



**Regulatory  
Transparency  
Project**  
*Unlocking Innovation & Opportunity*

# The Proper Role of Rules in a Gloriously Unruly Economy

## Regulatory Process

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## Introduction

Hard work, ingenuity, and entrepreneurship built America. Respect for democratic processes, the rule of law, property rights, and honest competition rewarded those noble traits, promoting prosperity, economic growth, and opportunities for all people. Yet, the past few decades have seen a decline in economic growth and opportunity, and research suggests that misguided government policies that have strayed from American ideals have contributed to this stagnation.<sup>1</sup> In particular, poorly designed regulations have tended to advantage the well-connected, stifle innovation, and undermine the American spirit. Recent efforts at regulatory reform, along with tax reform, are widely credited with the recent increase in economic growth, business confidence, and employment.<sup>2</sup> This paper explores the relationship between regulation and well-being with illustrations of regulations done poorly, and also some examples of regulatory reform success stories. It finds that an approach to regulation that encourages, rather than dampens, creativity and competition, that targets real problems, and is based on sound evidence will lead to a stronger, more resilient, and more inclusive economy.

### The Public Bears the Unconstrained Cost of Regulations

#### I.

Regulations, or rules, are binding laws written and enforced by unelected government officials. Few would argue with the expressed goals of most regulations, such as a clean environment, safe foods and drugs, and fair work practices. But, in practice, the costs of compliance can be quite high. The public is often unaware of this, even though they ultimately bear these costs through higher prices, fewer available products and services, and stifled wages and job opportunities. Businesses don't simply "absorb" such losses; they must fall on real people.

Regulatory costs can rarely be traced to their source. We cannot know the total impact of government regulation because, unlike non-regulatory government programs supported by a fiscal budget, the cumulative costs of regulation are never assigned to an agency or tallied up. Regulatory costs imposed by the government on the public do not face an annual budget review from elected

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1 Dawson, J.W. & Seater, Federal regulation and aggregate economic growth, J.J. J Econ Growth (2013) 18: 137. <https://doi.org/10.1007/s10887-013-9088-y>

2 See, e.g., Binyamin Appelbaum & Jim Tankersley, The Trump Effect: Business, Anticipating Less Regulation, Loosens Purse Strings, N.Y. Times (Jan. 1, 2018), <https://www.nytimes.com/2018/01/01/us/politics/trump-businesses-regulation-economic-growth.html>. Since early 2017, the Trump Administration has taken a number of steps aimed at reducing regulatory burdens. Executive Order 13771 directs executive agencies to repeal two regulations for every new regulation they adopt. Exec. Order No. 13771, 82 Fed. Reg. 9339 (Jan. 30, 2017). It also instructs agencies to hold the net costs of new regulations to zero—i.e., for all new regulatory costs an agency imposes on the private sector, it must save at least that much by repealing or streamlining other regulations. Id. Executive Order 13777, moreover, directs agencies to appoint Regulatory Reform Officers and Regulatory Reform Task Forces that are charged with identifying outdated or costly regulations that can be repealed or reformed. Id. Finally, a number of agencies from across the federal government have embarked on projects to limit the use of sub-regulatory "guidance" documents that agencies often issue with little public notice or opportunity for comment.

officials nor do they compete for budget dollars with other priorities, as government appropriations do. From a regulator’s perspective, costs are not limited by available resources.<sup>3</sup>

Congress authorizes regulation through statutes that express broad (usually laudatory) goals, but it delegates the power to write and enforce detailed rules— “the fine print”—to regulatory agencies. Lacking the budget constraints that their nonregulatory counterparts face, regulatory agencies tend to pursue their narrow missions without regard to other legitimate goals, such as a strong and growing economy and consumer choice.<sup>4</sup> To a hammer, everything looks like a nail; to a regulatory agency, the solution to any problem is more regulation.

Further, once they are in place, agencies rarely evaluate regulations to see if they are working as intended. Unfortunately, too often rules can end up doing more harm than good. For instance, well-connected groups—those who can hire lobbyists and know the right people in Washington—can manipulate new or revised regulations so that the groups’ members gain at the expense of ordinary citizens. Large, established interest groups, such as large companies, trade associations, environmental groups, trial lawyers, unions, and state, local, and tribal governments, generally have much better access to legislators and regulatory officials and thus can better influence how regulations are designed and enforced.<sup>5</sup> This can disadvantage everyone else: ordinary consumers, taxpayers, workers, small businesses, the middle class, and the poor.

