

NEW RULES FOR THE 21ST CENTURY:

CORPORATE POWER, PUBLIC POWER, AND THE FUTURE OF PRESCRIPTION DRUG POLICY IN THE UNITED STATES

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INTRODUCTION

Today's pharmaceutical industry is failing most Americans. Every day, a new story emerges about an outrageous price spike for a lifesaving drug, a fraud perpetrated on the American people in the name of profit, or the revolving door of administration officials entering an agency from a drug company or leaving to go to one—a practice so common it hardly raises an eyebrow. In 2016, total drug costs in the US increased by 6.3 percent, approximately triple the rate of other goods and services (Gill 2018), and Americans pay as much as six times more for brand-name prescription drugs than do their global counterparts (Kounang 2015). In an attempt to keep their health care costs under control, Americans are increasingly rationing their care to address these increased costs; roughly 11 percent of adults skip doses, delay filling prescriptions, or take less than prescribed (Cohen, Boersma, and Vahratian 2019).

This broken system may not be producing good health outcomes for Americans, but it is resulting in record profits for the pharmaceutical industry. Between 2006 and 2015, revenue from pharmaceutical and biotechnology sales rose from \$534 billion to \$775 billion in adjusted dollars (US GAO 2017). During that time, 67 percent of drug companies increased their annual profits—with some seeing as much as 20 percent higher profit margins in a single year (US GAO 2017).

The common refrain from the health care industry is that high costs are the price we must pay for innovation. This refrain is based on highly contested empirics: While US pharmaceutical companies claim the cost of bringing a new drug to market is around \$2.6 billion, there is evidence that their methodology is flawed, and estimates suggest the cost for at least some types of drugs is less than a third of what pharmaceutical companies claim (Prasad and Mailankody 2017). The relationship between high prices and research and development (R&D) is also belied by drug companies' pattern of raising prices on generic drugs or other products for which the R&D was completed long ago.

Moreover, these statements from the industry about the cost of innovation accept the notion that these innovation costs should be passed on to *consumers through the market*, rather than absorbed by the public more broadly. Investments in research need not—perhaps should not—be

paid for by individual patients in need of prescription drugs, but by the public, directed by the public, and accountable to the public. The idea that the high costs of medicines are the price we must pay for innovation evinces a worldview that is wholly blind to anything but a marketized approach to prescription drug provision, despite the ways that such an approach cannot and will never meet the needs of American patients.

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The purpose of this issue brief is to propose another way. Building on a framework recently developed by the Roosevelt Institute’s Nell Abernathy, Darrick Hamilton, and Julie Margetta Morgan in *New Rules for the 21st Century: Corporate Power, Public Power, and the Future of the American Economy*, this brief will propose a series of structural reforms that deploy the tools of government in expansive ways—as Abernathy et al. describe it, a “one-two punch”—to rein in the industry’s extractive practices through stiffer market regulation and a substantially more aggressive use of direct public provisioning and democratically-accountable drug development (Abernathy, Hamilton, and Morgan 2019).

This paper is the final installment in our series on prescription drugs. Drawing on previous papers by Roosevelt Institute experts, the first part briefly outlines how the rules of our economy—and a cramped, marketized approach to government power—have created the extractive, inefficient, and broken pharmaceutical industry we have today. The second part, building on the framework developed in *New Rules for the 21st Century* and the work of several scholars, proposes a series of structural reforms that, taken together, would create a pharmaceutical system that meets patients’ needs and sets a new course for drug policy around the world.

Importantly, the purpose of this paper is not to argue for the specific policy proposals outlined here or suggest that they are the only iterations available. Instead, this paper offers a framework to address the pharmaceutical industry and explores the kinds of policies that scholars are contemplating that would, together, meet patients’ needs.

THE RULES OF THE ECONOMY HAVE STRUCTURED TODAY'S PHARMACEUTICAL INDUSTRY

In *New Rules for the 21st Century*, Abernathy et al. describe a vicious cycle: Policymakers, extolling the virtues of unfettered markets, cut regulations and taxes, which increased the power of corporations to generate profits by extracting wealth from workers, small businesses, and communities. Then, as their wealth and power grew, these corporations used that power to further write the rules of the economy in their favor—not only rewriting the rules to shape and structure the private sector, but reshaping the public sector to serve their interests as well.

