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Tell Me How It Ends: The Path to Nationalizing the U.S. Pharmaceutical Industry

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**TELL ME HOW IT ENDS:
THE PATH TO NATIONALIZING THE U.S.
PHARMACEUTICAL INDUSTRY**

By Fran Quigley*

ABSTRACT

The U.S. medicines system is broken. Millions of Americans suffer and some even die because they cannot afford medicines discovered by government-funded research. At the same time, corporations holding monopoly patent rights to those medicines collect some of the largest profits in modern capitalist history.

It does not have to be this way. The global legacy of treating essential medicines as a public good and the robust U.S. history of government seizure of private property for the public interest reveals a better path: the United States should nationalize its pharmaceutical industry.

U.S. statutory law already provides broad powers for the executive branch to immediately order the substantial manufacturing and distribution of patent-free medicines. That statutory authority should be immediately implemented and further expanded. In addition, U.S. constitutional law justifies a full seizure of all industry assets.

Given the pharmaceutical industry's substantial reliance on government funding and licensing, along with the industry's widespread malfeasance that harms the public welfare, the amount of compensation for this seizure will be limited. That seizure and compensation will finally conclude the tragic era of medicines profiteering and launch a new system that restores life-saving medications to their rightful role as affordable, accessible public goods.

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INTRODUCTION

When they started, it was still light. Several dozen individuals marched to a street corner just south of downtown Indianapolis, where others were waiting for them. People kept arriving, some carrying banners and signs, until the crowd spilled over the curb of the broad sidewalk and into the street. A microphone was turned on; some brief introductions were given. Then they began.

First, Janelle Lutgen spoke about her son Jesse. The only health insurance Jesse could find had a \$10,000 deductible, so he tried to pay for his insulin out of pocket—and routinely came up short. He died on February 7, 2018. Mindi Patterson talked about her sister-in-law, Meaghan, who also rationed the insulin she could not af-

ford. Meaghan died of diabetic ketoacidosis on Christmas Eve in 2018. Antroinette Worsham found her twenty-two-year-old daughter Antavia lying in bed, not breathing. She had an empty vial of insulin by her side.

Dusk began to fall. Candles were passed out and lit. Family members kept coming forward, weeping, and carrying pictures of their loved ones. All of those eulogized were Americans with Type 1 diabetes. Most were working, and some even had limited insurance. But none of them could afford the insulin manufactured by corporations like Eli Lilly and Company, whose headquarters the crowd had gathered in front of. After each family took their turn, a local minister offered a prayer. “I stand in solidarity tonight with all of the families who lost loved ones, not to a disease they carry, but to a disease corporations carry. A disease called greed.”

Then Nicole Smith-Holt walked to the middle of the intersection, stopping directly in front of impressive fountains and colorful signs with the Eli Lilly logo. Police cars surrounded her, and one officer using a loudspeaker ordered her to leave the street. She ignored him and began reading the names of all the young Americans who had died from rationing insulin in the past two years. Published accounts collected by the vigil organizer, T1International, include at least a dozen such deaths.¹ That is likely a significant undercount, as one in four Americans with Type 1 diabetes admit to rationing their insulin at least once in the past year, each of them risking a fatal onset of diabetic ketoacidosis.²

The police officer repeated his order. Smith-Holt spoke the names a second time, this time prefacing each with the phrase “Justice for . . .” The crowd repeated the phrase and the names back to her, their voices growing louder with each one. When it was time for Smith-Holt to speak the name of her son Alec, who died in 2017 at age twenty-six after rationing his insulin, her composure broke. She started sobbing. She took a deep breath, and yelled, “Justice for Alec!” Smith-Holt was then arrested for blocking traffic.³

1. See generally T1INTERNATIONAL: #INSULIN4ALL USA, <https://www.t1international.com/blog/category/usa-insulin4all> (last visited May 28, 2020).

2. T1INTERNATIONAL, *Costs and Rationing of Insulin and Diabetes Supplies: Findings from the 2018 T1International Patient Survey* 6 (2018), https://www.t1international.com/media/assets/file/T1International_Report_-_Costs_and_Rationing_of_Insulin_Diabetes_Supplies_2.pdf.

3. Mike Hoskins, *Diabetes Advocate Forces Police Arrest at Insulin Vigil*, HEALTHLINE (Sept. 19, 2019), <https://www.healthline.com/diabetesmine/diabetes-advocate-arrest-insulin-vigil#1>; T1International, *T1International #insulin4all Vigil 2019*, YOUTUBE (Oct. 21, 2019), <https://www.youtube.com/watch?v=IECE592N1bU>.

Nearly one in three Americans say they have skipped medication doses in the past year due to cost.⁴ Thirty-four million Americans say they personally know someone who died from the inability to pay for medicines or other care.⁵ Hospital emergency rooms across the country regularly see patients in crisis because they could not afford their asthma inhaler, blood pressure medicines, or insulin.⁶ Globally, the United Nations estimates that nearly two billion people do not receive the medications they need, including children who go without vaccines. Ten million of those people, approximately the population of New York City, die each year because medicines are unaffordable to them.⁷

This suffering stands in contrast to the robust health of the for-profit pharmaceutical industry. Although most medicines are manufactured at costs of just pennies per dose, corporations hold government-granted patent monopolies on many of them, enabling prices to be set at levels that are hundreds and even thousands of times higher than their cost.⁸ U.S. drug prices are the highest in the world and are raised annually at a rate far beyond overall inflation.⁹ As a result, the pharmaceutical industry is one of the most profitable sectors in modern times, with annual corporate profit margins reaching as high as forty percent.¹⁰

Consider the case of insulin, the medicine that Alec Raeshawn-Smith and the other young Americans eulogized on that Indianapolis street corner could not afford. A vial of insulin that cost pharmaceutical corporations only about \$6 to manufacture has in-

4. Ashley Kirzinger et al., *KFF Health Tracking Poll – February 2019: Prescription Drugs*, KAISER FAM. FOUND. (June 11, 2019), <https://www.kff.org/health-reform/poll-finding/kff-health-tracking-poll-february-2019-prescription-drugs>.

5. Dan Witters, *Millions in U.S. Lost Someone Who Couldn't Afford Treatment*, GALLUP (Nov. 12, 2019), <https://news.gallup.com/poll/268094/millions-lost-someone-couldn-afford-treatment.aspx>.

6. See Kohei Hasegawa et al., *Emergency Department Visits for Acute Asthma by Adults Who Ran Out of Their Inhaled Medications*, 35 ALLERGY & ASTHMA PROC. e42, e49 (2014).

7. Paul Hunt (Special Rapporteur on the Right to Health), *Promotion and Protection of Human Rights: Human Rights Questions, Including Alternative Approaches for Improving the Effective Enjoyment of Human Rights and Fundamental Freedoms*, U.N. Doc. A/63/263 at 15 (Aug. 11, 2008), http://www.who.int/medicines/areas/human_rights/A63_263.pdf.

8. See Andrew Hill et al., *Minimum Costs for Producing Hepatitis C Direct-Acting Antivirals for Use in Large-Scale Treatment Access Programs in Developing Countries*, 58 CLINICAL INFECTIOUS DISEASES 928, 928–36 (2014); Dzintars Gotham et al., *Production Costs and Potential Prices for Biosimilars of Human Insulin and Insulin Analogues*, BRIT. MED. J. GLOBAL HEALTH, Sept. 25, 2018, at 1, 3, <https://gh.bmj.com/content/3/5/e000850.full.pdf>.

9. Dena Bunis, *Prescription Drug Prices Increase by Double the Rate of Inflation*, AARP (Sept. 19, 2019), <https://www.aarp.org/politics-society/advocacy/info-2019/prescription-drug-price-report.html>; STAFF OF H. WAYS AND MEANS COMM., 116TH CONG., A PAINFUL PILL TO SWALLOW: U.S. VS. INTERNATIONAL PRESCRIPTION DRUG PRICES 6 (2019), https://waysandmeans.house.gov/sites/democrats.waysandmeans.house.gov/files/documents/U.S.%20vs.%20International%20Prescription%20Drug%20Prices_0.pdf.

10. Richard Anderson, *Pharmaceutical Industry Gets High on Fat Profits*, BBC NEWS (Nov. 6, 2014), <https://www.bbc.com/news/business-28212223>.

creased in price more than one thousand percent in recent years. That single vial is now priced as high as \$300.¹¹ Most Americans with Type 1 diabetes face medicine and supplies costs of \$1300 a month or more.¹² The three corporations that dominate the global insulin market report annual profits that are double the average of other Fortune 500 companies.¹³

The crowd gathered in front of the Eli Lilly and Company headquarters reflected the mood of the U.S. public: Americans are furious. Multiple polls show U.S. respondents identifying medicine costs as the top issue Congress should tackle.¹⁴ Americans are increasingly aware of their government's role in funding the discovery of drugs, granting monopoly patents on those discoveries to private companies, and then paying, through Medicare and other government programs, the monopoly mark-up price for the medicines produced. "Taxpayers paying twice" has become a refrain repeated by politicians and advocates.¹⁵

The same polls show that Americans are ready for a bold response to the crisis. Eighty-four percent support breaking patent monopolies to allow for production of lower-cost medicines.¹⁶ Two-thirds support making prescription drugs public goods paid for by the federal government.¹⁷ The U.S. public's demands are not outlandish. They are fully in line with the global legacy of treating prescription medicines as a public good and with U.S. law and history justifying swift nationalization of private industry in a time of crisis. The United States can nationalize its pharmaceutical industry, and it should.

11. Ed Silverman, *Insulin Prices Could Be Much Lower and Drug Makers Would Still Make Healthy Profits*, STAT (Sept. 25, 2018), <https://www.statnews.com/pharmalot/2018/09/25/insulin-prices-profits-diabetes>.

12. Cf. Peter Callaghan, *How the Death of Alec Smith Pushed Minnesota Lawmakers to Address The Rising Cost of Insulin*, MINNPOST (Jan. 23, 2019), <https://www.minnpost.com/state-government/2019/01/how-the-death-of-alec-smith-pushed-minnesota-lawmakers-to-address-the-rising-cost-of-insulin>.

13. U.S. GOV'T ACCOUNTABILITY OFF., GAO-18-40, DRUG INDUSTRY: PROFITS, RESEARCH AND DEVELOPMENT SPENDING, AND MERGER AND ACQUISITION DEALS (2017), <https://www.gao.gov/assets/690/688472.pdf>.

14. Ashley Kirzinger et al., *KFF Health Tracking Poll - September 2019: Health Care Policy in Congress and on the Campaign Trail*, KAISER FAM. FOUND. (Sept. 12, 2019), <https://www.kff.org/health-costs/poll-finding/kff-health-tracking-poll-september-2019>.

15. Robert Pear, *Paying Twice: A Push for Affordable Prices for Taxpayer-Funded Drugs*, N.Y. TIMES (May 28, 2018), <https://www.nytimes.com/2018/05/28/us/politics/drug-prices.html>.

16. HART RESEARCH ASSOCS., PRESCRIPTION DRUG PRICES: THE VOTER SPEAKS 2 (2019), https://craftmediabucket.s3.amazonaws.com/uploads/AV-Summary-of-Polling-Project_052119_FINAL.pdf.

17. LAKE RESEARCH PARTNERS & ASO COMM'NS, PUBLIC SUPPORT FOR PRESCRIPTION DRUG PRICE REFORM: FINDINGS FROM A SURVEY OF 1,503 AMERICAN ADULTS 3 (2016).

I. THE FALLACY OF MEDICINE PATENTS INCENTIVIZING INNOVATION

The pharmaceutical industry's justification for retaining the current system and rejecting a public pharmaceutical model is that patent monopolies and the inflated prices they enable are necessary to spur life-saving innovation in medicines research.¹⁸ There is a fundamental flaw in that argument. The true innovators in medicines discovery are not the holders of those monopolies, but rather the entities that award them: governments.

Governments are far and away the dominant funder of the basic science research that makes up the earliest stage of the medicines development process, the riskiest and most lengthy component of medicines discovery.¹⁹ The U.S. National Institutes of Health (NIH) has an annual budget of \$40 billion that is largely devoted to funding the early-stage research that creates the building blocks for follow-on development of medicines.²⁰ Virtually every significant pharmaceutical breakthrough of the past half-century has government provenance, and each of the 210 new drugs approved by the U.S. Food and Drug Administration from 2010 to 2016 traces its roots back to government-funded research.²¹ Of course, the critical role played by government funding is not limited to the medicines field. The internet, the discovery of the chemical structure of DNA, and breakthroughs in nuclear energy were all based on publicly funded research.²²

Until the 1980s, U.S.-financed research breakthroughs were either owned by the federal agency that funded them or placed in the public domain.²³ But today, those discoveries end up in private, for-profit hands complete with long-term patent monopolies. The

18. See, e.g., PHRMA, IMPLICATIONS OF SPEAKER PELOSI'S DRUG PRICING PLAN 10 (2019), https://www.phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/Media-Briefing-Slides-on-HR-3_101019-FINAL.pdf.

19. See MARIANA MAZZUCATO, THE ENTREPRENEURIAL STATE: DEBUNKING PUBLIC VS. PRIVATE SECTOR MYTHS 73–77 (2015).

20. See *Budget*, NAT'L INSTS. HEALTH, <https://www.nih.gov/about-nih/what-we-do/budget> (last reviewed May 20, 2020).

21. See, e.g., Aaron S. Kesselheim et al., *The Roles of Academia, Rare Diseases, and Repurposing in the Development of the Most Transformative Drugs*, 34 HEALTH AFF. 286, 286 (2015); Bhaven N. Sampat & Frank R. Lichtenberg, *What Are the Respective Roles of the Public and Private Sectors in Pharmaceutical Innovation?*, 30 HEALTH AFF. 332, 334 (2011), <https://www.healthaffairs.org/doi/10.1377/hlthaff.2009.0917>; *History of Medicine Timeline*, DATESANDEVENTS.ORG, <http://www.datesandevents.org/events-timelines/10-history-of-medicine-timeline.htm> (last visited June 27, 2020); *A Question of Utility*, THE ECONOMIST, Aug. 8, 2015, at 50–52.

22. Peter Drahos & John Braithwaite, *Who Owns the Knowledge Economy? Political Organising Behind TRIPS*, THE CORNER HOUSE (Sept. 30, 2004), at 26, <http://www.thecornerhouse.org.uk/resource/who-owns-knowledge-economy>.

23. Lorelei Ritchie de Larena, *The Price of Progress: Are Universities Adding to the Cost*, 43 HOUS. L. REV. 1373, 1378 (2007).

change came about with the 1980 passage of the Patent and Trademark Law Amendments Act, more commonly known as the Bayh-Dole Act.²⁴ Pushed by the pharmaceutical industry, Congress decided to allow universities and corporations that receive federal research funding to claim patents for the discoveries that come out of that research. The result is that private companies benefit from a process that socializes the risks of medicines research and privatizes its rewards. As economist Marianna Mazzucato says, the United States “invests in the most uncertain stage of the business cycle and lets businesses hop on for the easier ride down the way.”²⁵

Government support for the pharmaceutical development process does not end at the early research stage. In addition to their patent rights, pharmaceutical corporations are often eligible for tax credits as high as fifty percent to support their follow-on research.²⁶ In addition, the government provides corporations with tax deductions for the cost of clinical trials.²⁷ And one in four medicines benefit from direct government support for that late-stage research as well.²⁸

24. Bayh-Dole Act, 35 U.S.C. §§ 200–12 (2012).

25. MAZZUCATO, *supra* note 19, at 1. The COVID-19 pandemic provides an example of this phenomenon. Before the pandemic outbreak in 2020, the NIH had already invested almost \$700 million into the coronavirus research that is the foundation for the vaccine and therapeutics research being conducted. *Government Funds Coronavirus Research While Pharma Sits By*, PUB. CITIZEN (Feb. 20, 2020), <https://www.citizen.org/news/government-funds-coronavirus-research-while-pharma-sits-by>. In March 2020, Congress allocated \$3 billion more for this research. Lauren Hirsch & Kevin Breuniger, *Trump Signs \$8.3 Billion Emergency Coronavirus Spending Package*, CNBC (Mar. 6, 2020), <https://www.cnbc.com/2020/03/06/trump-signs-8point3-billion-emergency-coronavirus-spending-package.html>. Patient activists worried that the current pharmaceutical development model meant that even this enormous public investment would not ensure that the resulting treatments would be affordable. “Once government funded research identifies a vaccine or treatment, under current policy, a drug corporation will bring the product to market at any price—and without regard to the taxpayer’s integral role in its discovery.” David Mitchell, *COVID-19 Treatments Won’t Work if We Can’t Afford Them*, PATIENTS FOR AFFORDABLE DRUGS (Mar. 28, 2020), <https://www.patientsforaffordabledrugs.org/2020/03/26/covid-19>.