Improving regulatory processes—demanding better justification for regulatory actions, increasing checks and balances, and ensuring more realistic feedback and evaluation—could greatly improve regulatory outcomes, achieving regulatory benefits at much lower costs. Doing so could unleash greater economic growth, well-being, and prosperity for all Americans.

The next section illustrates some of the problems our current regulatory process creates, both the misuse of regulation by special interests and the unintended consequences of well-meaning regulation. The section following that examines successes realized when regulations were removed or loosened, sometimes temporarily. Comparing these experiences shows what kind of regulatory process changes might encourage the achievement of important regulatory goals faster and cheaper than current practice.

II.

## When Regulations Go Wrong

Regulation can confer advantages on certain groups at the expense of others. Well-connected or well-organized interests may improperly benefit from regulations when they dominate the rulemaking process and shape regulations to their advantage. Even when developed with the best of

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<sup>3</sup> Executive Order 13771, “Reducing Regulation and Controlling Regulatory Costs,” issued in January 2017, seeks to impose a budget constraint on certain federal agencies. Among other things, it requires them to offset the costs of new regulations by reducing costs of existing regulations. *Id.*

<sup>4</sup> See H. Beales et al., *Government Regulation: The Good, The Bad, & The Ugly*, FEDERALIST SOCIETY REGULATORY TRANSPARENCY PROJECT (June 12, 2017), <https://regproject.org/wp-content/uploads/RTP-Regulatory-Process-Working-Group-Paper.pdf>.

<sup>5</sup> *Id.*

intentions, moreover, regulations can have unintended and negative consequences that perversely harm, rather than protect, the public. Below are examples illustrating both results.

### Dying patients denied promising treatment

It was early March 2001 when doctors told twenty-one-year-old Abigail Burroughs that they had exhausted conventional options for treating her cancer. However, she was told, a new drug, Erbitux, might save her life . . . the problem was that the U.S. Food and Drug Administration (FDA) had not approved its use.<sup>6</sup>

Abigail, with her father, Frank, and family and friends, embarked on a life-or-death effort to gain access to Erbitux. First, the drug companies insisted they could not provide the drug without FDA approval. So Abigail and her supporters petitioned Congress and gained widespread and sympathetic media coverage. This did not budge the FDA. The FDA housed great expertise, but its regulatory process emphasized caution in every instance, even when a drug may be a patient's last chance. The FDA's monopoly power over drug approval allowed it to proceed at its own unhurried pace and ignore special circumstances.

Abigail died on Saturday, June 9, 2001. By the time the FDA finally approved Erbitux in February 2004, almost 179,000 people like her had died from a similar, treatable, form of cancer.<sup>7</sup>

Sadly, Abigail's story is not unique. A few years ago, Ronald Trowbridge and Steven Walker explained in *The Wall Street Journal* what they called the "tragic standard for loss of life" set by the FDA through the inefficiencies inherent in its cumbersome drug approval process.<sup>8</sup> They documented twelve examples of drugs produced to treat life-threatening conditions, all eventually approved by the FDA, that were available only to the limited number of patients enrolled in clinical trials. Had these twelve drugs "been available to people denied entry to clinical trials" by the FDA, "it might have helped more than one million mothers, fathers, sons and daughters live longer, better lives."<sup>9</sup>

At least in principle, the FDA does offer seriously ill patients limited options for obtaining access to unapproved medicines. For example, some patients may be able to gain access to experimental treatments by enrolling in a clinical trial. But for many conditions, large numbers of patients are not eligible to enroll in a clinical trial for reasons as varied as their age, physical condition, severity or progression of the disease, co-morbidity and risk factors, and countless other criteria.<sup>10</sup>

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<sup>6</sup> Donald Devine, *Abigail's 16-Year Senate Victory Over FDA Bureaucrats*, AM. SPECTATOR (November 16, 2017, 12:00 AM), <https://www.wsj.com/articles/SB118705547735996773>.

<sup>7</sup> Id.

<sup>8</sup> Ronald L. Trowbridge & Steven Walker, *The FDA's Deadly Track Record*, WALL ST. J. (Aug. 14, 2007 12:01 AM), <https://www.wsj.com/articles/SB118705547735996773>.

<sup>9</sup> Id.