The pharmaceutical industry is a prime example. As Katy Milani and Devin Duffy detail in *Profit over Patients: How the Rules of Our Economy Encourage the Pharmaceutical Industry's Extractive Behavior*, the first in our series, lax and poorly-designed antitrust enforcement; an increase in the power of the financial industry and wealthy shareholders; a patent and exclusivity system that creates misaligned incentives; and insufficient countervailing power from other stakeholders have fueled many of the extractive industry practices we see today (Milani and Duffy 2019). As Milani explores in *Profit over Patients: Americans are Paying for a Financialized Pharmaceutical Industry*, this extraction has real opportunity costs for patients: For example, the \$18.1 billion drugmaker AbbVie spent on stock buybacks and dividends was equivalent to 91 percent of the money the company made from its best-selling arthritis drug, Humira (Milani 2019). Concentration within the industry can also have pernicious effects. A recent study found that “killer acquisitions”—in which one company purchases another to suppress research and the development of rival drugs—prevent the availability of 5 percent more drugs a year from coming to market (Cunningham, Ederer, and Ma 2019).

The pharmaceutical industry is also profiting from government subsidy, in a range of direct and indirect ways. The US government paid approximately 43 percent of all retail prescription drug costs in 2015, including 29 percent through Medicare and 10 percent through Medicaid (Olsen and Sheiner 2017). Since the 2003 law that expanded Medicare to include prescription drug coverage expressly prohibited the Centers for Medicare and Medicaid Services (CMS) from negotiating drug prices in the way that other current government payors, like the Veterans Administration, currently do, Medicare is substantially overpaying for its goods. One analysis found that the government is paying an excess of \$2.8 billion every year through the Medicare program, just for the top 20 most commonly prescribed brand-name medicines (HSGAC Minority Staff Report 2015). The government subsidizes the industry in other ways: Research funded by the National Institutes of Health (NIH),¹ for example, contributed to each

¹ In addition to the National Institutes of Health, there are several other sources of public funding for biomedical research, including the Department of Defense, the Veterans Health Administration, and some state-level entities. For a detailed description, see https://www.everycrsreport.com/files/20181004_R45150_b1e74cb2ae0572464424c4d2a0c30f3874a017bc.pdf.

of the 210 new drugs approved by the Food and Drug Administration (FDA) between 2010 and 2016 (Cleary et al. 2018). There are other submerged forms of government spending, as well; According to data reported by the Government Accountability Office (GAO), large drug companies deducted \$30.7 billion in research expenses from their 2013 tax returns in adjusted dollars (US GAO 2017).

This is both created and exacerbated by the increasing power, and often capture, of the pharmaceutical industry at all levels of government. In *The Cost of Capture*, Margetta Morgan and Duffy describe capture as “a form of corruption in which industry exerts undue influence over policymakers in regulatory and legislative bodies, often at the expense of the public interest or in contravention of democratic will,” and identify its consequences: increased risks to patient safety; higher drug prices for patients; less innovation; and misallocated resources, both within the health care system and beyond (Morgan and Duffy 2019).

These rules are creating misaligned incentives, misused resources, and poor outcomes for patients. The good news? We can rewrite them.

TO ADDRESS OUR NATION’S PRESCRIPTION DRUG CRISIS, WE MUST DEPLOY ALL THE TOOLS IN OUR POLICY TOOLBOX— A ONE-TWO PUNCH

Abernathy et al. argue in *New Rules for the 21st Century* that, in order to change the balance of power in our economy and meet Americans’ basic needs, we must do two things: 1) institute rules aimed at managing the concentration of wealth in the economy and steering economic growth toward productive and equitable means, and 2) deploy public power to serve public interests, by designing public programs in ways that address power dynamics and market structure, and by using the power of government to solve major social problems that markets cannot or will not on their own. The sections that follow apply this *New Rules* framework to the pharmaceutical industry.

Restructure Markets and Rewrite the Rules that Govern Firms to Prevent Extraction and Improve Drug Quality, Cost, and Access

To reform the pharmaceutical industry, the first “punch” needed is to rewrite the laws and policies that structure power relationships among stakeholders within firms and among firms within markets. One part of the solution is to rewrite the rules to prevent the kind of extractive practices we see across the economy, and within the industry, today.

End monopoly pricing and adopt serious reforms to antitrust laws that can reduce firms' ability to use their market power to exploit patients. *Profits over Patients* describes a series of policies adopted throughout the 1980s—based on the flawed premise that the promise of greater-than-otherwise-available returns generates a not-otherwise-existing drive to innovate—that has resulted in the pharmaceutical industry being able to charge extraordinarily high prices for drugs, with no alternatives competing in the market for years or even decades. Several scholars have argued that the patent protections afforded to the pharmaceutical industry cause economic distortions that render it an inefficient and inappropriate mechanism for financing prescription drug development (D. Baker 2004) (D. Baker, Jayadev, and Stiglitz 2017).