26. See Zachary Brennan, *Senate, House Agree to Cut Orphan Drug Research Credit in Half in Tax Bill*, RAPS: REG. FOCUS (Dec. 18, 2017), <https://www.raps.org/regulatory-focus%E2%84%A2/news-articles/2017/12/senate-house-agree-to-cut-orphan-drug-research-credit-in-half-in-tax-bill>.

27. See Thomas Moore et al., *Estimated Costs of Pivotal Trials for Novel Therapeutic Agents Approved by the US Food and Drug Administration, 2015-2016*, JAMA INTERNAL MED. (Sept. 24, 2018) (finding that clinical trials that support FDA approvals of new drugs have a median cost of \$19 million, far lower than the industry’s claims for the costs of trials).

28. Rahul K. Nayak et al., *Public Sector Financial Support for Late Stage Discovery of New Drugs in the United States: Cohort Study*, BRIT. MED. J. (2019), <https://www.bmj.com/content/367/bmj.l5766>; see generally James B. Krellenstein, *Taxpayer Funded Development of Truvada as PrEP*, THE PREP4ALL COLLABORATION (May, 2019) (unpublished manuscript) (on file with the University of Michigan Journal of Law Reform) (providing an example of publicly-funded clinical trials).

Predictably, private research dollars focus more on profit-seeking than public health. Of the drugs receiving FDA approval from 2005 to 2016, only thirteen percent addressed an unmet medical need or helped advance patient care. The rest were so-called “me too” drugs, providing little to no therapeutic benefit over products already available to consumers.²⁹ The intent is to carve out a share of an existing lucrative market, which is understandable from a corporate standpoint but wasteful from a public benefit perspective. Just as predictably, for-profit research concentrates on the development of medicines that can be sold at a high mark-up to wealthy consumers.³⁰ The current system provides no incentive for research that addresses the needs of the global poor. Of the 1,556 new chemical entities marketed between 1975 and 2004, only twenty-one were for tropical, sometimes known as “neglected,” diseases that primarily impact persons in developing countries.³¹

When direct government support and tax subsidies are all accounted for, some analysts estimate that private corporations pay for only one third of U.S. biomedical research.³² And the research that is sponsored by private corporations is often tainted by inappropriate methodology and selective reporting of findings, including the suppression of negative results, motivated by the drive for

29. U.S. GOV'T ACCOUNTABILITY OFF., GAO-18-40, DRUG INDUSTRY: PROFITS, RESEARCH AND DEVELOPMENT SPENDING, AND MERGER AND ACQUISITION DEALS 41–42 (2017), <https://www.gao.gov/assets/690/688472.pdf>; Victoria Costello, *Talking about Drug Prices & Access to Medicines Pt 1: By Els Torrele, Open Society Foundations*, PLOS BLOGS (Oct. 13, 2015), <https://blogs.plos.org/yoursay/2015/10/13/talking-about-drug-prices-access-to-medicines>.

30. Importantly, even the later stage development of patented medicines is rarely conducted by the companies that hold their rights: a recent report showed that eighty-one percent of two leading corporations' products listed in 2017 were developed elsewhere, at which time the large corporations—using resources earned from other drugs' patent-inflated pricing—purchased their rights. Emily H. Jung et al., *Do Large Pharma Companies Provide Drug Development Innovation? Our Analysis Says No*, STAT (Dec. 10, 2019), <https://www.statnews.com/2019/12/10/large-pharma-companies-provide-little-new-drug-development-innovation>.

31. Pierre Chirac & Els Torrele, *Global Framework on Essential Health R&D*, 367 LANCET 1560, 1560 (May 13, 2006), [https://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(06\)68672-8/fulltext](https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(06)68672-8/fulltext). One of the casualties of this model is the lack of financial incentive for for-profit pharmaceutical corporations to develop vaccines, antibiotics, and other responses to infectious diseases, in part because the widespread need for—and purchase of—such treatments is not assured, and in part because the affected population may be too poor to afford high treatment costs. In the case of both Ebola and COVID-19, this dynamic slowed development of promising treatments before the outbreaks occurred. Julia Belluz, Umair Ifan & Brian Resnick, *A Guide to the Vaccines and Drugs That Could Fight Coronavirus*, VOX (Mar. 27, 2020), <https://www.vox.com/science-and-health/2020/3/4/21154590/coronavirus-vaccine-treatment-covid-19-drug-cure>.

32. Michele Boldrin & David K. Levine, *The Case Against Patents*, 27 J. ECON. PERSP. 15, 15–16 (2013), <https://pubs.aeaweb.org/doi/pdf/10.1257/jep.27.1.3>.

profits instead of public health concerns.³³ Economist Dean Baker has calculated that if lawmakers withdrew the patent monopolies that support massive price mark-ups for medicines, the resulting savings would allow every dollar of privately funded medicines research and development to be more than matched by increased government investment. That investment could be focused on public health rather than profit-seeking.³⁴

It is worth noting that the fallacy of patent-motivated innovation is not limited to the medicines field. Patents are artificially-imposed zones of exclusivity acting as an “anti-commons” by blocking the follow-on use of information that could lead to further innovation.³⁵ As a result, multiple studies have shown monopolies are not only ineffective at incentivizing innovation, but they are also a barrier to follow-on discoveries.³⁶ By contrast, most of history’s great innovations have occurred outside the patent system.³⁷ Analyses of the effects of compulsory licensing, where a government overrides a patent and allows generic production, show that these patent bypasses open up the field and encourage innovation.³⁸

One of the anti-innovation effects of patents is to incentivize the creation of barriers to discovery, such as the voluminous patent “thickets” created by pharmaceutical corporations in the pursuit of extended monopolies. A 2018 report by Initiative for Medicines, Access and Knowledge (I-MAK) revealed that the twelve top-selling drugs in the United States average a remarkable 125 patent applications per drug, many of them frivolous.³⁹ The effect of this thickening is that each drug carries an average of thirty-eight years of attempted patent protections—far beyond the baseline twenty-year

33. Adam Gaffney and Joel Lexchin, *Healing an Ailing Pharmaceutical System: Prescription for Reform for United States and Canada*, BRIT. MED. J., May 17, 2018, at 2, 9, 12, <https://doi.org/10.1136/bmj.k1039>. Gaffney and Lexchin also point to concerns that the U.S. drug review and approval process has been corrupted by the Food and Drug Administration’s fiscal reliance on fees paid by pharmaceutical companies. *Id.* at 11.

34. DEAN BAKER, RIGGED: HOW GLOBALIZATION AND THE RULES OF THE MODERN ECONOMY WERE STRUCTURED TO MAKE THE RICH RICHER 106–16 (2006).

35. Micheal A. Heller & Rebecca S. Eisenberg, *Can Patents Deter Innovation? The Anti-commons in Biomedical Research*, 280 SCI. MAG. 698, 698–701 (1998), <https://science.sciencemag.org/content/280/5364/698>.

36. DEAN BAKER ET AL., CTR. FOR ECON. & POLICY RESEARCH, INNOVATION, INTELLECTUAL PROPERTY, AND DEVELOPMENT: A BETTER SET OF APPROACHES FOR THE 21ST CENTURY 10 (2017), <http://cepr.net/images/stories/reports/baker-jayadev-stiglitz-innovation-ip-development-2017-07.pdf>.

37. Petra Moser, *Patents and Innovation in Economic History* 9–11, 16–17 (Nat’l Bureau of Econ. Research, Working Paper No. 21964, 2016), <http://dx.doi.org/10.2139/ssrn.2712428>.

38. *Id.*

39. I-MAK, OVERPATENTED, OVERPRICED: HOW EXCESSIVE PHARMACEUTICAL PATENTING IS EXTENDING MONOPOLIES AND DRIVING UP DRUG PRICES (2018), <http://www.i-mak.org/wp-content/uploads/2018/08/I-MAK-Overpatented-Overpriced-Report.pdf>.

patent life.⁴⁰ For example, Sanofi, which sells Lantus, a long-acting insulin relied upon by persons with Type 1 diabetes, has taken out seventy-four patents on the drug.⁴¹ Sixty-nine of those patents were obtained not during the development process, but after the insulin was already on the market.⁴² This protectionism clashes with the well-established benefits of open access practices like creative commons licenses, open access journals, and especially the open-source-software movement that has contributed to transformative innovations in the fields of healthcare, education, and communication.⁴³

The U.S. Supreme Court's 2013 decision in *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.* is a powerful example of the positive effects on innovation when patent barriers are removed.⁴⁴ The Court's ruling, that naturally-occurring genes could not be patented, enabled research on a previously patent-protected gene that increases the probability of breast cancer. The new research quickly led to more accurate testing for the gene at lower prices.⁴⁵ Association for Molecular Pathology was part of a comprehensive 2017 review of the current medicines patenting system by economists Dean Baker, Arjun Jayadev, and Joseph Stiglitz. They concluded that the system should be radically revised, if not completely abandoned:

Intellectual Property Rights are not an end in themselves but only a means towards greater economic welfare for all. We tolerate and sanction known economic inefficiencies such as those that arise from the private monopolies that are created and sustained through the IPR regime as a

40. *Id.* at 2.

41. I-MAK, OVERPATENTED, OVERPRICED: LANTUS SPECIAL EDITION (2018), <http://www.i-mak.org/wp-content/uploads/2018/10/I-MAK-Lantus-Report-2018-10-30F.pdf>.

42. *Id.* at 4.

43. See Aseem Sharma, *The Impact of Open Source on Business and Social Good*, OPENSOURCE.COM (Feb. 4, 2013), <https://opensource.com/business/13/1/impact-open-source-business>; cf. JÜRGEN BITZER & P. J. H. SCHRÖDER, *The Impact of Entry and Competition by Open Source Software on Innovation Activity*, in THE ECONOMICS OF OPEN SOURCE SOFTWARE DEVELOPMENT 219, 242–44 (2013).

44. *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. 576 (2013).

45. See BAKER ET AL., *supra* note 36, at 14 (citing *Ass'n for Molecular Pathology*, 569 U.S. 576). In response to the COVID-19 pandemic, researchers made public calls for open sharing of data to speed discovery of treatments and vaccines and to ensure the safety and efficacy of new discoveries that will come from the flurry of research activity. E. Richard Gold, *The Coronavirus Pandemic Has Shattered the Status Quo on Drug Development. We Should Build on That*, FORTUNE (Mar. 26, 2020), <https://fortune.com/2020/03/26/coronavirus-vaccine-drug-development-open-science-covid-19-treatment>; Christopher J. Morten et al., *To Help Develop the Safest, Most Effective Coronavirus Tests, Treatments, and Vaccines, Ensure Public Access to Clinical Research Data*, HEALTH AFF. (Mar. 26, 2020), <https://www.healthaffairs.org/doi/10.1377/hblog20200326.869114/full>.

gamble in this regard. Our contention is that this gamble has not paid adequate dividends.⁴⁶

II. MEDICINES AS A PUBLIC GOOD

Fortunately, an alternative to the patent system exists. Instead of treating life-essential medicines as for-profit commodities ripe for monopolizing and price-gouging, they should be treated as public goods available to all. Considering medicines as public goods is consistent with both economic theory and the multi-century, global legacy of preventing private entities from monopolizing and price-gouging drugs that are essential for life and health.

Economists define public goods as being non-rivalrous, meaning any person can benefit from the good without reducing the opportunity of others to benefit. Public goods are also non-excludable, meaning a person cannot be prevented from consuming the good in question.⁴⁷ The classic example of a non-rivalrous, non-excludable public good is a lighthouse. One ship benefitting from its warning does not prevent any other ship from enjoying the same benefit, and the lighthouse's warnings are open to all. Collectively, U.S. society has determined that no one should die because they cannot afford privately-set prices for fire and disaster response, police protection, or safety inspections for food and water. Government action has instead placed services like law enforcement, fire response, and public health protections, along with tangible goods like infrastructure and parks in the category of public goods.

Essential medicines should be on that list. Medicines fit the definition of a public good; although an individual pill is available to only one person, the formula for creating it can be widely shared. Overall, knowledge is a classic public good because its distribution demands no sacrifice from its original owner. Medicines possess another core quality of public goods: positive externalities.⁴⁸ One person's consumption of an essential medicine provides clear soci-

46. BAKER ET AL., *supra* note 36, at 70.

47. Fran Quigley, *Corporations Killed Medicine. Here's How to Take It Back*, THE NATION (Feb. 12, 2016), <https://www.thenation.com/article/corporations-killed-medicine-heres-how-to-take-it-back>; see also Brook Baker & Tenu Avafia, *The Evolution of IPRs from Humble Beginnings to the Modern Day TRIPS-plus Era: Implications for Treatment Access* (Tech. Advisory Grp. of the Glob. Comm'n on HIV & the Law, Working Paper, 2011), <http://www.hivlawcommission.org/index.php/working-papers?task=document.viewdoc&id=101>.

48. Quigley, *supra* note 47.

etal benefits beyond the direct consumer. For example, vaccines halt the spread of disease and effective treatment leads to greater productivity.

So, it is no surprise that human societies have been treating medicines as a public good for centuries. The notion of intellectual property only began to achieve broad acceptance in the last 150 years. But even as nations signed on to the 1883 Paris Convention, the 1886 Berne Convention, and the United Nations' World Intellectual Property Organization in 1967, many deliberately chose to exclude medicines from the items eligible for patent protection.⁴⁹ For example, Germany's patent law of 1877 labeled medicines, along with food and chemicals, as "essential goods" and prohibited any attempts to patent them.⁵⁰ During the mid-20th century, India, Brazil, Mexico, and several other Central and South American countries adopted explicit limits on the patentability of medicines.⁵¹

European countries like Italy and Sweden did not grant pharmaceutical patents until the 1970s, and Spain refused to do so until 1992.⁵² Even in nations that allowed medicine patents, liberal access to compulsory licenses for patented drugs was common.⁵³ Compulsory licenses bypass patents by allowing the government to either directly manufacture the patented invention or to license another entity to manufacture it, with a royalty paid to the patent-holder. In the mid-20th century, Canada issued hundreds of licenses to import or manufacture pharmaceutical products. During the same period, even the United States issued dozens of compulsory licenses for medicines.⁵⁴ The law reflected the culture. When asked why he sold his patent for insulin for just \$1 in 1923, Nobel laureate Frederick Banting said that "insulin does not belong to me; it belongs to the world."⁵⁵ When Jonas Salk was asked in 1952 why he did not seek a patent on the polio vaccine, he replied, "could you patent the sun?"⁵⁶

But, in the late 20th century, the pharmaceutical industry launched a concerted attack on this centuries-long tradition. Leveraging its lobbying and political power in the United States, where

49. *Id.*

50. *Id.*

51. *Id.*

52. *Id.*

53. See Baker & Avafia, *supra* note 47, at 4–5.

54. See Hannah Brennan et al., *A Prescription for Excessive Drug Pricing: Leveraging Government Patent Use for Health*, 18 YALE J. LAW & TECH 275, 305–06 (2016).

55. Sir Fredrick Banting, MD, CANADIAN MEDICAL HALL OF FAME, <http://www.cdnmedhall.org/inductees/frederickbanting> (last visited Mar. 26, 2020).

56. GLOBAL CITIZEN, *Could You Patent the Sun?*, YOUTUBE (Jan. 29, 2013), <https://www.youtube.com/watch?v=erHXKP386Nk>.

much of the industry is located, corporations convinced successive presidential administrations to prioritize intellectual property protection in all trade negotiations. Nations that did not provide “adequate and effective” protection for U.S. patents, a term created by the pharmaceutical industry-supported 1984 U.S. Trade Act, faced severe sanctions.⁵⁷ Soon after the law was passed, the United States placed India and Brazil, two countries that resisted medicine patents most vigorously, on its “priority” watch list, a precursor to trade sanctions.⁵⁸

At the same time, the World Trade Organization in 1986 convened talks to create a global intellectual property pact, which eventually became the 1994 Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement). When the negotiations began, nearly half of the countries involved blocked patents for medicines and most of the rest had established strict limits on their use. But the United States aggressively pressured its trade partners, many of whom relied heavily on the economic value of the trading relationship, to change their approach. The result: by 1994, one hundred and twenty-three countries signed on to TRIPS, which established a twenty-year global baseline for patent protections for inventions, including medicines.⁵⁹

Yet the longtime character of medicines as public goods was not fully extinguished. The TRIPS Agreement protects national rights to bypass patents by way of compulsory licenses or importation of medicines, especially when public health is at stake.⁶⁰ And the post-TRIPS medicines system continues to be the antithesis of a laissez-faire market model, given the massive government subsidies for research, bulk government purchases of medicines, and widespread, if not comprehensive, government provision of medicines to their citizens at low or no cost.⁶¹

As Dana Brown chronicled in her discussion of the extensive benefits to be gained from public ownership of the pharmaceutical process, Sweden, Brazil, Cuba, Thailand, China, and other nations embrace public ownership of key components of their medicines

57. 19 U.S.C. § 2242 (2012); see Sean Flynn, *What is Special 301? A Historical Primer*, INFOJUSTICE (May 1, 2013), <http://infojustice.org/archives/29465>.

