggests he may not be reflexively opposed to legal protections for gay and transgender Americans.) Thomas’s eclectic approach to constitutional law often cuts against liberal interests but also occasionally intersects with them: He has called into question the reasoning behind qualified immunity and recently suggested that some federal bans on marijuana are no longer constitutionally tenable.

But there are still clear trends in how the court’s conservative majority hears and decides cases. Religious freedom claims are generally favored by the court unless they involve Muslims, death-row prisoners, or both. Class-action lawsuits are viewed skeptically by a court that has sought to limit them on multiple fronts. Long-standing precedents and well-established rules that strengthen unions and help workers organize are often disfavored. Death-row prisoners are treated with skepticism at best and hostility at worst, with their claims dismissed as bad-faith impediments to a state’s right to execute. Constraining the administrative state and bolstering executive power are frequent favorites.

There are strong reasons to believe a six-justice conservative majority will broaden its horizons even further in the coming years. Gun rights advocates will press the court to embrace a broader reading of the Second Amendment, one that could invalidate state and local restrictions across the country. Opponents of affirmative action in higher education recently asked the justices to review a major challenge to Harvard’s admissions policies. And the Supreme Court has already docketed its most highly anticipated case in years for next fall: Dobbs v. Jackson Women’s Health Organization, where the justices could reverse a half-century of abortion rights precedents.

#### Decisions like the aff can’t affect legitimacy – public needs a defined opinion for the case to be salient

Crane 13 – Professor of law at the University of Michigan.

Daniel A. Crane, “Antitrust and the Judicial Virtues,” *Columbia Business Law Review*, no. 1, 2013, pp. 4, https://core.ac.uk/download/pdf/232689875.pdf.

Antitrust law is not plagued by a substantial countermajoritarian difficulty and thus presents no reason for judges to exercise passive or avoidant virtues. Judges making antitrust law do not have to worry that their decisions will trump the popular will, except in the limited sense that they may reject suits by public enforcers like the Justice Department or Federal Trade Commission ("FTC"). To the extent that judges promulgate legal norms different from those favored by the executive branch, a small countermajoritarian difficulty is presented. But since judicial antitrust decisions are theoretically reversible by Congress, the courts do not have the final word on antitrust questions, as they do in constitutional cases. There is therefore little reason for judges to worry that their decisions in antitrust cases will compromise the legitimacy of the courts by undermining popular will.