Some scholars and policymakers have proposed an end to the current system that grants drug companies decades-long monopolies on new treatments before generic competitors can come on the market, arguing that it is an inefficient and unnecessary mechanism by which to incent innovation, and that it puts the onus on those in need of prescription drugs—those who can least bear it—to fund the social benefits of such product innovation. An example of such a proposal is a bill previously introduced by Sen. Bernie Sanders (I-VT) that would eliminate the current system of patent protection and market exclusivity for pharmaceuticals and replace it with an alternative mechanism by which to incent private sector innovation.

Others have proposed to substantially limit the extent and duration of patent protections and periods of FDA-authorized exclusivity. For example, the FDA could maintain the discretion to amend or override exclusivities when necessary to curb excessively high prices and abusive, anticompetitive practices at pharmaceutical companies or to meet pressing public health needs. Other reforms could address the patchwork of monopoly protections to work together more appropriately, including shortening the exclusivity periods on certain classes of drugs, particularly biologics; and eliminating patent term extensions based on FDA delays.

Ending or substantially reforming patent protections is a needed step, but itself is not enough to curb the industry's market power or to rein in their anticompetitive practices. Concentration in the pharmaceutical industry, the recent spate of vertical integration in the health care sector that creates walled gardens that drive up drug prices for consumers, and the range of anticompetitive practices in which the industry engages must be addressed both directly and through a range of broader reforms to our antitrust laws.

As a first step, government should address the specific anticompetitive activities the industry engages in. For example, the government must halt “pay for delay” arrangements, in which a patent holder pays a generic competitor a portion of their profits to delay the generic's entry into the market.

More substantial actions are also needed – actions that would impact both the drug industry and the economy more broadly. To address market power in the pharmaceutical industry and across the economy, policymakers should replace the “consumer welfare standard,” which serves as the basis courts and regulators use for evaluating anticompetitive activity, including mergers, and which has resulted in an unnecessarily cramped view of when the government should act in the service of protecting competition. An alternative is the “effective competition standard,” proposed by Marshall Steinbaum and Maurice Stuckey, which would encourage regulators to evaluate harms to a broader array of stakeholders beyond just consumers, including buyers, suppliers, and workers (Steinbaum and Stucke 2018). Having a more holistic standard is particularly important in the context of the health care industry for a variety of reasons. The health care industry maintains opaque pricing and procurement systems and operates in a multi-payer environment; a focus on consumer welfare may give insufficient consideration to how these factors might be affected by consolidation. In addition, pharmaceutical companies tend to have single-source supplies of essential medications that are very sensitive to disruptions; the potential for massive drug shortages ought to be considered as a factor in any merger. Additionally, policymakers should adopt a more accurate set of indices for when market power is present and shift the burden on firms with market power such that anticompetitive activity is presumptively illegal.

Adopting a progressive tax code can shift many of the incentives that corporations, including those in the health care industry, have to hoard wealth and prioritize financial transactions at the expense of productive investments.

Adopt progressive tax policy, which can work as a deterrent against extraction and wealth hoarding. The financialization of the pharmaceutical industry, which centers the interests of wealthy investors and shareholders in corporate decision-making, plays a key role in the extractive practices evident in the industry. Adopting a progressive tax code can shift many of the incentives that corporations, including those in the health care industry, have to hoard wealth and prioritize financial transactions at the expense of productive investments. By raising the statutory rate on corporations and modernizing the corporate tax code to better serve the global economy, the US can discourage corporate extraction and reduce the benefits of corporate tax arbitrage. Adopting sales factor apportionment as a means of modernizing our global tax system would eliminate the current incentives pharmaceutical companies have to engage in intellectual property (IP) offshoring, a profit-shifting strategy frequently used to evade taxes (Clausing 2016a) (Clausing 2016b). Next, by raising top marginal tax rates, policymakers can reduce the incentive for powerful corporate entities to accumulate profits at the expense of productive investments. The preferential tax treatment of capital gains (the profit from the sale of property, such as stock or real estate) and capital income (dividends and interest payments)

incentivizes an array of unproductive economic activities. In addition to recouping more than \$100 billion annually in lost public revenues (US Department of the Treasury 2019), raising the tax rate for capital gains will reduce incentives that have led to our financialized economy and that drive the shareholder and investor primacy in health care markets.²