58. Flynn, *supra* note 57; Quigley, *supra* note 47.

59. Agreement on Trade-Related Aspects of Intellectual Property Rights, art. 33 (1994), https://www.wto.org/english/docs_e/legal_e/27-trips_01_e.htm [hereinafter TRIPS Agreement].

60. *Id.* at art. 31.

61. See Alfred B. Engelberg, *How Government Policy Promotes High Drug Prices*, HEALTH AFF. (Oct. 29, 2015), <https://www.healthaffairs.org/doi/10.1377/hblog20151029.051488/full>.

system.⁶² Much of this enduring character of medicines as public goods reflects popular demand. U.S.-focused activism in the 1980s and 1990s led to groundbreaking government-funded discoveries in HIV/AIDS treatment. And global activism in the early 2000s led to governments bypassing patents on those discoveries and directly providing treatment to millions at zero cost.⁶³

The public good roots of medicines are alive, and they can be nurtured as an alternative to the current system that is weighed down by private interests and monopoly distortions. The savings gained from removing the massive patent-created profits from the system can fund alternative mechanisms for innovation, including expanded publicly-funded research, like the enormously successful programs of the NIH, increased tax credits or deductions that subsidize private research as it occurs, prize funds to reward groundbreaking innovations with cash instead of monopoly rights, and other non-profit approaches.⁶⁴

The legacy of the NIH, along with that of the National Science Foundation and the Defense Advanced Research Projects Agency (creator of the internet), prove the effectiveness of publicly funded approaches to innovation. So too does the non-profit, government-supported track record of organizations devoted to drug development. For example, the Drugs for Neglected Diseases Initiative has led over forty research and development projects and delivered eight highly impactful treatments, with twenty new chemical entities in its pipeline.⁶⁵ And the Mario Negri Institute's researchers

62. DANA BROWN, DEMOCRACY COLLABORATIVE, MEDICINE FOR ALL: THE CASE FOR A PUBLIC OPTION IN THE PHARMACEUTICAL INDUSTRY, Sept. 2019, https://thenextsystem.org/sites/default/files/2019-09/MedicineforAll_WEB.pdf; Linda McQuaig, *That Time Canada Had A Public Lab that Made Life-Saving Drugs*, THE TYEE (Nov. 8, 2019), https://theyee.ca/Analysis/2019/11/08/Canada-Public-Lab-Life-Saving-Drugs/?utm_source=national&utm_medium=email&utm_campaign=141119. Brown discusses the pharmaceutical nationalization process in Sweden (existing private corporations transformed into state-owned companies, which was later split into two state-owned companies) and Cuba (existing companies consolidated under the Ministry of Health). BROWN, *supra*, at 35–36, 57–58. Those examples, and the more advanced discussion of the fate of insurance companies under a single-payer Medicare for All-type transformation, can inform the pharmaceutical transformation process in the United States. For example, there are proposals for absorbing some private insurance employees into a government-run system while retraining or offering early retirement to others. See Robert Pollin et al., *Economic Analysis of Medicare for All*, PERI U. MASS. 108–19 (Nov. 30, 2018), <https://www.peri.umass.edu/publication/item/1127-economic-analysis-of-medicare-for-all>. Similarly, a nationalized pharmaceutical system would likely retain—or even expand—the private research-focused workforce but would need to retrain or transition most sales and marketing personnel.

63. See generally, RAYMOND A. SMITH & PATRICIA D. SIPLON, DRUGS INTO BODIES: GLOBAL AIDS TREATMENT ACTIVISM (2006).

64. Fran Quigley, *Making Medicines Accessible: Alternatives to the Flawed Patent System*, HEALTH & HUM. RTS. J. (Nov. 23, 2015), <https://www.hhrjournal.org/2015/11/making-medicines-accessible-alternatives-to-the-flawed-patent-system-2>.

65. Fran Quigley, *Escaping Big Pharma's Pricing with Patent-Free Drugs*, N.Y. TIMES (July 28, 2017), <https://www.nytimes.com/2017/07/18/opinion/escaping-big-pharmas-pricing-with->

have published over 12,000 oft-cited articles in scientific journals, and average eighty clinical trials being conducted at any one time, with over 70,000 patients enrolled.⁶⁶

All of these entities offer demonstrated advantages over the current model: they prioritize public health over drugs' potential profitability, they avoid the well-chronicled ethical problems associated with research fueled by the profit motive, they allow the fruits of research to be available for follow-on discoveries, and they can distribute medicines at dramatically lower prices as compared to private companies.⁶⁷

III. THE UNITED STATES' HISTORICAL TREATMENT OF PRIVATE PROPERTY AND GOVERNMENT SEIZURES SUPPORT NATIONALIZING THE PHARMACEUTICAL INDUSTRY

The United States is often characterized as a society with unshakeable reverence for private property rights and a reluctance to sanction the government seizing private property for collective use. Yet the historical record tells a different story. Local and state governments have widely and continually used eminent domain rights, and the United States has a lengthy track record of nationalizing private companies and entire industries and local and state governments. Nationalizing the pharmaceutical industry would be consistent with a multi-century legacy of elevating the public good over private property rights.

A. *The U.S. Reverence for Private Property: Mythology vs. Reality*

The cultural and political ties between the United States and private property date back to the original European settlers in the territory, many of whom fled feudalist systems in the hopes of claiming and owning their own land.⁶⁸ From the very beginning,

patent-free-drugs.html; DRUGS FOR NEGLECTED DISEASES INITIATIVE, <https://www.dndi.org/about-dndi> (last visited Apr. 10, 2020).

66. Fran Quigley, *Want Good Pharma? Here is One Example of What it May Look Like*, HEALTH & HUM. RTS. J. (Dec. 6, 2016), <https://sites.sph.harvard.edu/hhrjournal/2016/12/want-good-pharma-one-example-of-what-that-may-look-like>.

67. Fran Quigley, *Remove the For-Profit Variable from Clinical Drug Trials*, HEALTH & HUM. RTS. J. (May 21, 2017), <https://www.hhrjournal.org/2017/05/remove-the-for-profit-variable-from-clinical-drug-trials-2>.

68. LINCOLN INST. LAND POLY, PROPERTY RIGHTS AND LAND POLICIES 54 (Gregory K. Ingram & Yu-Hung Hong, eds. 2009), <https://www.lincolnst.edu/sites/default/>

the image of a self-reliant, agrarian colonial American freeholder took on powerful political symbolism. Thomas Jefferson was one of many of the nation's founders who equated private property rights (for white males) with democracy. John Adams often sparred with Jefferson, but on this point they agreed. "Property must be secured or liberty cannot exist," Adams wrote. "The moment the idea is admitted into society that property is not as sacred as the laws of God, and that there is not a force of law and public justice to protect it, anarchy and tyranny commence."⁶⁹

Those are ringing words, but they only carried so far. Even in Adams' era, local governments were exercising eminent domain over private property, and cities barred some businesses from locating within their boundaries. The American Revolution set the stage for widespread seizures of British-held property, including redistribution of two-thirds of New York City and its suburbs.⁷⁰ Although Jefferson and Adams concurred on the preeminence of private property, their view was not uniform among their fellow founders. Benjamin Franklin said, "private property is a creature of society, and is subject to the calls of the society whenever its necessities require it, even to the last farthing."⁷¹ There is evidence that Jefferson's original vision for the Declaration of Independence echoed John Locke's call for protection of "life, liberty, and property," but the reference to property was replaced with "pursuit of happiness" by the drafting committee, which included Franklin.⁷²

Thirteen years later, the Fifth Amendment to the U.S. Constitution balanced those competing interests, sanctioning in its Takings Clause both public appropriation of private property and the right of those property holders to be reimbursed: "Nor shall private property be taken for public use, without just compensation."⁷³ As the industrial revolution and the urbanization of the country led to more regulation and seizures of private property, generations of Supreme Court justices were left to interpret the Amendment's reference to both private property and just compensation. The Court's conclusions usually ran counter to the cultural notion of the United States as a private property-focused nation.

files/pubfiles/2077_1400_LP2008-ch03-U.S.-Private-Property-Rights-in-International-Perspective_0.pdf.

69. *Id.*

70. Gerald Friedman, *The Sanctity of Property Rights in American History* 5 (Political Econ. Research Inst., Working Paper No. 14, 2001), https://scholarworks.umass.edu/cgi/viewcontent.cgi?article=1008&context=peri_workingpapers.

71. Carol V. Hamilton, *Why Did Jefferson Change "Property" to the "Pursuit of Happiness"?*, HIST. NEWS NETWORK (Jan. 27, 2008), <https://historynewsnetwork.org/article/46460>; LINCOLN INST. LAND POL'Y, *supra* note 68, at 55.

72. *Id.*

73. U.S. CONST. amend. IV.

In a recent example, in the 2005 case *Kelo v. City of New London*, the U.S. Supreme Court affirmed the city's Fifth Amendment right to seize private property, even if the "public use" was to redistribute the property to other private entities in the name of economic development.⁷⁴ The decision triggered a public backlash in support of private property rights, including dozens of state legislative efforts to prohibit government takings for mere economic development purposes or private gain. Many takings limits were adopted in state legislation or construed by state courts to exist in state constitutions.⁷⁵

It should be noted that the post-*Kelo* debate and the subsequent state law limitations would not impact the seizure of pharmaceutical industry assets envisioned here. That debate aims at the outer boundaries of the Court's interpretation of public use and public purpose, while the seizures called for here are squarely in the multi-century tradition of takings for public use. These takings will not be conducted for broad non-governmental economic development purposes and they will not result in gain for other private interests, the characteristics that triggered the backlash against the *Kelo* decision.

Land policy and property rights historian Harvey Jacobs concluded that the rhetorical bark of property rights advocates in recent decades has proved to be more formidable than their bite. "They had been ineffective in changing the fundamental way government at the national, state, and local levels acted toward and upon property."⁷⁶ Indeed, the U.S. Supreme Court has never rejected a government seizure on the grounds that the taking was not for "public use."⁷⁷

Beyond court decisions, the U.S. cultural and political posture venerating private property has long been at odds with the comparatively quiet but widespread embrace of public ownership and operation of property, goods, and services. The list of publicly owned entities at the core of U.S. societies is well-known and substantial enough to deserve noting: public safety (police, fire departments, courts, and prisons), infrastructure (streets, sewers, and public utilities that are often the providers of water and electricity), schools from pre-kindergarten to post-graduate levels, the postal

74. 545 U.S. 469, 478 (2005). In 1897, the Supreme Court incorporated the Fifth Amendment's Takings Clause, making it applicable against the states through the Fourteenth Amendment's Due Process Clause. *Chicago, B. & Q. R. Co. v. Chicago*, 166 U.S. 226 (1897).

75. See *Eminent Domain*, INST. JUST., <https://ij.org/issues/private-property/ eminent-domain> (last visited Dec. 26, 2019).

76. LINCOLN INST. LAND POL'Y, *supra* note 68, at 60.

77. R. George Wright, *Fundamental Property Rights*, 21 VAL. L. REV. 75, 95 n.93 (1986).

service, public transportation, and much of the healthcare system from local clinics and community hospitals to the nationwide Veterans Administration system.⁷⁸ A full sixteen percent of the federal budget is spent on security and defense costs.⁷⁹ Although much of that funding goes to private contractors, the government typically retains intellectual property rights on what is invented and manufactured, in contrast to the medicines model.⁸⁰ Recognizing the success of that approach and its ready applicability to the goal of developing new medicines, some economists have called for a “NASA for Prescription Drugs.”⁸¹

One-third of the nation’s real estate is public land—from the neighborhood dog run to airports, commercial ports, and the fifty-two million acres of national parks. Some of that public land makes up the interstate highway system, a product of the largest public works program in U.S. history. Like many other government projects, it was made possible by aggressive exercise of eminent domain, which is both the most enduring refutation of the preeminence of private property rights in the United States and the most widespread use of the government powers secured by the Fifth Amendment Takings Clause.

Across the country, governments at all levels routinely use their eminent domain power to seize privately held land to further public safety, protect the environment, and build or expand roads, railways, government buildings, and parks. The Fifth Amendment usually mandates compensation be paid for these seizures, but the government authority to conduct them is unquestioned.⁸² As the U.S. Supreme Court said in *Boom Co. v. Patterson* in 1879, the government right to seize private property “requires no constitutional

78. Admittedly, the list of publicly owned institutions is even larger in many European and Asian countries, where rail lines, airlines, banks, internet services and energy companies are routinely publicly owned. GAR ALPEROVITZ, *WHAT THEN MUST WE DO?: STRAIGHT TALK ABOUT THE NEXT AMERICAN REVOLUTION* 95 (2013).

79. *Policy Basics: Where Do Our Federal Tax Dollars Go?*, CTR. BUDGET & POL’Y PRIORITIES, (Jan 29, 2019), <https://www.cbpp.org/research/federal-budget/policy-basics-where-do-our-federal-tax-dollars-go>.

80. See Fran Quigley, *Building a NASA for Prescription Drugs*, THE NEW REPUBLIC, (May 2018), <https://newrepublic.com/article/148361/building-nasa-prescription-drugs>.

81. *Id.*

82. Some scholars have argued that there is no economic justification for government compensation for private losses due to takings. Since losses due to other causes, such as fire or natural disaster, are protected against by private insurance, the argument goes, that insurance should be the source of protection against takings losses, not government compensation. Louis Kaplow, *An Economic Analysis of Legal Transitions*, 99 HARV. L. REV. 509, 534–35 (1986); see generally Laurence Blume & Daniel L. Rubinfeld, *Compensation for Takings: An Economic Analysis*, 72 CALIF. L. REV. 569, 572 (1984) (arguing that without private insurance providing this type of coverage, it “may be appropriate for government to provide such insurance in the form of compensation”).

recognition; it is an attribute of sovereignty.”⁸³ The practical justification for eminent domain reflects the untenable position a government would inhabit if a private land owner refused to sell, or set an exorbitant price for, land needed to build roads, establish waterways, place utilities, etc. for the benefit of the public.

The broad disbursement of authority among government entities to exercise eminent domain means that there is no centralized data available on how often it is exercised.⁸⁴ But historic examples reveal its significant scope, beginning with the 19th century Supreme Court cases affirming the federal government’s right to seize private land to build a Cincinnati post office (*Kohl v. United States*) and a battlefield memorial (*United States v. Gettysburg Electric Railroad Co.*).⁸⁵ During the New Deal era of the 1930s, the government vigorously asserted its eminent domain powers to establish national parks and to enable public works programs.⁸⁶

World War II saw the acquisition of twenty million acres of private property for airports, proving grounds, military storage, and other defense uses. The Assistant Attorney General of the United States called the Lands Division of the Department of Justice, “the biggest real estate office of any time or any place.”⁸⁷ After the war, the Federal-Aid Highway Act of 1956, signed into law and enthusiastically implemented by Republican President Dwight Eisenhower, set the stage for the United States and other governments to exercise eminent domain in more than a half-million instances as they constructed the interstate highway system.⁸⁸

This lengthy and ongoing legacy of government assertion of ownership of private property creates a substantial precedent for nationalizing the U.S. pharmaceutical industry. While the eminent domain examples in particular pertain to real property, Part V will show that government use of privately held intellectual property is even more well-established in the law.

83. *Miss. & Rum River Boom Co. v. Patterson*, 98 U.S. 403 (1878).

84. U.S. GOV’T ACCOUNTABILITY OFF., GAO-07-28, EMINENT DOMAIN (2006), <https://www.gao.gov/assets/260/253936.html>.

85. *Kohl v. United States*, 91 U.S. 367 (1875); *United States v. Gettysburg Elec. R.R. Co.*, 160 U.S. 668 (1896).

86. *See Early Evolution of Eminent Domain*, U.S. DEP’T JUST., <https://www.justice.gov/enrd/history-federal-use-eminent-domain>.

87. *Id.*

88. Josh Stephens, *Reclaiming the Interstates from Ike*, CAL. PLAN. & DEV. REP. (Dec. 8, 2011), <http://www.cp-dr.com/articles/node-3072>.