Regulate hedge funds, private equity, and other shadow institutions’ roles throughout the economy. Between 2013 and 2015, 20 of the 25 largest drug price increases came from firms with strong ties to the financial sector (Hedge Clippers 2017). The rise of shadow institutions, including hedge funds and private equity, both throughout our economy and within the health care industry, must be addressed in order to stem the extractive corporate practices in which today’s firms engage. Private equity firms, for example, borrow money to take public companies private, often with the stated intention of conducting value-increasing changes and selling the companies at a higher price. Though the rationale behind these firms is that they target distressed companies and manage them back to health, private equity firms “overwhelmingly target healthy companies and boost their balance sheets in the short term by cutting the kinds of costs that build long-term value“ (Abernathy, Konczal, and Milani 2016). In the context of the pharmaceutical industry, this extraction not only affects the costs of medicines; it also affects the capital available for innovation and investments in new drug development that affects the public’s health. There are several proposals to address the extractive practices of these institutions, including prohibiting them from using debt-leveraged funds, in order to mitigate the potential for systemic effects and to give them “skin-in-the-game” for the changes they are making to these companies.

Between 2013 and 2015, 20 of the 25 largest drug price increases came from firms with strong ties to the financial sector. The rise of shadow institutions, including hedge funds and private equity, both throughout our economy and within the health care industry, must be addressed in order to stem the extractive corporate practices in which today’s firms engage.

Reform the laws that structure how corporations are governed. As Roosevelt Institute Fellow Lenore Palladino has argued, corporate boards should be required to include, at a minimum, a substantial proportion of workers, as well as representatives of other non-shareholder corporate stakeholders, to encourage boards to reflect the interests of all stakeholders, not just those of executives and the investment community (Palladino 2019).

² Since financialization contributes to economic inequality, which contributes to health inequalities, attacking financialization in this sector could have a doubly-beneficial impact on society.

One promising avenue for further research is whether an expanded set of corporate stakeholders should include patients or their representatives, with clear conflict of interest standards, on corporate boards of drug companies. This is not unprecedented: Community health centers, for example, are required as a condition of receipt of their federal grant funding to have governing boards, a majority of which are comprised of health center patients and which reflect the demographic characteristics of their patient population (Heisler 2017). Diversifying corporate boards to include a range of stakeholders may be particularly important in the context of the pharmaceutical industry. When companies are required to deliver fair prices to consumers, as some proposals require, one potential consequence is that they do so by squeezing workers or cutting corners in other ways, which could have consequences for quality or safety. Improving representation on boards serves to mitigate some of these potential harms.

Other needed corporate governance reforms include expanding a board’s “fiduciary duty”—the legal standards of care and loyalty that directors owe—beyond shareholders, instead requiring them to weigh the interests of all other corporate stakeholders, including employees, customers, and the public at large. Another corporate governance reform to consider is requiring companies to have a socially beneficial purpose, a requirement akin to what a number of states have adopted as an option for companies in the form of benefit corporations. Finally, Congress must take steps to ban the practice of stock buybacks, which would prevent the artificial inflation of stock prices as a means of enriching executives and wealthy shareholders, often at the expense of alternative ways to reinvest profits.

Deploy Government Power to Restructure Pharmaceutical Markets and Drug Innovation Systems

In order to create a less extractive pharmaceutical industry, we must rewrite the rules that structure relationships among stakeholders within a firm and among firms within and across the industry. But market regulation alone is insufficient to achieve the quality, efficiency, and universality to which we aspire. To do that, we argue that direct public provisioning is a necessary complement to rebalancing power in a range of markets, and that more substantial government intervention, in the form of industrial policy, is needed to provide the kind of coordination that markets cannot and will not do on their own. Abernathy et al. describe recent work by Darity, Hamilton, and Mabud on how public options serve to create competition within markets:

“The public production of a particular good or service gives the government control over quality, quantity, and pricing, which when designed to operate alongside private providers, can serve as the option that shapes the rest of the market by ensuring a base

level of quality, quantity, and access. In essence, if firms want to participate in a market that offers a public option, they must do so by providing products and services that are at least as desirable to consumers as what the government provides” (Darity, Hamilton, and Mabud 2019).

Industrial policy is another critical tool that must be more robustly deployed to create a more effective and efficient drug system. A brief by Roosevelt Institute Fellow Todd Tucker defines industrial policy as “any government policy that encourages resources to shift from one industry or sector into another,” which should be made through public choices about which industries and economic activities will best position the country to deliver on the needs of the population now and in the future (Tucker 2019). Taken together, these tools—public options and industrial policy—provide important ways to think about the kinds of interventions needed to restructure the pharmaceutical industry and ensure that American patients have the medicines they need.

Create a public option for all or some prescription drugs. A number of scholars and policymakers have made the public case for the federal government to directly develop, produce, and manufacture certain prescription drugs and provide them to consumers at accessible prices—a form of public option for pharmaceuticals. One recent proposal is a bill introduced by Sen. Elizabeth Warren (D-MA) and Rep. Jan Schakowsky (D-IL) that would create an Office of Drug Manufacturing within the Department of Health and Human Services to produce generic drugs in cases of drug shortages, limited competition, or where prices have spiked (Warren and Schakowsky 2018). This legislation follows recent proposals by Dana Brown of the Democracy Collaborative and others, as well as existing policy in Brazil and other countries, to create a public entity that produces pharmaceuticals—developing and manufacturing drugs based on need and providing them to patients at accessible prices (Brown 2019).

Use the government’s substantial bargaining power as a purchaser to negotiate lower drug prices. The United States does not operate a centralized system for procuring drugs and setting drug prices as many other countries do; rather, each federal agency that oversees the various health programs operates independently and in accordance with the specific statutes that govern its programs (Kirchhoff, Johnson, and Thaul 2018). While the Veterans Administration generally functions through direct government purchasing in accordance with a national drug formulary, Medicare Part D cannot directly intervene in setting prices and instead relies on a market-based approach in which insurers negotiate with manufacturers for various forms of price concessions. There have been several proposals introduced in the House of Representatives that would amend the current “non-interference clause” to allow or require the Medicare program to negotiate drug prices with pharmaceutical companies. Professor Amy Kapczynski’s recent testimony before the House

Ways and Means Committee argues that any such proposal should include as a “backstop,” in circumstances where the manufacturer and the government fail to reach an agreement over a fair price, that “the government could exercise its right to purchase the drug on the competitive market, affording the originator company a royalty while ensuring that patients are able to access the medicine in question” (Kapczynski 2019). Others have proposed creating a single government entity that negotiates drug prices across federal government programs.

Use existing safeguards that allow the government to correct the balance between encouraging innovation and creating unaccountable monopolies. In addition, existing law already permits the federal government and its contractors to procure products without regard to patents, as long as “reasonable” compensation is afforded (Kapczynski and Kesselheim 2016), and, under the Bayh-Dole Act, allows the government to “march in” where the benefits of an invention developed using federal funding are not “available to the public on reasonable terms.”³ That is, patent and exclusivity laws expressly include safeguards that allow the government to correct the balance between encouraging innovation and creating unaccountable monopolies by stepping in to allow the government to directly manufacture a product or assigning a license to another company to do so—as long as the government provides reasonable compensation to the patent holder.⁴ Many experts agree that, in the case of pharmaceutical products with drastic price increases, it would be both reasonable and prudent for the government to use this power more frequently (Kapczynski and Kesselheim 2016) (Brennan et al. 2017).

There are several steps that could be taken through executive action that would make it substantially easier for the government to use these authorities as they were intended. This includes designating a single agency to be responsible for identifying pharmaceutical products with unfairly high prices and determining whether these products would be good candidates for government patent use. This agency could be tasked with developing rules and processes for the use of the government’s manufacture and licensing authority under patent law, as well as the guidelines for determining reasonable compensation for the patent holder, and could direct the National Institutes of Health to develop rules for the exercise of Bayh-Dole march-in rights in the case of excessively high prices for drugs developed using federal funding. Additionally, Congress could smooth the path to lower-cost drugs by giving the FDA the authority to waive exclusivity periods granted to brand-name drug

³ US Code 35 §201(f); US Code 35 §203(a).

⁴ Past payments for government use of patented pharmaceuticals suggest that “reasonable payments” would be far below the patent holder’s lost profits: In one case, the government paid a royalty of 2 percent of the patented price. Additionally, in cases not involving pharmaceuticals, courts have held that lost profits do not control in the determination of reasonable compensation; rather, courts look to “residual profits” (the amount the patent infringer netted that exceeds its average profits on other products) as well as other relevant factors.

manufacturers in the event of excessively high prices; appropriating funds specifically for the manufacture of high-priority, highly effective generic drugs; and amending the Bayh-Dole Act to specifically *require* march-in rights to be exercised in the event of excessively high drug prices.