B. *The U.S. Legacy of Nationalizing Companies and Industries*

Even for those familiar with the widespread use of eminent domain in the United States, the nationalization of entire companies by converting them from private to public control may seem un-American. Nationalization is a practice at odds with the political and cultural reputation of the United States as an uber-capitalist nation. Yet nationalization of companies and even entire industries is fully permissible under U.S. law, thanks to the broad powers granted to Congress under Article I of the Constitution and Fifth Amendment. In its 1952 decision in *Youngstown Sheet & Tube Co. v. Sawyer*, the U.S. Supreme Court underscored this right: “The power of Congress to adopt such public policies as those proclaimed by the order (nationalizing the steel industry) is beyond question. It can authorize the taking of private property for public use.”⁸⁹

In fact, the U.S. federal government has quite often exercised the right to nationalize. As Thomas Hanna writes in his chronicle of this legacy, *A History of Nationalization in the United States: 1917-2009*, “The United States actually has a long and rich tradition of nationalizing private enterprise, especially during times of economic and social crisis.”⁹⁰ Hanna and others cite a pattern that includes the World War I-era nationalization of the railroad industry, which constituted one-twelfth of the U.S. economy at the time, along with the nation’s telephone and telegraph networks, the radio industry, arms manufacturers, and pharmaceutical companies, among others.⁹¹ During World War II, the U.S. again nationalized railroads, along with coal mines, the nation’s gold and silver reserves, and manufacturers of airplanes and arms.⁹² In one high-profile case, the U.S. government nationalized some components of the Montgomery Ward department store chain, complete with National Guard troops carrying the resistant company CEO Sewell Avery out of his Chicago office.⁹³

The World War II-era nationalizations were so voluminous that for a period in 1945, the government was taking over on average one industrial plant per week.⁹⁴ After the war, nationalization of railroads, oil companies, mines, and transportation facilities continued. Many of these efforts were enabled by the Defense Produc-

89. *Youngstown Sheet & Tube Co. v. Sawyer*, 343 U.S. 579, 588 (1952).

90. THOMAS HANNA, NEXT SYS. PROJECT, A HISTORY OF NATIONALIZATION IN THE UNITED STATES: 1917-2009, at 2 (2019), <https://thenextsystem.org/history-of-nationalization-in-the-us>.

91. *Id.* at 4–10.

92. *Id.* at 10–20.

93. *Id.* at 14.

94. *Id.* at 16.

tion Act of 1950, which gives the President broad authority to take action within the domestic industrial base in response to military or disaster response needs.⁹⁵ The Defense Production Act, which includes the rights of the President to assert control over materials, services, and facilities, has been repeatedly re-authorized by Congress and remains in force today.⁹⁶ President Trump invoked the Act in 2018 to order electricity distributors to buy power from the coal industry, and certain private industry leaders have urged him to nationalize the country's only rare earth minerals mine.⁹⁷

The regularity of mid-20th century government takeovers of private industry was likely the reason President Harry Truman was confident that his unilateral seizure of the nation's steel mills would stand. But Truman's action led to the *Youngstown* decision that sets limits on executive authority for seizures. In *Youngstown*, even as the Supreme Court ruled that Truman overreached, they reaffirmed Congress's power to pass legislation authorizing a President to conduct such seizures. Further, a majority of the justices affirmed that, even without congressional authorization, the President possesses powers to seize private property in a more severe emergency than the possible, but not yet occurring, steel shortage. The emergency seizure power will be discussed further in Part VI.

The *Youngstown* ruling did not deter the federal government from continuing a regular pattern of nationalizations throughout the rest of the 20th century and into the 21st, much of it through so-called "bailouts" of banks, automobile manufacturers, insurance companies, railroads, and airlines, culminating in the nationalization of several of the nation's largest companies during the economic crisis of 2008.⁹⁸ Like nationalizations during the world wars, most nationalizations during economic crises have been temporary, with control over the companies eventually returned to the original owners or new private interests.

95. Defense Production Act of 1950, 50 U.S.C. §§ 4501–4568 (2012).

96. See 15 C.F.R. §700.30; JARED T. BROWN, CONG. RESEARCH SERVS., R43767, THE DEFENSE PRODUCTION ACT OF 1950: HISTORY, AUTHORITIES, AND CONSIDERATIONS FOR CONGRESS 6 (2018).

97. Phillip Bump, *Trump's Plan To Use A Cold War-Era Law To Bolster The Coal Industry*, WASH. POST (June 1, 2018), <https://www.washingtonpost.com/news/politics/wp/2018/06/01/trumps-plan-to-use-a-cold-war-era-law-to-bolster-the-coal-industry-explained/>; Sally Bakewell & Steven Church, *This CEO Wants Trump to Nationalize the Only Rare-Earth Mine in America*, BLOOMBERG (July 18, 2017), <https://www.bloomberg.com/news/articles/2017-07-18/trump-urged-by-ceo-to-nationalize-the-only-u-s-rare-earths-mine>. In response to the need to quickly produce medical equipment for the COVID-19 pandemic, President Trump invoked the Defense Production Act in March 2020. Charlie Savage, *How the Defense Production Act Could Yield More Masks, Ventilators and Tests*, N.Y. TIMES (Mar. 20, 2020), <https://www.nytimes.com/2020/03/20/us/politics/defense-production-act-virus.html>.

98. See Nestor M. Davidson, *Resetting the Baseline of Ownership: Takings and Investor Expectations After the Bailouts*, 75 MD. L. REV. 722–23 (2016).

But there were dissenting voices about the wisdom of returning control to private hands. After World War I, President Woodrow Wilson and some members of Congress argued that the railroads and radio networks were best suited to remain under federal ownership.⁹⁹ The same theme was echoed a few decades later by conservative Chicago School of Economics professor Henry Simons, who called for the government to be prepared to take over and manage any industry where competition could not be ensured.¹⁰⁰ In 1969, one of the most influential economists of the mid-to-late 20th century, John Kenneth Galbraith, argued that the entire defense industry was being anti-competitive by nature and thus should be nationalized.¹⁰¹ Galbraith cited as rationale the lack of competition and the firms' close relationship to the government as the purchaser of the firms' products.¹⁰² Both characteristics run parallel to the pharmaceutical industry's reliance on monopolies and government-funded research and bulk purchases.¹⁰³ Further, Galbraith argued that greater efficiency and relief from the government spending distortions created by the lobbying activities of privately held defense firms could come from nationalization.¹⁰⁴ In the 1960s and 1970s, some U.K. physicians and the prime minister echoed similar arguments while proposing that at least some of the pharmaceutical industry be nationalized.¹⁰⁵

There are three notable examples of the federal government executing a full and permanent nationalization. All supply lessons for the task of nationalizing the pharmaceutical industry. First, in 1933, Congress passed and President Franklin Roosevelt signed into law the Tennessee Valley Authority (TVA), creating a federal corporation to provide electricity, flood control, and agricultural and economic development to a struggling region.¹⁰⁶ As with the pharmaceutical industry currently, there were private companies

99. See HANNA, *supra* note 90, at 8.

100. See ALPEROVITZ, *supra* note 78, at 79.

101. See John Kenneth Galbraith, *The Big Defense Firms Are Really Public Firms and Should be Nationalized*, N.Y. TIMES, Nov. 16, 1969, at SM50.

102. *Id.*

103. *Id.*

104. *Id.*

105. See Kieran O'Brien, *Researchers Ask: Should the Pharmaceutical Industry be Nationalized?*, ADVANCED SCI. NEWS (Mar. 5, 2020), <https://www.advancedsciencenews.com/researchers-ask-should-the-pharmaceutical-industry-be-nationalized>. In a March, 2020 BMJ article, Mariana Mazzucato and Henry Lishi Li argued that the pharmaceutical industry should be nationalized. But they went on to state the case in favor of a public option for pharmaceutical manufacturing, and said they are not in favor of full government ownership of the sector. Mariana Mazzucato, Henry Lishi Li & Ara Darzi, *Head to Head: Is It Time to Nationalise the Pharmaceutical Industry?*, BRIT. MED. J., Mar. 4, 2020, at 1, <https://doi.org/10.1136/bmj.m769>.

106. Tennessee Valley Authority Act, 16 U.S.C. §§ 831–831(dd) (2012).

already in the energy business in the TVA region when Congress and the President took action. Nineteen of those companies, led by the Tennessee Electric Power Company (TEPCO), the largest power company in the state, sued to block the TVA.

But the U.S. Supreme Court in 1939 upheld the lower court's dismissal of the companies' claim.¹⁰⁷ In an analysis that provides important guidance for the review of the pharmaceutical nationalization steps outlined in this Article, the Court found that the TVA undoubtedly damaged the private companies' business models, including through its aggressive use of eminent domain powers. But the harm caused was "damnum absque injuria—a damage not consequent upon the violation of any right recognized by law."¹⁰⁸ After the Court's ruling, the TVA and other public energy corporations purchased TEPCO's electric system for \$78 million, and TEPCO shut down its energy business.¹⁰⁹

The TVA is a successful, enduring, and popular example of full nationalization. It is credited with helping lift impoverished areas out of the Great Depression and continues to provide electricity to ten million persons, with services and facilities paid for by customers and not government appropriation.¹¹⁰ TVA's popularity as a public entity makes the occasional proposals to sell it to private interests political non-starters. The most recent suggestion of selling off the TVA, floated in President Trump's proposed budget in 2018, was deemed "a looney idea" by Tennessee's Republican Senator Lamar Alexander. "It has zero chance of becoming law," he said.¹¹¹ The TVA's unapologetic use of government powers, including eminent domain, to successfully subdue challenges by private competitors is valuable precedent for the nationalization steps outlined in Part VI.

In 1970, another permanent nationalization occurred when Congress created the National Railroad Passenger Corporation, better known as Amtrak. As with the TVA, there were multiple private companies in the same business when the legislation was passed. Amtrak is a quasi-public corporation, so those companies

107. See *Tennessee Elec. Power Co. v. Tennessee Val. Auth.*, 306 U.S. 118, 119 (1939).

108. *Id.* at 140.

109. See *Tennessee Valley Authority 1933-1939*, ENCYCLOPEDIA.COM, <https://www.encyclopedia.com/education/news-and-education-magazines/tennessee-valley-authority-1933-1939> (last updated June 12, 2020).

110. See *id.*

111. Press Release, Lamar Alexander, U.S. Senator, Alexander: Proposal to Sell TVA Transmission Lines "a Looney Idea . . . with Zero Chance of Becoming Law" (Feb. 12, 2018), <https://www.alexander.senate.gov/public/index.cfm/2018/2/alexander-proposal-to-sell-tva-transmission-lines-a-looney-idea-with-zero-chance-of-becoming-law>.

with passenger rail service were invited to shutter their services and instead accept stock in Amtrak. Most did so.¹¹²

Finally, in the wake of the September 11, 2001 attacks, Congress passed and President George W. Bush signed into law legislation to nationalize airport security. The Aviation and Transportation Security Act directed that the Under Secretary of Transportation for Security assume all security and screening functions at United States airports.¹¹³ The legislation had a devastating impact on private companies such as Huntleigh USA Corporation, which, at the time of the Act's passage, had contracts with approximately seventy-five airlines to cover passenger and baggage screening at thirty-five airports across the United States.

Just like the private corporations harmed by the TVA, Huntleigh filed suit—and suffered the same fate. The U.S. Court of Appeals for the Federal Circuit rejected Huntleigh's claim against the United States under the Fifth Amendment Takings Clause, ruling that the government “merely frustrated [Huntleigh's] business interests,” but did not take its property.¹¹⁴ The U.S. Supreme Court refused to hear Huntleigh's appeal.¹¹⁵ The process that created the Transportation Security Administration demonstrated again the federal government's clear power to quickly and comprehensively nationalize an industry when public safety and attendant political pressures are in play. It is also worth noting that the Transportation Security Administration nationalization, like that of Amtrak, occurred under the watch of a Republican president.

IV. FIFTH AMENDMENT TAKINGS LAW AND THE NATIONALIZATION OF THE PHARMACEUTICAL INDUSTRY: A FOUR-STEP PROCESS

As outlined above, the United States has a substantial history of nationalizing firms and even entire industries in times of national crisis when the dysfunctions of private-sector ownership pose a danger to the well-being of the nation. Furthermore, the harm caused by the private sector domination of the pharmaceutical manufacturing and distribution process has advanced far beyond prospective danger: the status quo is sickening and even killing Americans, while also condemning millions to physical and financial suffering.

112. See *Amtrak Year-Year: 1970-1972*, AMTRAK (May 9, 2012), <https://history.amtrak.com/blogs/blog/the-early-years>.

113. 49 U.S.C. § 44901 (2012).

114. *Huntleigh USA Corp. v. United States*, 525 F.3d 1370, 1384 (Fed. Cir. 2008).

115. *Huntleigh USA Corp. v. United States*, 555 U.S. 1045 (2008).

That suffering is in significant part inflicted by corporations either fully headquartered in the United States or doing a considerable amount of business here. Measured by revenue, six of the top ten pharmaceutical companies are based in the United States.¹¹⁶ The United States represents forty-five percent of the global pharmaceutical market.¹¹⁷ The damage being inflicted domestically by these corporations can and must be relieved by the federal government using the legal tools of public seizure that have been recognized and implemented since the country's birth.

Not only is the seizure of private property by federal, state, and local governments squarely supported by the nation's laws, those laws justify nationalization of the pharmaceutical industry at a cost far below the current value of pharmaceutical corporations. Under U.S. constitutional law, the federal government can provide quite limited compensation upon seizure, an important factor when nationalizing an industry that globally collects revenue of more than a trillion dollars per year.¹¹⁸

A four-step process for nationalizing the U.S. pharmaceutical industry, with limited compensation and in full compliance with U.S. law, would proceed as follows.

A. *Step One: Congress Passes Legislation Creating and Empowering a U.S. Medicines Agency (USMA)*

As an initial action, Congress should pass legislation creating a U.S. Medicines Agency (USMA). The USMA should be given specific authority to manufacture and distribute medicines to the U.S. population, to issue compulsory licenses, and to seize private property to fulfill the legislation's broad purpose to make medicines widely available. Past similar legislation includes the Army Appropriations Act of 1916, the Smith-Connally Act/War Labor Disputes Act of 1943, and the Defense Production Act of 1950, the last of which remains in effect.¹¹⁹

In the medicines context, similar but more narrow legislation was proposed as recently as 2018 and again in 2019, when Senator Elizabeth Warren and Representative Jan Schakowsky introduced the Affordable Drug Manufacturing Act, aimed at creating a new

116. Matej Mikulic, *U.S. Pharmaceutical Industry - Statistics & Facts*, STATISTA (May 9, 2017), <https://www.statista.com/topics/1719/pharmaceutical-industry>.

117. *Id.*

118. *Id.*

119. Army Appropriations Act of 1916, ch. 418, 39 Stat. 619-668; War Labor Disputes (Smith-Connally) Act of 1943, Pub. L. No. 78-79; Defense Production Act, 50 U.S.C. §§ 4501-4568 (2012).

federal Office of Drug Manufacturing with the power to manufacture and distribute generic medicines, where the patents have expired, and any medicines still protected by patents but eligible for manufacture via compulsory licenses issued by the federal government.¹²⁰

As another example, when the United States faced the potential of widespread infection from anthrax and a possible shortage of the antibiotic ciprofloxacin in 2001, then-Representative Sherrod Brown introduced the Public Health Emergency Medicines Act. The legislation would have empowered the Secretary of Health and Human Services to issue compulsory licenses for medicines patents needed to address public health emergencies. The legislation called for “reasonable remuneration” for the use of the patents, an amount to be determined in the context of factors including public health needs, the invention’s reliance on publicly funded research, and the need to address anti-competitive practices.¹²¹

Article 31 of the TRIPS Agreement preserves the rights of party nations to use “a patent without the authorization of the right holder, including use by the government or third parties authorized by the government,” with “adequate remuneration” paid to the patent-holder.¹²² The TRIPS language creates far broader space for compulsory licensing legislation than the United States has ever exercised. As discussed below, existing compulsory licensing rights under the Bayh-Dole Act of 1980 and 28 U.S.C. § 1498 provide a platform for significant executive branch action to increase access to affordable medicines. But as explained below, those statutes have limits on their applicability. Therefore, Congress in its USMA-establishing legislation should enact a comprehensive medicines-focused compulsory licensing rule. Such a rule would be similar to the 2001 Public Health Emergency Medicines Act and to many of the rules adopted in the medicines context by other TRIPS signatory nations.¹²³

120. Affordable Drug Manufacturing Act, S. 3775, 115th Cong. (2018); Press Release, Elizabeth Warren, U.S. Senator, Schakowsky, Warren Reintroduce Affordable Drug Manufacturing Act, Legislation to Radically Reduce Drug Prices through Public Manufacturing of Prescription Drugs (Dec. 20, 2019), <https://www.warren.senate.gov/newsroom/press-releases/schakowsky-warren-reintroduce-affordable-drug-manufacturing-act-legislation-to-radically-reduce-drug-prices-through-public-manufacturing-of-prescription-drugs>.