Adopt a robust industrial policy that prioritizes and deploys government resources in the service of clearly articulated public health goals. Leading thinker Mariana Mazzucato argues for an approach to pharmaceutical policy, akin to what Roosevelt Institute Fellow Todd Tucker describes as industrial policy, whereby “governments can set the direction of health innovation by focusing the energy of state, civil society and the private sector on clearly articulated public health goals” (Mazzucato et al. 2018). To achieve this, Mazzucato argues for a mission-oriented approach to improving health outcomes through a government entity modeled after the Defense Advanced Research Projects Agency (DARPA), which “demonstrates how the state can play a role in developing groundbreaking innovation while enduring the uncertainty and risks inherent in the innovation process.” Similarly, Dean Baker and Amitabh Chandra have proposed a “NASA for drug development,” in which the government contracts with universities and firms for research and clinical testing, and then maintains ownership of the resulting products. The purpose of such an approach is two-fold: First, it disaggregates the profit-seeking motive from drug innovation priorities. As Roosevelt Institute Chief Economist Joseph Stiglitz has written, “It is a matter of simple economics: Companies direct their research where the money is, regardless of the relative value to society. The poor can’t pay for drugs, so there is little research on their diseases” (Stiglitz 2007). Second, it proposes to deploy robust government tools to achieve this mission-oriented approach. This includes delinking high prices from innovation, by using some alternative form of inducements to engage in research and development that is not centered in the intellectual property system, as well as by setting conditions for price and availability for drug products that are developed through public investment (Mazzucato et al. 2018).

Take meaningful steps to mitigate agency capture and government corruption. In *The Cost of Capture: How the Pharmaceutical Industry Has Corrupted Policymakers and Harmed Patients*, authors Margetta Morgan and Duffy propose a series of ways to curb government capture and corruption (Morgan and Duffy 2019). This includes establishing an anti-corruption agency to protect the public against blatant conflicts of interest; enacting lifetime bans on lobbying for senior executive branch officials and banning golden parachutes to slow the revolving door; amending the rulemaking process to give consumer and public interest organizations standing to challenge agency rulemaking; and imposing greater transparency and disclosure obligations on certain patient advocacy organizations and their sources of funding.

Reform international trade and economic processes and rules. For the last several decades, trade agreements have increasingly been used by the pharmaceutical industry to capture markets overseas and lock in privileges at home. This includes, for example, the Agreement on Trade-Related Aspects of Intellectual Property Rights (or TRIPS), which required any country that benefitted from the World Trade Organization’s tariff reductions to have a 20-year minimum patent term. Since this was three years longer than the term offered under US law at the time, the US had to change then-current domestic law in order to implement this requirement. Subsequent agreements, such as the proposed Trans-Pacific Partnership or the Trump administration’s proposed reworking of the 1993 North American Free Trade Agreement, have tended to extend various privileges for ever more categories of drugs. In addition, the pharmaceutical industry also gets privileged procedural protections, ranging from early access to negotiating documents through the government’s industry advisory committee system, to special privileges to sue (for cash compensation) governments that companies believe are weakening intellectual property protection (B. K. Baker and Geddes 2017).

While this paper is not the place to explore every change needed for international trade agreements to allow for ambitious domestic reforms, it is important to note that, should these newer trade rules pass now, it is possible that the nation’s trade obligations could be in conflict with many of the ambitious domestic reforms contemplated here. As such, any set of ambitious proposals to curb the power of the pharmaceutical industry and deploy public power in more expansive ways must contemplate proposals to strip these and other special privileges out of current and future trade deals, and instead to have new agreements that internationalize many of the proposals we outline here.

CONCLUSION

As *New Rules for the 21st Century* argues, achieving real structural reforms requires both sides of the equation, curbing extractive corporate power and deploying public power in expansive and newly designed ways: “Only by considering both sides of the power equation—private and public—can we achieve outcomes that will meet every American’s needs.” While beyond the scope of this paper, additional research is needed to determine which of these specific options to deploy and which order of policy choices would create real and lasting change. As political will continues to build, the key here is this: Realigning incentives and restoring public accountability in our nation’s drug system will require deploying far more of the tools in our policy toolkit to provide access to medicines that patients need and that our country deserves.