121. Public Health Emergency Medicines Act, H.R. 3235, 107th Cong. (2001) § 158(b).

122. TRIPS Agreement, *supra* note 59, at art. 31.

123. See generally, ELLEN 'T HOEN, PRIVATE PATENTS AND PUBLIC HEALTH: CHANGING INTELLECTUAL PROPERTY RULES FOR ACCESS TO MEDICINES (2016); James Packard Love, *Recent Examples of the Use of Compulsory Licenses on Patents*, KNOWLEDGE ECOLOGY INT'L (Mar. 31, 2007), https://www.keionline.org/misc-docs/recent_cls_8mar07.pdf; Maricel Estavillo, *India Grants First Compulsory License, For Bayer Cancer Drug*, INTELL. PROP. WATCH (Mar. 12, 2012), <http://www.ip-watch.org/2012/03/12/india-grants-first-compulsory-licence-for-bayer-cancer-drug>; *Brazil: Ten Years of a Compulsory License on the HIV Drug Efavir-*

Privately held patents operate as the chief barrier to accessing essential medicines in the United States. But there are other potential barriers to the USMA's ability to deploy needed resources and manufacturing techniques for producing medicines, especially biologic medicines. The USMA legislation will need to explicitly prevent the use of data and marketing exclusivities to bar the government from accessing the technology necessary to produce medicines.¹²⁴ Potential trade secret and confidentiality agreement barriers should be acknowledged and removed as well. Again, it is important to emphasize that such barriers are government-created and can therefore be just as readily dismantled by government action, as the TRIPS Agreement acknowledges.¹²⁵ There are already calls for the reduction or elimination of data and market exclusivity in the medicines context, along with significant recognition of the need for a public health or public interest exception to trade secrets protections.¹²⁶

The path to pharmaceutical industry nationalization mapped out here contemplates the executive branch taking action based on explicit congressional approval for all steps. Indeed, some of the actions called for in Step Two are already statutorily authorized. The Supreme Court in *Hawaii Housing Authority v. Midkiff*, applying reasoning later affirmed in the 2005 decision of *Kelo v. City of New London*, additionally made it clear that congressional determinations regarding whether takings are justified will rarely be questioned by courts. "Judicial deference is required because, in our system of government, legislatures are better able to assess what public purposes should be advanced by an exercise of the taking power. . . . Thus, if a legislature, state or federal, determines

renz, MAKE MEDICINES AFFORDABLE (Oct. 2, 2017), <http://makemedicinesaffordable.org/en/brazil-10-years-of-a-compulsory-license-on-hiv-drug-efavirenz>. In the early days of the COVID-19 pandemic, at least four countries (Chile, Ecuador, Israel, and Canada) took steps to issue compulsory licenses for medicines or medical products. Other nations pressed the World Health Organization to collect patent rights and data so that medicines could be made available without the monopoly price mark-ups. Ed Silverman, *A Canadian Bill Would Make It Easier To Issue Compulsory Licenses for COVID-19 Products*, STAT (Mar. 25, 2020), <https://www.statnews.com/pharmalot/2020/03/25/canada-compulsory-license-oronavirus-covid19>.

124. See, e.g., *Frequently Asked Questions on Patents and Exclusivity*, U.S. FOOD & DRUG ADMIN. (May 2, 2018), [http://www.fda.gov/Drugs/DevelopmentApprovalProcess/ucm079031.htm#How long is exclusivity granted for?](http://www.fda.gov/Drugs/DevelopmentApprovalProcess/ucm079031.htm#How%20long%20is%20exclusivity%20granted%20for%3F) (explaining the role of exclusivities in blocking competitor drugs).

125. Ellen 't Hoen et al., *Data Exclusivity Exceptions and Compulsory Licensing To Promote Generic Medicines in the European Union: A Proposal for Greater Coherence in European Pharmaceutical Legislation*, J. PHARMACEUTICAL POLY & PRAC. 10 (2017), <https://jopp.biomedcentral.com/articles/10.1186/s40545-017-0107-9>.

126. *Id.*; Julie E. Zink, *When Trade Secrecy Goes Too Far: Public Health and Safety Should Trump Corporate Profits*, 20 VAND. J. ENT. & TECH. LAW 1135 (2018), http://www.jetlaw.org/wp-content/uploads/2018/06/4_Zink-Article_Final-Review-Complete.pdf.

there are substantial reasons for an exercise of the taking power, courts must defer to its determination that the taking will serve a public use.”¹²⁷

It is also important to note that, given the national emergency at hand, a lack of explicit congressional approval does not rob the President of the power to act on her own while Congress proceeds with its deliberations over an eventual course of action. Over the years, U.S. presidents have conducted dozens of seizures without explicit congressional approval, including President Lincoln seizing rail and telegraph lines, President Wilson seizing coal mines, and President Franklin Roosevelt seizing an aviation plant.¹²⁸

Even when a President’s seizure was blocked by the Supreme Court in *Youngstown*, a review of the Court’s decision affirms that emergency executive action in response to the medicines crisis is permissible.¹²⁹ President Harry Truman, responding to a threatened strike that had the potential to interrupt the production of steel needed to support the ongoing Korean War effort, ordered his Secretary of Commerce to seize and operate most of the country’s steel mills.¹³⁰ In the preceding years, Truman had seized dozens of plants and industries with similar justifications.¹³¹

In *Youngstown*, however, a majority of the justices held that the President, by acting without congressional approval, had overstepped his bounds. Yet the court’s majority was careful not to handcuff a future President who might need to act unilaterally in a time of crisis. Seven of the nine justices declined to hold that the President could not execute a similar seizure on her own in more dire circumstances or when Congress had absented itself from the process.¹³²

Those seven included Chief Justice Fred Vinson, who in his dissent recited multiple instances of Presidents taking bold action on their own, including property seizures, in times of emergency. “Presidents have taken prompt action to enforce the laws and protect the country whether or not Congress happened to provide in advance for the particular method of execution,” he wrote.

[T]he fact that Congress and the courts have consistently recognized and given their support to such executive action indicates that such a power of seizure has been accept-

127. *Haw. Hous. Auth. v. Midkiff*, 467 U.S. 229, 244 (1984).

128. *Youngstown Sheet & Tube Co. v. Sawyer*, 343 U.S. 579, 683–700 (1952).

129. *Id.* at 637.

130. *Id.*

131. HANNA, *supra* note 90, at 21.

132. *Youngstown*, 343 U.S. at 580.

ed throughout our history. History bears out the genius of the Founding Fathers, who created a Government subject to law but not left subject to inertia when vigor and initiative are required.¹³³

Justice Robert Jackson's concurring opinion advanced a since oft-cited framework for evaluating the limits of presidential authority to act on her own. Justice Jackson wrote,

there is a zone of twilight in which [the President] and Congress may have concurrent authority, or in which its distribution is uncertain. Therefore, congressional inertia, indifference or quiescence may sometimes, at least as a practical matter, enable, if not invite, measures on independent presidential responsibility. In this area, any actual test of power is likely to depend on the imperatives of events and contemporary imponderables rather than on abstract theories of law.¹³⁴

Thus, the majority of justices in *Youngstown* preserved important options for the President to confront the current medicines crisis. With Americans suffering and dying daily because of the crisis created by private ownership of the pharmaceutical process, Justice Jackson's contemplated "imperative of events" is surely in play, at least until Congress takes the necessary steps to create a U.S. Medicines Agency.

B. *Step Two: The Executive Branch Exercises Powers to Issue Compulsory Licenses for the USMA to Manufacture Patented Medicines*

Congress has already provided the executive branch with significant powers to address the current medicines crisis. Specifically, the U.S. Code in two notable instances preserves for the federal government the right to issue compulsory licenses.

The best-known of these legislative platforms for compulsory licenses was created by the Bayh-Dole Act of 1980.¹³⁵ As discussed above, Bayh-Dole unwisely enables the surrender of the patent rights to government-discovered inventions to private corpora-

133. *Id.* at 700 (Vinson, J., dissenting).

134. *Id.* at 637 (Jackson, J., concurring).

135. *See* 35 U.S.C. § 200 (2012).

tions. But when passing the legislation, Congress supplied an escape hatch. Responding to significant criticism of what was called a multi-billion dollar giveaway, Congress via Bayh-Dole provided the executive branch with the right to “march in” and issue a compulsory license for a federally-funded discovery.¹³⁶

March-in rights are triggered when the invention is not available to the public on “reasonable terms” from the patent holder or if a health or safety need arises.¹³⁷ Those rights are limited to medicines discovered with U.S. government funding. Although that category encompasses a wide scope of initial patents, as discussed in Part II, it may not include technology protected by secondary patents that corporations obtain after the initial rights transfer from the government.¹³⁸

However, there are no such federal-funding-source limitations in 28 U.S.C. § 1498’s compulsory licensing provision.¹³⁹ In legislation that the U.S. Court of Federal Claims analogized to eminent domain powers, the statute provides a straightforward grant of rights to the federal government to use or manufacture patent-protected goods for use “by and for” the government, with only the obligation to provide “reasonable and entire compensation” to the patent-holder.¹⁴⁰ The statute first adopted in 1910 was amended in 1942, and the legislative history of those amendments makes it clear that Congress granted the government this patent-bypass right in part to address potential price-gouging by patent-holders.¹⁴¹

Although the existing U.S. compulsory licensing rights are underused in the medicines context, they are not mere theoretical tools. The United States has been a global leader in issuing compulsory licenses to restore competition to a monopolized market.¹⁴² Compulsory licenses have been issued for medical technologies including stem cells, laser eye surgery, gene therapy, and ultrasound

136. 126 Cong. Rec. 29,898 (1980) (statement of Rep. Brown) (“I am aware of the concern that granting contractors exclusive rights to federally funded inventions is a ‘give-away’ of the taxpayers’ property.”); *Hearings on S. 1215 Before the Subcomm. on Sci., Tech., & Space of the S. Comm. On Commerce, Sci., & Transp.*, 96th Cong. 400 (1979) (statement of Rep. Brown).

137. 35 U.S.C. §§ 200–212 (2012).

138. *Id.*

139. 28 U.S.C. § 1498 (2012).

140. *Decca Ltd. v. United States*, 640 F.2d 1156, 1167 (Ct. Cl. 1980).

141. Brennan et al., *supra* note 54, at 300–01.

142. JAMES LOVE, U.N. DEVELOPMENT PROGRAMME & WHO, REMUNERATION GUIDELINES FOR NON-VOLUNTARY USE OF A PATENT ON MEDICAL TECHNOLOGIES 15 (2005), <https://www.undp.org/content/dam/aplaws/publication/en/publications/hiv-aids/access-to-drugs-via-compulsory-licensing-guidelines—non-voluntary-patent-use/22.pdf>.

imaging catheters.¹⁴³ In the period between 2006 and 2011 alone, U.S. courts issued six different compulsory licenses for medical technologies.¹⁴⁴ Beyond the health context, the United States has also issued compulsory licenses for advances in energy technology, methods to reduce air pollution, truck parts, plastics, personal computers, corn seeds, microprocessors, animal vaccines, and gasoline.¹⁴⁵

When compulsory licenses are issued, the compensation to patent-holders has typically been set at ten percent or less of total sales of the items manufactured by the licensees, and courts have routinely rejected the idea of compensating the patent-holder for lost profits.¹⁴⁶ Importantly, when licenses have been issued to remedy anti-competitive practices, royalties are usually quite low and often denied altogether, an approach protected by the terms of the TRIPS Agreement.¹⁴⁷

When it comes to the medicines context, the U.S. Department of Defense's Military Medical Supply Agency during the 1950s and 1960s relied on § 1498 to procure dozens of drugs from non-licensed manufacturers, despite U.S. corporations holding patents on those medicines.¹⁴⁸ In 1994, the United States issued a compulsory license for the irritable bowel syndrome drug dicyclomine.¹⁴⁹ In recent decades, the U.S. has twice threatened patent-holders with compulsory licensing in order to reduce the price of HIV/AIDS medicines.¹⁵⁰ In 2001, the George W. Bush administration threatened Bayer, whose antibiotic ciprofloxacin was the only approved oral treatment for anthrax, with a compulsory license. In response, Bayer cut the drug's price in half and pledged a huge increase in production.¹⁵¹

143. James Love, *KEI Research Note: Recent United States Compulsory Licenses*, 2014:1 KNOWLEDGE ECOLOGY INT'L 6 (Mar. 7, 2014), http://keionline.org/sites/default/files/Annex_A_US_Compulsory_Licenses_7Mar2014_8_5x11.pdf.

144. James Love, *Open Letter to Those Who Collectively Produced the May 23, 2012 Statement to the WIPO SCP on the Topics of Patents and Health*, KNOWLEDGE ECOLOGY INT'L (May 25, 2012), <https://www.keionline.org/21854>.

145. Love, *supra* note 143.

146. Amy Kapczynski & Aaron Kesselheim, *Government Patent Use: A Legal Approach To Reducing Drug Spending*, 35 HEALTH AFF. 791, 793 (2016); Brennan et al., *supra* note 54, at 311.

147. TRIPS Agreement, *supra* note 59, at art. 40; LOVE, *supra* note 142, at 12.

148. Brennan et al., *supra* note 54, at 305.

149. The Dow Chemical Company et al., 59 Fed. Reg. 34,625, 34,626–27 (F.T.C. 1994) (proposed consent agreement).

150. Jennifer Penman & Fran Quigley, *Better Late Than Never: How the U.S. Government Can and Should Use Bayh-Dole March-In Rights to Respond to the Medicines Access Crisis*, 54 WILLAMETTE L. REV. 71, 188 (2017).

151. Keith Bradsher & Edmund Andrews, *A Nation Challenged: U.S. Says Bayer Will Cut Cost of Its Anthrax Drug*, N.Y. TIMES (Oct. 24, 2011), <http://www.nytimes.com/2001/10/24/business/a-nation-challenged-cipro-us-says-bayer-will-cut-cost-of-its-anthrax-drug.html>.

In Step Two, the U.S. government should immediately and thoroughly exercise its existing compulsory licensing rights to create a supply of low-cost medicines.¹⁵² Some urgently needed medicines would include insulin and asthma inhalers. Both are in high demand, with well-documented barriers to access due to private pharmaceutical company pricing.¹⁵³

This is not the first call for broader use of Bayh-Dole march-in rights and § 1498 for medicines access.¹⁵⁴ Indeed, some might argue that more robust exercise of existing compulsory licensing rights will be a sufficient response to the current medicines crisis. But the federal government response to the medicines crisis cannot stop at Step Two, no matter how broadly conducted. The best argument for pressing forward is revealed in the contrast between the clear remedies for responding to a medicines pricing crisis via march-in rights and § 1498 and the government's overall unwillingness to avail itself of these remedies.¹⁵⁵

Consider that in the thirty-nine-year history of the Bayh-Dole Act, the federal government has not once exercised the march-in rights created by the legislation.¹⁵⁶ Democrat and Republican ad-

152. In 1983, Congress passed the U.S. Orphan Drug Act, an effort to spur research for diseases that affect a small number of people, or otherwise do not suggest a lucrative U.S. market for private corporations. The law provides those corporations an early-stage push, in the form of research grants and increased tax credits, along with a late-stage pull from government-granted market exclusivity for the resulting drugs. ORPHANET, *About Orphan Drugs* (2015), <http://www.orpha.net/national/AU-EN/index/about-orphan-drugs>. Since nationalizing the pharmaceutical industry removes the distorting profit motive from research prioritization, the U.S. Medicines Agency would be able to focus on developing and making available medicines such as "orphan drugs" without concern over profitability.

153. Fran Quigley, Opinion, *This Free Clinic Is a Study in the US Healthcare Struggle*, NAT'L CATHOLIC REP. (July 2, 2019), <https://www.ncronline.org/news/opinion/free-clinic-study-us-healthcare-struggle>.