REFERENCES

- Abernathy, Nell, Darrick Hamilton, and Julie Margetta Morgan. 2019. "New Rules for the 21st Century: Corporate Power, Public Power, and the Future of the American Economy." New York: Roosevelt Institute. <https://rooseveltinstitute.org/new-rules-for-the-21st-century/>.
- Abernathy, Nell, Mike Konczal, and Katy Milani. 2016. "Untamed: How to Check Corporate, Financial, and Monopoly Power - Roosevelt Institute." New York, NY: Roosevelt Institute. <https://rooseveltinstitute.org/untamed-how-check-corporate-financial-and-monopoly-power/>.
- Baker, Brook K., and Katrina Geddes. 2017. "The Incredible Shrinking Victory: Eli Lilly v. Canada, Success, Judicial Reversal, and Continuing Threats from Pharmaceutical ISDS." *Loy. U. Chi. LJ* 49: 479.
- Baker, Dean. 2004. "Financing Drug Research: What Are the Issues?" Washington, DC: Center for Economic and Policy Research. http://cepr.net/documents/publications/intellectual_property_2004_09.pdf.
- Baker, Dean, Arjun Jayadev, and Joseph Stiglitz. 2017. "Innovation, Intellectual Property, and Development: A Better Set of Approaches for the 21st Century." AccessIBSA: Innovation & Access to Medicines.
- Brennan, Hannah, Amy Kapczynski, Christine H. Monahan, and Zain Rizvi. 2017. "A Prescription for Excessive Drug Pricing: Leveraging Government Patent Use for Health." *Yale Journal of Law and Technology* 18 (1). <https://digitalcommons.law.yale.edu/yjolt/vol18/iss1/7>.
- Brown, Dana. 2019. "Medicine For All: The Case for a Public Option in the Pharmaceutical Industry." Washington, DC: The Next System Project. <https://thenextsystem.org/medicineforall>.
- Clausing, Kimberly A. 2016a. "The US State Experience Under Formulary Apportionment: Are There Lessons for International Reform?" *National Tax Journal* 69 (2): 353–86.
- . 2016b. "The Effect of Profit Shifting on the Corporate Tax Base in the United States and Beyond." Social Science Research Network. https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2685442.
- Cleary, Ekaterina Galkina, Jennifer M. Beierlein, Navleen Surjit Khanuja, Laura M. McNamee, and Fred D. Ledley. 2018. "Contribution of NIH Funding to New Drug Approvals 2010–2016." *Proceedings of the National Academy of Sciences* 115 (10): 2329–34. <https://doi.org/10.1073/pnas.1715368115>.
- Cohen, Robin A., Ph.D., Peter Boersma M.P.H., and Anjel Vahratian Ph.D., M.P.H. 2019. "Strategies Used by Adults Aged 18–64 to Reduce Their Prescription Drug Costs, 2017." National Center for Health Statistics, Centers for Disease Control and Prevention. <https://www.cdc.gov/nchs/products/databriefs/db333.htm>.
- Cunningham, Colleen, Florian Ederer, and Song Ma. 2019. "Killer Acquisitions." SSRN Scholarly Paper ID 3241707. Rochester, NY: Social Science Research Network. <https://papers.ssrn.com/abstract=3241707>.
- Darity, William "Sandy," Darrick Hamilton, and Rakeen Mabud. 2019. "Increasing Public Power to Increase Competition: A Foundation for an Inclusive Economy." New York, NY. <https://rooseveltinstitute.org/increasing-public-power-to-increase-competition/>.
- Gill, Lisa L. 2018. "How to Pay Less for Your Meds." Consumer Reports. <https://www.consumerreports.org/drug-prices/how-to-pay-less-for-your-meds/>.
- Hedge Clippers. 2017. "Hedge Papers No. 51 Trump's Wealthcare Plan: Helping Hedge Funds Profit from Soaring Drug Prices." Hedge Clippers. <http://hedgeclippers.org/wp-content/uploads/2017/10/Hedge-Papers-No.-51-Pharma-Hedge-Funds1.pdf>
- Heisler, Elayne J. 2017. "Federal Health Centers: An Overview." Washington, DC: Congressional Research Service. <https://fas.org/sgp/crs/misc/R43937.pdf>.