154. Penman & Quigley, *supra* note 150, at 213; Kapczynski & Kesselheim, *supra* note 146, at 794.

155. The pharmaceutical industry has not only been able to block implementation of the pro-patient terms in the Bayh-Dole Act, it has taken the similarly pro-patient intentions of the 1983 Orphan Drug Act and leveraged many of the incentives created by the legislation to support development of medicines that turn out to be enormously profitable to corporations. Sarah Jane Tribble & Sidney Lupkin, *Government Investigation Finds Flaws in the FDA's Orphan Drug Program*, KAISER HEALTH NEWS (Nov. 30, 2018), <https://khn.org/news/government-investigation-finds-flaws-in-the-fdas-orphan-drug-program>. A high-profile example of the for-profit gaming of the orphan drug system occurred in the early days of the COVID-19 pandemic. Gilead Sciences requested from the Food and Drug Administration orphan drug status for potential coronavirus treatment remdesivir. Gilead's request was an apparent effort to get the benefits of orphan drug designation before official confirmation that one of the most widespread diseases in history was far from a "rare disease." Under pressure from advocates, Gilead withdrew the request. Sidney Lupkin, *Gilead Declines 'Rare Disease' Status For Experimental Coronavirus Drug*, NPR (Mar. 25, 2020), <https://www.npr.org/sections/health-shots/2020/03/25/821534016/drugmaker-asks-fda-to-rescind-rare-disease-status-perks-for-covid-19-drug>.

156. Ryan Whalen, *The Bayh-Dole Act & Public Rights in Federally Funded Inventions: Will the Agencies Ever Go Marching In?*, 109 NW. U. L. REV. 1083, 1083 (2015). The industry has also managed to rebound from the setbacks from the massive global advocacy that led to the

ministrations alike, at times urged on by former senators-turned-drug-industry-lobbyists, have stretched the boundaries of credulity by concluding that the law's requirement to make medicines available on "reasonable terms" does not refer to affordability.¹⁵⁷ Thus, even the current deadly pricing crisis has not led to a single march in action, despite an extensive legislative history showing that affordability was precisely what Congress had in mind when preserving the government's rights to bypass the patents via compulsory licensing.¹⁵⁸ The explanation for this remarkable breach of duty is clear: the pharmaceutical industry has succeeded in a multi-decade process of regulatory capture. The industry's success is thanks to its generous campaign contributions, lobbying expenditures, and the revolving door between pharmaceutical management, federal agency leadership, and even congressional leadership.¹⁵⁹

With widespread issuances of compulsory licenses in Step Two, the executive branch could finally reverse this shameful legacy. But

dramatic reduction in prices for antiretroviral medicines to treat HIV/AIDS and the U.S.-focused pushback against ciprofloxacin costs in the face of a potential anthrax crisis. The reduction in the costs of one set of medicines has not prevented overall costs from consistently climbing. SMITH & SIPLON, *supra* note 63; Bradsher & Andrews, *supra* note 151. Beyond the pharmaceutical context, there is a quite recent example of the danger that exists when an industry is left intact with enormous resources and an existential motive to thwart the reform intended by legislation. Despite the fact that the 2010 Dodd-Frank Wall Street Reform and Consumer Protection Act was considered to be the most sweeping banking regulatory legislation since the 1930s, the financial industry has been able to block much of its most impactful intentions from taking effect. Gary Rivlin, *How Wall Street Defanged Dodd-Frank*, THE NATION (Apr. 30, 2013), <https://www.thenation.com/article/archive/how-wall-street-defanged-dodd-frank> ("The same financial behemoths that had fought so ferociously to block Dodd-Frank were not going to let the mere fact of the bill's passage ruin their plans. 'Halftime,' shrugged Scott Talbott, chief lobbyist for the Financial Services Roundtable, a lobbying group representing one hundred of the country's largest financial institutions. . . . Whereas commercial banks such as Wells Fargo, Citigroup and JPMorgan Chase, along with their trade groups, spent \$55 million lobbying in 2010 (the year Dodd-Frank became law), they would collectively spend \$61 million in 2011 and again in 2012, according to OpenSecrets.org. "). Further examples of regulated-but-not-nationalized industries regrouping as once-again exploitative entities include the government antitrust efforts to break up manipulative monopolies that were successful in the short term but saw the corporations eventually reconsolidate. ALPEROVITZ, *supra* note 78, at 77–79.

157. Francis S. Collins, *Letter from Francis Collins to Andrew Goldman*, NAT'L INSTS. HEALTH, (June 20, 2016), <https://www.keionline.org/sites/default/files/Final-Response-Goldman-6.20.2016.pdf>; Birch Bayh & Bob Dole, *Our Law Helps Patients Get New Drugs Sooner*, WASH. POST (Apr. 11, 2002), https://www.washingtonpost.com/archive/opinions/2002/04/11/our-law-helps-patients-get-new-drugs-sooner/d814d22a-6e63-4f06-8da3-d9698552fa24/?utm_term=.c5ffebd548d2; Alicia Mundy, *Just the Medicine*, WASH. MONTHLY, (Nov./Dec. 2016), <https://washingtonmonthly.com/magazine/novemberdecember-2016/just-the-medicine>.

158. Penman & Quigley, *supra* note 150, at 187–88.

159. OPENSECRETS.ORG, CTR. FOR RESPONSIVE POL., *Industries* (2019), <https://www.opensecrets.org/federal-lobbying/industries?cycle=2019>; Sheila Kaplan, *From FDA Expert to Biotech Insider: The Drug Industry Thrives on the Revolving Door*, STAT (Sept. 27, 2016), <https://www.statnews.com/2016/09/27/fda-biopharma-revolving-door-study>; David Kirkpatrick & Duff Wilson, *One Grand Deal Too Many Costs Lobbyist His Job*, N.Y. TIMES (Feb. 12, 2010), <https://www.nytimes.com/2010/02/13/health/policy/13pharm.html>.

the issuance of compulsory licenses is not a full taking, as it does not extinguish the rights of patent-holders to continue to produce and sell their medicines. When critical medicines patents continue to be held by private corporations, even vigorous licensing of those medicines to others cannot prevent the re-capture of the system by those politically powerful patent-holders. Therefore, outright seizures will be necessary to prevent backsliding into another profiteering-caused medicines crisis.

C. *Step Three: The USMA Executes Seizures that Are Exempt from the Fifth Amendment's Compensation Requirement*

As noted above, the Fifth Amendment's dual protection of government seizure rights and compensation has governed centuries of eminent domain practices. As courts have interpreted the Takings Clause in the context of specific disputes, two principles have emerged with particular application to the task of nationalizing the pharmaceutical sector.

First, in determining whether a Fifth Amendment taking has occurred, the Supreme Court in *Pennsylvania Central Transportation Co. v. New York City* developed a framework for considering the government's level of interference with reasonable "distinct investment-based expectations."¹⁶⁰ The more the private property owner reasonably anticipated that she would enjoy unencumbered rights, the greater the obligation of the government to compensate for interfering with them. This holds true even if the governmental interference is only by regulation that severely limits the owner's use of property—a so-called regulatory taking.

Second, although the long history of government takings in the United States has been dominated by the seizure or regulation of real property (i.e. land and attached buildings), the Supreme Court in *Horne v. Department of Agriculture* made clear that it considers some government seizures of personal property—in that case, a portion of a California farmer's raisin crop—to also be subject to the limits of the Takings Clause.¹⁶¹

Given these two principles, it is difficult to envision the U.S. government being able to execute a full seizure of all pharmaceutical industry assets without triggering a constitutional obligation to provide some level of reimbursement in the spirit of "just compensation." A broad government takeover of medicines development,

160. *Penn Cent. Transp. Co. v. City of New York*, 438 U.S. 104, 124 (1978).

161. *Horne v. Dep't of Agric.*, 576 U.S. 350, 360-61 (2015).

manufacturing, and distribution would undoubtedly be achieved more quickly and efficiently via federalization of pharmaceutical corporations' plants and key personnel, as was the case in multiple past U.S. corporate seizures. What should be the amount of compensation for such seizures?

The broad rule in government seizure cases is that the dispossessed owner should be compensated for the "highest and best use" of their property. U.S. courts have interpreted the highest and best use standard to mean "[t]he reasonably probable and legal use of [property], which is physically possible, appropriately supported, financially feasible, and that results in the highest value."¹⁶²

But here, the argument is that the amount of compensation due to pharmaceutical corporations upon seizure is much more limited than the baseline amount of highest and best use would suggest. Fifth Amendment takings law provides strong arguments in support of "just compensation" upon nationalization being far below any current value estimation for the corporations that make up that industry. Those value estimates are dependent on government-granted patents, heavy government subsidies, and widespread malfeasance that has boosted profits at the expense of the public welfare. All of those factors support the nationalization of the industry at a cost far less than its present value.

1. Patents Are Not Property in Fifth Amendment Takings Context.

When executing the seizure of private pharmaceutical company assets, the U.S. government's compensation obligations are significantly reduced if we accept that corporate-held drug patents are not "property" in the context of the Fifth Amendment Takings Clause. This is a conclusion with immense impact, since the value of patents represents the lion's share of the assets of pharmaceutical companies. For example, the corporation AbbVie in 2018 relied on a single patent-protected medicine, Humira, for nearly \$20 billion of its revenue, fifty-eight percent of the company's total.¹⁶³ For Celgene and Bristol-Meyers Squibb, two patent-protected drugs

162. *Brace v. United States*, 72 Fed. Cl. 337, 350 (2006) (quoting *Loveladies Harbor, Inc. v. United States*, 21 Cl. Ct. 153, 156 (1990)).

163. *AbbVie Reports Full-Year and Fourth-Quarter 2018 Financial Results*, ABBVIE (Jan. 25, 2019), <https://news.abbvie.com/news/abbvie-reports-full-year-and-fourth-quarter-2018-financial-results.htm>.

accounted for more than sixty percent of their revenue in that same year.¹⁶⁴

This reliance on patent protection is not an anomaly. A few years earlier, a dozen of the companies that produced the twenty-five best selling drugs in the world were each found to be collecting more than ten percent of their revenue from just a single patent-protected medicine.¹⁶⁵ In 2015, Gilead Science's \$32 billion revenue stream topped the Barron's rankings of the 500 largest public companies.¹⁶⁶ But that world-leading revenue came almost solely from a single group of closely-related patent-protected medicines used to treat Hepatitis C.¹⁶⁷

The enormous monopoly-provided boost from patents allows corporations to charge as much as one thousand times their manufacturing costs.¹⁶⁸ Without that boost, their revenue collapses. When patents expire and competitors enter the market to sell the drugs at prices as low as ten percent of the monopoly price, pharmaceutical companies' value can tumble off what is known as the "patent cliff." The pharmaceutical industry lives in constant fear of that cliff.¹⁶⁹ Industry analysts report that between 2018 and 2024, patent expirations in the prescription drug industry are expected to put up to \$251 billion in sales at risk.¹⁷⁰

These patent monopolies are a government creation. As noted above, they are also a recent one. Late into the 20th century, dozens of countries still refused to grant patents on essential medicines. Even today the U.N. Commissioner on Human Rights takes pains to emphasize the primacy of human rights obligations over

164. Naomi Kresge & John Lauerma, *Big Pharma Faces The Curse Of The Billion-Dollar Blockbuster*, BLOOMBERG (Jan. 11, 2019), <https://www.bloomberg.com/news/articles/2019-01-11/big-pharma-faces-the-curse-of-the-billion-dollar-blockbuster>.

165. Max Nisen, *The Drugs Big Pharma Depends On The Most*, QUARTZ (Mar. 2, 2015), <https://qz.com/353008/cash-cows/>.

166. Jacqueline Doherty, *The Barron's 500: Gilead Sciences Ranks No. 1*, BARRON'S (May 2, 2015), <https://www.barrons.com/articles/the-barrons-500-an-exclusive-ranking-1430541320>; Press Release, Gilead Scis., Inc., *Gilead Sciences Announces Fourth Quarter and Full Year 2015 Financial Results* (Feb. 2, 2016), <https://www.gilead.com/news-and-press/press-room/press-releases/2016/2/gilead-sciences-announces-fourth-quarter-and-full-year-2015-financial-results>.

167. Gilead Scis., Inc., *supra* note 166.

168. Simon Collins, *1,000-Fold Mark-Up for Drug Prices in High Income Countries Blocks Access to HIV, HCV and Cancer Drugs*, BODY PRO (Oct. 24, 2016), <https://www.thebodypro.com/article/1000-fold-mark-up-for-drug-prices-in-high-income-c>.

169. *See Merck and Pfizer Downgrades on Patent Cliff Concerns Signal Importance of Patents to Pharma*, IPWATCHDOG (Feb. 23, 2019), <https://www.ipwatchdog.com/2019/02/23/analysts-downgrade-merck-and-pfizer-on-patent-cliff-exclusivity-concerns/id=106497/>.

170. Samantha DiGrande, *Second Patent Cliff Lies Ahead for Pharma with \$251 Billion in Sales at Risk by 2024*, CTR. FOR BIOSIMILARS (June 7, 2018), <https://www.centerforbiosimilars.com/news/second-patent-cliff-lies-ahead-for-pharma-with-251-billion-in-sales-at-risk-by-2024>.

the discretionary economic policies that can create intellectual property such as patents.¹⁷¹

U.S. courts have also recognized the ephemeral, dependent nature of patents, holding in two prominent cases that they do not meet the definition of property under the Fifth Amendment's Takings Clause.¹⁷² Under U.S. law, the federal government may not be sued for actions like patent infringement unless it has waived its immunity, as it has via statutes such as the Federal Tort Claims Act.¹⁷³ The U.S. Supreme Court, in *Schillinger v. United States*, and the Federal Circuit Court, in *Zoltek Corp. v. United States*, both held that the constitution does not include any waiver of the federal government's rights to sovereign immunity from liability for infringement of patent rights. Both courts flatly rejected claims for a Fifth Amendment Takings Clause "just compensation" remedy for government infringement on a privately held patent.¹⁷⁴

However, the Supreme Court in 2015, in the aforementioned raisins seizure case of *Horne v. Department of Agriculture*, created some confusion on the question of whether patents are property under the Takings Clause.¹⁷⁵ The *Horne* Court repeated the language of an 1882 decision, *James v. Campbell*, stating that patent-holders do possess the entitlement to just compensation for government appropriation.¹⁷⁶ Pointing to the *Horne* and *James* language, some legal academics have since argued that patents should be considered property under the Takings Clause.¹⁷⁷

Despite that claim, the argument in support of patents being considered takings-applicable property is unsupported by the most relevant sources of law.¹⁷⁸ Neither the Court in *Horne* nor in *James* actually ruled on patent questions, making their pronouncements *dicta* on this issue. By contrast, the *Schillinger* Court did rule on the patent takings question, rejecting the idea of patents as takings property. And the *Schillinger* Court addressed the question a dozen

171. U.N. OHCHR, Sub-Comm'n on the Promotion & Prot. of Human Rights, 53d Sess., 25th mtg. at 2, U.N. Doc. E/CN.4/Sub.2/RES/2000/7 (Aug. 17, 2000).

172. *Schillinger v. United States*, 155 U.S. 163 (1894); *Zoltek Corp. v. United States*, 442 F.3d 1345, 1351 (Fed. Cir. 2006), *vacated on reh'g en banc*, 672 F.3d 1309 (Fed. Cir. 2012).

173. The Fifth Amendment's guarantee of due process of law—as opposed to a promise of just compensation for government seizure—has been held to apply to a wider definition of property than the Takings Clause. For example, welfare benefits have been held to represent sufficient property interests to invoke due process guarantees of review if the government takes them away. *Goldberg v. Kelly*, 397 U.S. 254 (1970).

174. *Schillinger*, 155 U.S. at 172; *Zoltek Corp.*, 442 F.3d at 1351.

175. *Horne v. Dep't. of Agric.*, 576 U.S. 350, 359-360 (2015).

176. *Id.* (quoting *James v. Campbell*, 104 U.S. 356, 358 (1881)).

177. Gregory Dolin & Irena D. Manta, *Taking Patents*, 73 WASH. & LEE L. REV. 719, 771 (2016).

178. Camilla A. Hrdy & Ben Picozzi, *The AIA is Not a Taking: A Response To Dolin & Manta*, 72 WASH. & LEE L. REV. ONLINE 475 (2016).

years after *James*, making it the Supreme Court's most recent case on the issue.¹⁷⁹

Schillinger was decided in 1894, but it holds up to modern standards. As mentioned above, Fifth Amendment Takings Clause jurisprudence places great emphasis on how the government taking may interfere with the impacted party's reasonable "investment-backed expectations" of uninterrupted, unencumbered ownership.¹⁸⁰ In the 1992 case *Lucas v. South Carolina Coastal Council*, the Supreme Court made it clear those expectations are limited in instances where the government exercises a "traditionally high degree of control," to the extent that "new regulation might even render his property economically worthless."¹⁸¹ The application in the medicines context is clear. There is no U.S. corporation holding a patent on a medicine that has not known from day one that the granting of a patent is a discretionary government action. They know, or should know, that the federal government retains rights under the Bayh-Dole Act and § 1498, as well as sweeping compulsory licensing powers protected by the TRIPS Agreement, to immediately and summarily access any patented invention or technology.

Section 1498 provides a statutory path for the patent-holder to receive compensation for government use. But its existence and legislative history further support the conclusion that patents are not Fifth Amendment takings property. In 2012, the Federal Circuit Court in *Zoltek* noted that § 1498 was originally passed as the Patent Act of 1910, sixteen years after the *Schillinger* court held that there was no constitutional requirement for just compensation for government patent infringement.¹⁸² Section 1498, the *Zoltek* court noted, was Congress's effort to provide a remedy to patent-holders via statute where one did not exist by virtue of the constitution.¹⁸³ Congress's decision after *Schillinger* to waive federal government immunity from those claims further undermines any argument that there is a constitutional guarantee to such compensation. The Supreme Court refused to hear the patent-holder's appeal from *Zoltek*.

Assuming § 1498 remains in its current iteration at the time of nationalization of the pharmaceutical industry, the United States would be subject to that statutory obligation to provide "reasonable

179. *Schillinger*, 155 U.S. at 172; see also *Christy, Inc. v. United States*, 141 Fed. Cl. 641, 658 (2019) (holding that patents are not considered property for Takings Clause purposes);

180. *Penn. Cent. Transp. Co. v. City of New York*, 438 U.S. 104, 124 (2018).

181. *Lucas v. S.C. Coastal Council*, 505 U.S. 1003, 1027–28 (1992).

182. *Zoltek v. United States*, 672 F.3d 1309, 1315 (Fed. Cir. 2012).

183. *Id.*

and entire compensation” to the patent-holder for use of the patent. Of course, that is a congressionally-granted remedy to the patent-holder, and Congress could amend § 1498 to exempt pharmaceutical patent infringements from that waiver of sovereign immunity. That congressional action could even be added to Step One contemplated here. Even if § 1498 remains undisturbed, however, the compensation level under the statute has traditionally been set far below the windfall gains currently realized by the patent-possessing private pharmaceutical companies.

The most current and applicable law holds that patent seizures do not trigger the “just compensation” obligation under the Fifth Amendment. The statutory remedy of compensation exists alone and can be removed by Congress. The government can and should seize medicines patents in Step Three and can do so without a constitutional obligation to compensate.

2. Most of the Value of Pharmaceutical Corporations Comes From Discretionary Government Actions—Including Early and Late-stage Research, Patent Licensure, Tax Breaks, and Government Purchases—and the Government Should not be Required to Compensate for that Lost Value Upon Seizure.

Although the windfall profits from the current U.S. pharmaceutical system flow into private hands, those profits and the assets that generate them are largely the products of discretionary government action. This phenomenon is best illustrated by a simple walk-through of the pharmaceutical process, from the laboratory to a patient’s medicine cabinet.

As noted above, the early-stage research that forms the most risky and lengthy segment of the medicines development process is funded almost entirely by government resources.¹⁸⁴ For the 210 new medicines approved by the FDA from 2010 to 2016, every one traces its origins back to government-funded research.¹⁸⁵ Next, the Bayh-Dole Act prods the government to award to private entities the monopoly patents that create most of the financial value of these medicines.¹⁸⁶ When those private companies conduct follow-up research and market their eventual product, the government

184. FRAN QUIGLEY, *PRESCRIPTION FOR THE PEOPLE: AN ACTIVIST’S GUIDE TO MAKING MEDICINE AFFORDABLE FOR ALL* 87–91 (2017).

185. Ekaterina G. Cleary et al., *Contribution Of NIH Funding To New Drug Approvals 2010–2016*, 115 PNAS 2329 (2018), <https://www.pnas.org/content/115/10/2329>.

186. 35 U.S.C. §§ 200–12 (2012).

allows them to deduct those costs from their tax obligations. And much of the late-stage research is federally funded as well.¹⁸⁷

Finally, federal and state governments step in to become the industry's number one customer for the medicines produced.¹⁸⁸ The prices they pay are artificially enhanced not just by government-granted patents, but also by the congressional decision in 2003 to prevent the Medicare system from using its substantial purchasing power to negotiate down the cost of the medicines it buys.¹⁸⁹ That no-negotiations promise costs the U.S. government as much as \$49 billion each year.¹⁹⁰

The government-dependent nature of the pharmaceutical industry business model has alarmed politically conservative advocates who typically support private industry. In 2018, Cato Institute scholars and law professors, Charles Silver and David Hyman, wrote in favor of eliminating the patent system for medicines. "Some conservatives defend this system on free-market grounds, arguing that any measure that reduces drug company profits will necessarily reduce innovation," they wrote. "But we are firm believers in the free market, and we think the system is a mess. It is deformed by monopolies and by misguided incentives tied to the payment system."¹⁹¹

The year before, conservative activist Mytheos Holt wrote in the *American Spectator* that "high drug prices are a result of specific government policy: something that decisively argues against the notion that the market for drugs is in any way free." Holt wrote that drug companies were benefitting from a "corporate welfare-driven pricing regime," and that legislation aimed at limiting patent-holders' ability to ward off generic alternatives was performing an important service by "smoking out the anticonservative nature

187. Rahul K. Nayak et al., *Public Sector Financial Support for Late Stage Discovery of New Drugs in the United States: Cohort Study*, BRIT. MED. J., Oct. 23, 2019, at 1, <https://doi.org/10.1136/bmj.l5766>.

188. Kerry Young, *Federal Government Emerges as Top Health Buyer in New Analysis*, CQ ROLL CALL (Dec. 5, 2016), <https://www.commonwealthfund.org/publications/newsletter-article/2016/dec/federal-government-emerges-top-health-buyer-new-analysis>; see also Ctrs. for Medicare & Medicaid Servs., *CMS Updates Drug Dashboards with Prescription Drug Pricing and Spending Data* (Mar. 14, 2019), <https://www.cms.gov/newsroom/press-releases/cms-updates-drug-dashboards-prescription-drug-pricing-and-spending-data> (discussing the U.S. government's overall spending on prescription medications for public insurance programs).

189. Peter Sullivan, *CBO: Pelosi Bill To Lower Drug Prices Saves Medicare \$345 Billion*, THE HILL (Oct. 11, 2019), <https://thehill.com/policy/healthcare/465491-cbo-pelosi-bill-to-lower-drug-prices-saves-medicare-345-billion>.

190. *Id.*

191. Charles Silver & David Hyman, *Here's a Plan To Fight High Drug Prices That Could Unite Libertarians and Socialists*, CATO INST. (June 21, 2018), <https://www.cato.org/publications/commentary/heres-plan-fight-high-drug-prices-could-unite-libertarians-socialists>.

of an industry that conservatives have been willing to accept uncritically as an ally for far too long.”¹⁹²

Beyond creating fissures in the free-market political support system that drug corporations have traditionally relied upon, the government-dependent nature of the pharmaceutical industry carries significance when determining just compensation for seizures. Common sense suggests that the seizing government should not be required to compensate private companies for any value that exists because of the government’s own actions. The Supreme Court agrees.

In the 1973 case *United States v. Fuller*, the Court held that Arizona ranchers were not entitled to Fifth Amendment takings compensation for the value of their seized land created by government permits for livestock grazing on adjacent federal lands.¹⁹³ The Court reviewed multiple cases holding that constitutionally-mandated just compensation does not include value created by government action, including when value was increased by anticipated government wartime boat purchases or planned government development on seized land. The *Fuller* Court wrote that “[t]hese cases go far toward establishing the general principle that the Government as condemnor may not be required to compensate a condemnee for elements of value that the Government has created”¹⁹⁴

The logic of this principle was recently explained by the conservative legal scholar and property rights activist Roger Pilon, writing for the Cato Institute where he serves as chair of constitutional studies:

[W]hen government actions incidentally reduce property values, but no rights are violated because nothing that belongs free and clear to the owner is taken, no compensation is due. If the government closes a military base or a neighborhood school, for example, or builds a new highway distant from the old one with its commercial enterprises, property values may decline as a result—but nothing was taken. We own our property and all the legitimate uses that

192. Mytheos Holt, *The Free Market Is Coming for Pharma*, AM. SPECTATOR (Feb. 13, 2017), <https://spectator.org/the-free-market-is-coming-for-pharma>.

193. *United States v. Fuller*, 409 U.S. 488 (1973).

194. *Id.* at 492.

go with it, not the value in our property, which is a function of many ever-changing factors.¹⁹⁵

The path to nationalization here includes the exercise of compulsory licensing power for pharmaceutical patents. Undoubtedly, that action will significantly reduce the government-created value currently enjoyed by pharmaceutical corporations. But those corporations have no right to that value, and it should be excluded from the calculation of what equals “just compensation” for seizure. As the Supreme Court stated in *Pennsylvania Coal v. Mahon*, “government hardly could go on if to some extent values incident to property could not be diminished without paying for every such change in the general law. As long recognized, some values are enjoyed under an implied limitation and must yield to the police power.”¹⁹⁶ The value possessed by pharmaceutical corporations due to discretionary government actions—charging prices inflated by government-granted patent monopolies and by selling medicines developed by government research—are in that category. Therefore upon seizure, the corporations are not entitled to compensation for that value.

3. The “Nuisance Exception” to Fifth Amendment Takings Law Along with Civil and Criminal Forfeiture Laws Exempt the Government from Any Obligation to Compensate Pharmaceutical Corporations for the Substantial Value Gained from Actions that Harm Public Health.

Much of the suffering and death occurring during the current national medicines crisis can be attributed to ill-advised government choices. The government grants private entities patent awards for government-funded discoveries via the Bayh-Dole Act, allows take-it-or-leave-it pricing via the 2003 Medicare program ban on negotiating down the price of medicines, and permits corporations to distort the market by gifting billions of dollars each year to prescribing physicians for non-research purposes such as honoraria, luxury goods, and travel.¹⁹⁷ These government actions, along

195. ROGER PILON, CATO INST., *Cato Handbook for Policymakers* 178 (2017), https://www.cato.org/sites/cato.org/files/serials/files/cato-handbook-policymakers/2017/2/cato-handbook-policymakers-8th-edition-16_0.pdf.

196. *Penn. Coal Co. v. Mahon*, 260 U.S. 393, 413 (1922).

197. *Persuading the Prescribers: Pharmaceutical Industry Marketing and its Influence on Physicians and Patients*, PEW (Nov. 11, 2013), <http://www.pewtrusts.org/en/research-and-analysis/fact-sheets/2013/11/11/persuading-the-prescribers-pharmaceutical-industry-marketing-and-its-influence-on-physicians-and-patients>.

with the broad retreat from the wise legacy of not awarding private monopolies for essential medicines, have all contributed to the crisis at hand.¹⁹⁸

There is no legal violation when pharmaceutical corporations work within existing regulatory structures to take advantage of a system rigged in their favor. But the corporations have not been content with fully ethical, legal opportunism. Instead, they have engaged in a wide range of well-documented, and pervasive practices that are either outright illegal or systematically abusive, inflicting grievous harm to public health in the process.

Industry practices such as price-fixing, abuses of the patent process, overcharging government programs, and a dizzying array of illegal marketing schemes have long been the subject of government investigations, criminal charges, and civil suits for misbehavior. There is a reason why the oft-sanctioned industry returns again and again to these practices, despite enduring billions of dollars in fines and penalties: these practices contribute substantially to the value of the companies. Under the nuisance exception to the Fifth Amendment's Takings Clause requirement for compensation, none of that value should be recovered by corporations when nationalization occurs.

It is beyond the scope of this Article to estimate the dollar amount of that ill-gotten value, but it is worth noting the breathtaking extent of the pharmaceutical industry's malfeasance. When the advocacy organization Public Citizen surveyed the major financial settlements and court judgments between pharmaceutical companies and federal and state governments from 1991 through 2017, it found that drugmakers entered into 412 settlements totaling \$38.6 billion in criminal and civil penalties.¹⁹⁹ These penalties included sanctions for dozens of major violations of the U.S. False Claims Act, the Anti-Kickback Statute, the Foreign Corrupt Practices Act, and multiple state laws prohibiting Medicaid fraud.

The most commonly-cited ethical offense involved violating restrictions on promoting off-label uses of products, prohibitions that exist because those uses have not been analyzed for possibly

198. Charles Ornstein et al., *We Found Over 700 Doctors Who Were Paid More Than a Million Dollars by Drug and Medical Device Companies*, PROPUBLICA (Oct. 17, 2019), <https://www.propublica.org/article/we-found-over-700-doctors-who-were-paid-more-than-a-million-dollars-by-drug-and-medical-device-companies>.

199. Sammy Almashat et al., *Twenty-Seven Years of Pharmaceutical Industry Criminal and Civil Penalties: 1991 Through 2017*, PUB. CITIZEN (Mar. 14, 2018), <https://www.citizen.org/article/twenty-seven-years-of-pharmaceutical-industry-criminal-and-civil-penalties-1991-through-2017>.

dangerous effects.²⁰⁰ For example, Pfizer was charged in 2009 with illegally promoting off-label uses of the pain medicine Bextra, which was later pulled from the market for safety reasons.²⁰¹ GlaxoSmithKline was fined \$12 billion in response to allegations it illegally promoted its antidepressant Paxil for use in adolescents, and Eli Lilly paid \$1.4 billion in response to claims it unlawfully promoted its antipsychotic drug Zyprexa—even to the point of training its sales persons in how to avoid legal requirements.²⁰² Despite the large settlements, the Public Citizen report and other advocates say the illegal marketing practices continue to be rampant. “Marketing departments of many drug companies don’t respect any boundaries of professionalism or the law,” says Jerry Avorn, a professor at Harvard Medical School.²⁰³

Multiple lawsuits and government investigations find that manufacturers of insulin, a drug that yields \$24 billion in annual revenue, have engaged in illegal price-fixing for decades.²⁰⁴ The three companies that dominate the global market for insulin—Sanofi, Novo Nordisk, and Eli Lilly—have raised the list prices of their products multiple times over many years in lock step. Current prices can reach as high as fifty times the estimated manufacturing cost.²⁰⁵ “Instead of falling prices, as one might expect after decades of competition, three drug makers who make different versions of insulin have continuously raised prices on this life-saving medication,” members of Congress wrote in 2016 when demanding the U.S. Department of Justice and Federal Trade Commission launch an investigation into price-fixing.²⁰⁶

200. Andreas Vilhelmsson et al., *Pharmaceutical Industry Off-Label Promotion and Self-Regulation: A Document Analysis of Off-Label Promotion Rulings by the United Kingdom Prescription Medicines Code of Practice Authority 2003–2012*, 13 PLOS MED. e1001945, e1001946 (2016), <https://journals.plos.org/plosmedicine/article?id=10.1371/journal.pmed.1001945>.

201. David Evans, *When Drug Makers’ Profits Outweigh Penalties*, WASH. POST (Mar. 21, 2010), <http://www.washingtonpost.com/wp-dyn/content/article/2010/03/19/AR2010031905578.html>.

202. *Id.*; Adriane Fugh-Berman, *How Basic Scientists Help the Pharmaceutical Industry Market Drugs*, 11 PLOS BIOLOGY e1001716 (2013), <https://journals.plos.org/plosbiology/article?id=10.1371/journal.pbio.1001716>.

203. Evans, *supra* note 201.

204. *\$24 Billion Insulin Markets – Global Intelligence Database 2012-2018 & 2019-2023*, GLOBE NEWSWIRE (May 29, 2019), <https://www.globenewswire.com/news-release/2019/05/29/1856512/0/en/24-Billion-Insulin-Markets-Global-Intelligence-Database-2012-2018-2019-2023.html>; Katie Thomas, *Drug Makers Accused of Fixing Prices on Insulin*, N.Y. TIMES (Jan. 30, 2017), https://www.nytimes.com/2017/01/30/health/drugmakers-lawsuit-insulin-drugs.html?_r=0.

205. See Dzintars Gotham et al., *Production Costs and Potential Prices for Biosimilars of Human Insulin and Insulin Analogues*, BRIT. MED. J. GLOBAL HEALTH, Sept. 25, 2018, at 1, 5, <https://gh.bmj.com/content/3/5/e000850>.

206. Ed Silverman, *Bernie Sanders Calls for Federal Investigation of Insulin Makers for Price Collusion*, STAT, (Nov. 13, 2016), <https://www.statnews.com/pharmalot/2016/11/03/sanders-insulin-investigation>.