- HSGAC Minority Staff Report. 2015. “Manufactured Crisis: How Better Negotiation Could Save Billions for Medicare and America’s Seniors.” Report Two. Washington, DC: US Senate Committee on Homeland Security & Governmental Affairs. <https://www.hsgac.senate.gov/imo/media/doc/REPORT-Manufactured%20Crisis-How%20Better%20Negotiation%20Could%20Save%20Billions%20for%20Medicare%20and%20America's%20Seniors.pdf>.
- Kapczynski, Amy. 2019. “US House Ways and Means Committee Testimony: Hearing on Promoting Competition to Lower Medicare Drug Prices Before the Committee on Ways and Means.” <https://waysandmeans.house.gov/sites/democrats.waysandmeans.house.gov/files/documents/Kapczynski%20Written%20Testimony.pdf>.
- Kapczynski, Amy, and Aaron S. Kesselheim. 2016. “‘Government Patent Use’: A Legal Approach To Reducing Drug Spending.” *Health Affairs* 35 (5): 791–97. <https://doi.org/10.1377/hlthaff.2015.1120>.
- Kirchhoff, Suzanne, Judith Johnson, and Susan Thaul. 2018. “Frequently Asked Questions About Prescription Drug Pricing and Policy.” Washington, DC: Congressional Research Service.
- Kounang, Nadia. 2015. “Pharmaceuticals Cheaper Abroad Because of Regulation.” *CNN*, September 28, 2015. <https://www.cnn.com/2015/09/28/health/us-pays-more-for-drugs/index.html>.
- Levitz, Eric. 2019. “Trump’s NAFTA 2.0 Puts Big Pharma First, America Second.” *Intelligencer*. March 29, 2019. <http://nymag.com/intelligencer/2019/03/trumps-nafta-2-0-usmca-trade-deal-puts-big-pharma-first-america-second.html>.
- Mazzucato, Mariana, Heidi Chow, Saoirse Fitzpatrick, Andrea Laplane, Tiziana Masini, Diarmaid McDonald, Victor Roy, and Ellen ‘t Hoen. 2018. “The People’s Prescription: Re-Imagining Health Innovation to Deliver Public Value.” UCL Institute for Innovation and Public Purpose. https://www.ucl.ac.uk/bartlett/public-purpose/sites/public-purpose/files/peoples_prescription_report_final_online.pdf.
- Milani, Katy. 2019. “Profit Over Patients: Americans Are Paying for a Financialized Pharmaceutical Industry.” New York: Roosevelt Institute. <https://rooseveltinstitute.org/profit-over-patients-americans-are-paying-for-a-financialized-pharmaceutical-industry/>.
- Milani, Katy, and Devin Duffy. 2019. “Profit over Patients: How the Rules of Our Economy Encourage the Pharmaceutical Industry’s Extractive Behavior.” New York: Roosevelt Institute. <https://rooseveltinstitute.org/profit-over-patients/>.
- Morgan, Julie Margetta, and Devin Duffy. 2019. “The Cost of Capture: How the Pharmaceutical Industry Has Corrupted Policymakers and Harmed Patients.” New York: Roosevelt Institute. <https://rooseveltinstitute.org/the-cost-of-capture/>.
- Olsen, Peter, and Louise Sheiner. 2017. “The Hutchins Center Explains: Prescription Drug Spending.” *Brookings, The Hutchins Center* (blog). April 26, 2017. <https://www.brookings.edu/blog/up-front/2017/04/26/the-hutchins-center-explains-prescription-drug-spending/>.
- Palladino, Lenore. 2019. “Ending Shareholder Primacy in Corporate Governance.” New York, NY: Roosevelt Institute. <https://rooseveltinstitute.org/ending-shareholder-primacy-corporate-governance/>.
- Prasad, Vinay, and Sham Mailankody. 2017. “Research and Development Spending to Bring a Single Cancer Drug to Market and Revenues After Approval.” *JAMA Internal Medicine* 177 (11): 1569–75. <https://doi.org/10.1001/jamainternmed.2017.3601>.
- Steinbaum, Marshall, and Maurice E. Stucke. 2018. “The Effective Competition Standard: A New Standard for Antitrust.” SSRN Scholarly Paper ID 3293187. Rochester, NY: Social Science Research Network. <https://papers.ssrn.com/abstract=3293187>.

- Stiglitz, Joseph. 2007. "Market Failure in Everything: The Pharmaceutical Drug Research Edition." Economist's Review. https://economistsview.typepad.com/economistsview/2007/03/market_failure__1.html.
- Tucker, Todd. 2019. "Industrial Policy and Planning: What It Is and How to Do It Better." New York, NY: Roosevelt Institute. https://rooseveltinstitute.org/2019/07/RI_Industrial-Policy-Planning-201707.pdf.
- US Department of the Treasury. 2019. "US Tax Expenditures, FY2019." Washington, DC: US Department of the Treasury.
- US GAO. 2017. "Drug Industry: Profits, Research and Development Spending, and Merger and Acquisition Deals." Washington, DC: US Government Accountability Office. <https://www.gao.gov/assets/690/688472.pdf>.
- Warren, Sen. Elizabeth, and Rep. Jan Schakowsky. 2018. "Warren, Schakowsky Introduce Bicameral Legislation to Radically Reduce Drug Prices Through Public Manufacturing of Prescription Drugs | US Senator Elizabeth Warren of Massachusetts." December 18, 2018. <https://www.warren.senate.gov/newsroom/press-releases/warren-schakowsky-introduce-bicameral-legislation-to-radically-reduce-drug-prices-through-public-manufacturing-of-prescription-drugs>.

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At a time when the daily news cycle keeps policymakers rushing from one outrageous incident to the next, it is easy to see why big, progressive ideas have taken a backseat. But if we focus only on responding to the torrent of tweet storms and near-daily political scandals or fending off efforts to slide a destructive policy agenda under the radar, we lose the opportunity to lay the groundwork for the policies of the future.