The industry's manipulation of the patent process is likely its most vigorous and lucrative abuse of the laws and regulatory systems. The 2018 report by Initiative for Medicines, Access and Knowledge (I-MAK) revealed that the twelve top-selling drugs in the United States average 125 patent applications per drug, many of them frivolous, giving each drug an average of thirty-eight years of attempted patent protections—far beyond the baseline twenty-year patent life.²⁰⁷ Additional patents are often sought for minor changes to the original medicine or adjustments to the dosage or delivery system, such as transforming multiple doses into a once-a-day pill or even turning a tablet into a capsule.²⁰⁸ This “patent thickening,” process has been condemned by commentators from the USA Today editorial board (“abusive tactics”, “shameless gamesmanship”) to U.S. Senators (“manipulating the patent system”) to public health advocates (“abuse of the patent system”).²⁰⁹

Yet it continues. AbbVie, the manufacturer of the world's top-selling drug, Humira, has sought a remarkable two hundred and forty-seven patents on its use. Humira remains monopoly-protected in the United States until 2023, despite the fact that its main ingredient has been off-patent for several years.²¹⁰ In 2015, AbbVie's CEO bragged about the effectiveness of this tactic, “Any company seeking to market a biosimilar version of Humira will have to contend with this extensive patent estate, which AbbVie intends to enforce vigorously.”²¹¹

The massive impact that abuse of the patent process has on medicine prices, and thus the value of these corporations, is clear. I-MAK's analysis of the patent thicket-protected twelve best-selling drugs in the United States showed that from 2012 to 2018, the prices of eleven of these best-sellers rose an average of eighty percent. By one analysis, AbbVie makes nearly \$50 million in addi-

207. I-MAK, *supra* note 41, at 11.

208. Robin Feldman, ‘One-and-Done’ for New Drugs Could Cut Patent Thickets and Boost Generic Competition, STAT (Feb. 11, 2019), <https://www.statnews.com/2019/02/11/drug-patent-protection-one-done>.

209. Editorial, *How Big Pharma Plays Games With Drug Patents And How To Combat It*, USA TODAY (July 18, 2019), <https://www.usatoday.com/story/opinion/2019/07/18/big-pharma-plays-games-drug-patents-you-pay-editorials-debates/1769746001>; Press Release, Richard Durbin, U.S. Senator, Durbin Gives Pharma Fleece Award to Drug Companies Abusing Patent System (May 15, 2019), <https://www.durbin.senate.gov/newsroom/press-releases/durbin-gives-pharma-fleece-award-to-drug-companies-abusing-patent-system>; David Branigan, *Brief: Report - Patent Abuse a Leading Cause of High Drug Prices in US*, INTELL. PROP. WATCH (Aug. 3, 2018), <https://www.ip-watch.org/2018/08/03/report-patent-abuse-leading-cause-high-drug-prices-us>.

210. See Ellen ‘t Hoen, *Humiragate: Abbvie's Desperate Attempts to Keep Its Monopoly*, MEDICINES L. & POL'Y (Mar. 27, 2019), <https://medicineslawandpolicy.org/2019/03/humiragate-abbvies-desperate-attempts-to-keep-its-monopoly>.

211. QUIGLEY, *supra* note 184, at 79.

tional revenue per day on Humira due to extended patents.²¹² Little wonder that the corporations are known to deploy “floors full of lawyers” to extend patents, overwhelming regulatory agencies and any comparatively underfunded opposition to patent thickening.²¹³ Economists studying the global intellectual property system have concluded that this phenomenon has led to many weak patents that go unchallenged.²¹⁴

Another way that pharmaceutical companies extend monopolies via unethical behavior is through so-called “pay-for-delay” schemes. For a would-be generic or biosimilar manufacturer, the patent thickets present a significant challenge. Before it can sell its product, the generic manufacturer faces costly, years-long, thicket-citing lawsuits filed by the deep-pocketed corporation that holds the patents. Knowing this, the patent-holding pharmaceutical companies offer would-be competitors a substantial sum in return for an agreement to postpone the entry of a generic drug into the market. A recent analysis showed that more than one-third of generic medicines approved by the FDA between 2016 and 2018 were not yet on the market, often because of thickening and pay-for-delay.²¹⁵ Pay-for-delay has been described as “one of the sleaziest and most blatantly self-serving” of all anti-competitive practices.²¹⁶ It is also effective. The Federal Trade Commission estimates that the extended monopoly price boost from pay-for-delay schemes costs U.S. patients an extra \$3.5 billion each year.²¹⁷

Upon government seizure, none of the value extracted by these manipulative practices should be reimbursed to pharmaceutical corporations. The Supreme Court has often explained that the just compensation guarantee “was designed to bar Government from forcing some people alone to bear public burdens which, in all

212. AbbVie’s \$19.9 billion increase in annual revenue amounts to \$54.5 million per day. See Press Release, AbbVie, AbbVie Reports Full-Year and Fourth-Quarter 2018 Financial Results (Jan. 25, 2019), <https://news.abbvie.com/news/abbvie-reports-full-year-and-fourth-quarter-2018-financial-results.htm>. When faced with generic competition in other countries, AbbVie cut the price of Humira by almost ninety percent. ‘t Hoen, *supra* note 210.

213. See Priti Radhakrishnan, *Pharma’s Secret Weapon to Keep Drug Prices High*, STAT (June 14, 2016), <https://www.statnews.com/2016/06/14/secondary-patent-gilead-sovaldi-harvoni/>.

214. See BAKER ET AL., *supra* note 36, at 37.

215. Jared S. Hopkins, *Generic-Drug Approvals Soar, but Patients Still Go Without*, WALL ST. J. (Nov. 20, 2019), <https://www.wsj.com/articles/many-generic-drugs-havent-hit-market-hindering-cost-control-efforts-11574198448>.

216. Zachary Roth, *Drug-Makers Paying Off Competitors to Keep Cheap Generics off Market*, TPM Muckraker, TALKING POINTS MEMO (Dec. 2, 2009), <http://talkingpointsmemo.com/muckraker/drug-makers-paying-off-competitors-to-keep-cheap-generics-off-market>.

217. Press Release, Jon Leibowitz, U.S. Fed. Trade Comm’n, ‘Pay-for-Delay’ Settlements (June 23, 2009), <https://www.ftc.gov/news-events/press-releases/2009/06/ftc-chairman-leibowitz-eliminating-pay-delay-pharmaceutical>.

fairness and justice, should be borne by the public as a whole.”²¹⁸ But the Court has also long made it clear that the “fairness and justice” justification for compensation is negated when the government seizes property in order to stop the private owner from deploying it in a manner that harms the public welfare.

This exception to Fifth Amendment takings law is known as the “nuisance” or “noxious use” exception. It traces its origins back to at least 1887, when the Supreme Court in *Mugler v. Kansas* rejected a challenge by a brewer to Kansas temperance laws that *de facto* destroyed the brewer’s business. The *Mugler* Court held that the government is within its police power to conduct a seizure to protect public health, safety, or welfare without the requirement of compensation:

The power which the states have of prohibiting such use by individuals of their property, as will be prejudicial to the health, the morals, or the safety of the public, is not—and, consistently with the existence and safety of organized society, cannot be—burdened with the condition that the state must compensate such individual owners for pecuniary losses they may sustain, by reason of their not being permitted, by a noxious use of their property, to inflict injury upon the community.²¹⁹

Importantly, the noxious use exception does not require a finding that the harmful acts were illegal prior to seizure. For example, the noxious use exception was applied when value was lost in *Mugler* (formerly legal liquor sales), *Goldblatt v. Town of Hempstead* (once-permissible gravel and sand mining zoned out by ordinance), *Miller v. Schoene* (diseased trees removed), and *Hadacheck v. Sebastian* (brick yard zoned out by ordinance).²²⁰ There is an argument to be made that a certain level of patent thicketing and even pay-for-delay schemes by pharmaceutical corporations are not violations of current law.²²¹ But there is no argument that these practices are not, in the words of the *Mugler* Court, “prejudicial to the health, the morals, or the safety of the public,” and therefore companies engaged in these practices are not required to be compensated for the fruits of their misdeeds.

218. *Armstrong v. United States*, 364 U.S. 40, 49 (1960).

219. *Mugler v. Kansas*, 123 U.S. 623, 669 (1887).

220. *Id.*; *Goldblatt v. Town of Hempstead*, 369 U.S. 590 (1962); *Miller v. Schoene*, 276 U.S. 272, (1928); *Hadacheck v. Sebastian*, 239 U.S. 394 (1915).

221. The U.S. Supreme Court in 2013 engaged in, but did not fully clarify, the pay-for-delay issue. *Fed. Trade Comm’n v. Actavis, Inc.*, 570 U.S. 136 (2013).

Throughout the 20th century, the nuisance/noxious use exception continued to be recognized, including in Justice Brandeis' dissent in the landmark 1922 decision *Pennsylvania Coal v. Mahon*, and six years later in *Miller v. Schoene*.²²² In *Miller*, the Court cited *Mugler* in refusing to allow compensation for the state of Virginia's destruction of infected red cedar trees on Miller's property, ruling that protecting the broader public at the expense of a property owner's interests was a core principle of legislative police powers.

As noted above, the *Mahon* decision was the first to hold that a governmental regulation can burden the use of private property such that the regulation rises to the level of a taking that requires compensation under the Fifth Amendment. But in 1987, the Court in *Keystone Bituminous Coal Ass'n v. DeBenedictis* reaffirmed that the requirement to compensate is removed when the regulation advances a legitimate state interest, such as the interest in stopping a threat to the common welfare.²²³ "Courts have consistently held that a State need not provide compensation when it diminishes or destroys the value of property by stopping illegal activity or abating a public nuisance."²²⁴ In 1992, the Court in *Lucas v. South Carolina Coastal Council* again recognized the "long line of this Court's cases" affirming the nuisance exception to the general rule requiring compensation.²²⁵ The *Lucas* facts involved a regulatory taking, not a full seizure of property, but the Court's reasoning and subsequent lower federal court decisions point in the direction of the nuisance exception applying to physical takings as well as regulatory takings.²²⁶

The nuisance exception coexists alongside multiple state and federal statutes enabling forfeiture of private property connected to illegal activity, as long as those forfeitures do not violate the "excessive fines" clause of the Eighth Amendment.²²⁷ As one report put it after the drug company GlaxoSmithKline was fined \$2.8 billion for its illegal marketing, the company had become a "sophisticated criminal enterprise."²²⁸ Of course, the U.S. government has

222. 260 U.S. 393 (1922) (Brandeis, J., dissenting); *Miller v. Schoene*, 276 U.S. 272 (1928).

223. 480 U.S. 470, 492 (1987).

224. *Id.*

225. *Lucas v. S.C. Coastal Council*, 505 U.S. 1003, 1022 (1992).

226. See *John R. Sand & Gravel Co. v. United States*, 60 Fed. Cl. 230 (2004); Miles E. Coleman, *Taking on a Nuisance: Applying Lucas to Physical Takings*, 21 FED. CIR. BAR J. 747, 754 (2012).

227. See Anne Teigen & Lucia Bragg, *Evolving Civil Asset Forfeiture Laws*, LEGISBRIEF (Nat'l Conf. of State Legislatures, Washington, D.C.), Feb. 2018, at 1, 1-2, <http://www.ncsl.org/research/civil-and-criminal-justice/evolving-civil-asset-forfeiture-laws.aspx>.

228. Matthew Kauffman, *Glaxosmithkline: From Pharmaceutical Powerhouse to Sophisticated Criminal Enterprise*, N.Y. DAILY NEWS (July 9, 2012), <https://www.nydailynews.com/hc-xpnm>

no obligation upon seizure of a criminal enterprise's assets to reimburse them for the value they extracted from illegal acts. Criminal convictions are not a prerequisite for forfeiture, just a showing that the seized property was involved in criminal activity. In fact, in a recent ten-year period, the U.S. Drug Enforcement Administration took at least \$3.2 billion in cash from people who were never charged with a crime.²²⁹ This civil forfeiture right to taking without compensation exists alongside the TRIPS Agreement-protected right to issue compulsory licensing with low or zero remuneration when necessary to remedy anti-competitive practices.²³⁰

In sum, the law provides both tools and justifications for the government to seize some pharmaceutical corporation assets and refuse to compensate on the grounds that the assets were used to further a public nuisance or criminal activity. In this context, the boundaries of the uncompensated seizures will be equal to a calculation of the value obtained by the corporations' actions that furthered a public nuisance. It is beyond the scope of this Article to estimate that precise amount. However, given the sordid record of marketing fraud and patent abuse outlined above, the total will be substantial. It is worth again quoting constitutional scholar and property rights advocate Roger Pilon of the Cato Institute, this time for his explanation for why the Fifth Amendment does not require compensation for value obtained by noxious or illegal acts. "When government acts, under its police power, to secure rights—when it stops someone from polluting, for example, or from excessively endangering others—the restricted owner is not entitled to compensation, whatever his financial losses, because the uses prohibited or "taken" were wrong to begin with. . . . [H]ere again the question is not whether value was taken but whether a right was taken. Proper uses of the police power take no rights. They protect rights."²³¹

2012-07-09-hc-glaxosmithkline-from-pharmaceutical-powerhouse-to-sophisticated-criminal-enterprise-20120709-story.html.

229. Christopher Ingraham, *No, Asset Forfeiture Will Not Pay for the Wall*, WASH. POST. (Jan. 14, 2019), <https://www.washingtonpost.com/business/2019/01/14/no-asset-forfeiture-will-not-pay-wall>.

230. Love, *supra* note 143.

231. PILON, *supra* note 195.

D. *Step Four: The USMA Seizes and Compensates Private Industry for the Remaining Assets that Trigger the Just Compensation Requirement*

As was the case with the Tennessee Valley Authority Act of 1933 and the Aviation and Transportation Security Act of 2001, if the U.S. government executed Steps One through Three outlined in this Article, it would inflict grievous damage on privately held corporations. That is a result that the United States has neither the moral nor the legal obligation to regret.

As the Supreme Court held in the challenge to the TVA by the private businesses it displaced, the harm experienced by pharmaceutical corporations is “damnum absque injuria—a damage not consequent upon the violation of any right recognized by law.”²³² As the Court later ruled in *United States v. Willow River Power Co.*, where the federal government raising of a river’s water level harmed the efficiency of the plaintiff’s hydroelectric plant, loss of economic value alone did not lead to a constitutional obligation to compensate. “[The Fifth Amendment] does not undertake, however, to socialize all losses, but those only which result from a taking of property.”²³³ Similar decisions upholding the government’s right to take actions even when they are injurious to private interests were issued by the Court in *Block v. Hirsch* (District of Columbia rent control is a legitimate use of state power, despite financial loss to landlords) and *Home Building and Loan v. Blaisdell* (widespread economic emergency justified Minnesota’s suspension of home creditors’ foreclosure rights).²³⁴

The TVA sequence provides the blueprint for the final stage of the nationalization of the pharmaceutical industry. After losing their legal challenge to the government’s action creating the TVA, the Tennessee Electric Power Company sold its electric system to the TVA and shut down its energy business.

Here, the U.S. pharmaceutical industry will be forced to choose the same option. Its business model will be undercut by widespread compulsory licensing in the United States, its most important market. Compensation will be denied for both the value of withdrawn government support and the value gained by the industry’s nuisance behavior. The remaining value of the pharmaceutical corporations will resemble that of an oil field run dry: the land and equipment have some residual worth, but it is a fraction of the value the land had when the oil flowed.

232. *Tenn. Elec. Power Co. v. Tenn. Valley Auth.*, 306 U.S. 118, 137 (1939).

233. *United States v. Willow River Power Co.*, 324 U.S. 499, 502 (1945).

234. *Block v. Hirsh*, 256 U.S. 135, 155–57 (1921).

In the process outlined here, the federal government will exercise its rights to shut off the flow of taxpayer-provided riches to the pharmaceutical industry. Once it does so, compensation for the remaining value, including manufacturing plants and distribution infrastructure, will come at a reasonable price. That transaction will finally conclude the tragic era of medicines profiteering and launch a new system that restores life-saving medications to their rightful place as affordable, accessible public goods.

CONCLUSION

Millions of Americans are in pain, at risk of emergency hospitalization, and even dying. They suffer because they cannot afford medicines that are inexpensive to manufacture and were discovered by government-funded research. Those medicines are held in monopolies by private, for-profit corporations that set prices at levels ensuring both record profit margins and a society-wide crisis in accessing essential treatment.

U.S. history and law have cleared the path towards ending this crisis. Medicines are a public good, and U.S. constitutional law justifies full seizure of all assets of the pharmaceutical industry. Moreover, the compensation for that seizure will be substantially reduced because of the industry's reliance on government funding and licensing and its widespread malfeasance that harms the public welfare.

Since the country's birth, the U.S. people, acting through their government, have shown time and again a willingness to elevate the needs of the community over the interests of private property. It is time to make that choice again. It is time for the United States to nationalize its pharmaceutical industry.