<sup>10</sup> See, e.g., Susan Jin, Richard Pazdur & Rajeshwari Sridhara, *Re-Evaluating Eligibility Criteria for Oncology Clinical Trials: Analysis of Investigational New Drug Applications in 2015*, 35 J CLIN ONCOL 3745 (2017).

Through FDA’s expanded access and Treatment Investigational New Drug programs—more familiarly known as “compassionate use”—patients with serious or immediately life-threatening illnesses for which there are no approved treatment options may be given permission to use an experimental drug outside a clinical trial.<sup>11</sup> However, the procedures and requirements for being granted a compassionate use exemption are complex and burdensome, which makes it difficult for patients and their doctors to apply. In addition, limitations on drug manufacturers, including restrictions on how much they can charge patients, often make the companies reluctant to participate.<sup>12</sup> And though the overwhelming majority of patients who manage to navigate the process are eventually granted permission,<sup>13</sup> it often comes too late for the drug to have any effect in terminally ill patients.<sup>14</sup>

Under pressure from Congress, the news media, and the public, the FDA has taken steps in recent years to streamline its expanded access application process and reduce approval times.<sup>15</sup> And in May 2018, Congress enacted and President Trump signed into law the Right to Try Act, which is intended to provide another pathway for granting seriously ill patients access to unapproved medicines.<sup>16</sup> But as of this writing, it is too soon to know how well either of these reforms will work in practice.

Even if they do work well for some patients, thousands of others will continue to suffer from the FDA’s extreme risk aversion and its demands for lengthy, burdensome reviews. For example, in March 2013, an outbreak of meningitis, an often-fatal inflammation of the tissues surrounding the brain and spinal cord, occurred at Princeton University. A similar outbreak occurred at the University of California, Santa Barbara.<sup>17</sup> The fatality rate for meningitis is about 10 percent, and some 4,000 new cases are diagnosed each year.<sup>18</sup> The campus outbreaks affected 13 people, causing one death and another student to lose his feet to amputation.

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<sup>11</sup> Expanded Access to Investigational Drugs for Treatment Use, 21 CFR part 312, subpart I.

<sup>12</sup> See Alison Bateman-House, *To Speed Access to Compassionate Use, Look Beyond the FDA*, HEALTH AFFAIRS BLOG (Aug. 10, 2017), <https://www.healthaffairs.org/doi/10.1377/hblog20170810.061480/full>.

<sup>13</sup> U.S. Government Accountability Office, INVESTIGATIONAL NEW DRUGS: FDA HAS TAKEN STEPS TO IMPROVE THE EXPANDED ACCESS PROGRAM BUT SHOULD FURTHER CLARIFY HOW ADVERSE EVENTS DATA ARE USED, GAO-17-564 (July 2017).

<sup>14</sup> See, e.g., Gregory Conko, *Sick Patients Need Cutting-Edge Drugs*, WALL ST. J. (Aug. 23, 2008) <https://www.wsj.com/articles/SB121944789005365195>; Anon., *How About a 'Kianna's Law'?* WALL ST. J. (Mar. 24, 2005) <https://www.wsj.com/articles/SB111163190273988429>.

<sup>15</sup> U.S. Government Accountability Office, *supra* note 8.

<sup>16</sup> Trickett Wendler, Frank Mongiello, Jordan McLinn, and Matthew Bellina Right to Try Act of 2018. Public Law No. 115-176.

<sup>17</sup> Brady Dennis, *Meningitis Outbreaks at Princeton, UC Santa Barbara Prompt Concern, Vaccine Efforts*, WASH. POST (Dec. 3, 2013), [https://www.washingtonpost.com/national/health-science/meningitis-outbreaks-at-princeton-uc-santa-barbara-prompt-concern-vaccine-efforts/2013/12/03/1f8ed938-5c68-11e3-bc56-c6ca94801fac\\_story.html?noredirect=on&utm\\_term=.c549311536f5](https://www.washingtonpost.com/national/health-science/meningitis-outbreaks-at-princeton-uc-santa-barbara-prompt-concern-vaccine-efforts/2013/12/03/1f8ed938-5c68-11e3-bc56-c6ca94801fac_story.html?noredirect=on&utm_term=.c549311536f5).

<sup>18</sup> *Bacterial Meningitis*, CTRS. FOR DISEASE CONTROL, <https://www.cdc.gov/meningitis/bacterial.html>.

A vaccine was available in Canada, Europe, and Australia—but not in the United States. It took until December for the FDA to give emergency approval to use the vaccine on these two college campuses.<sup>19</sup> And it was January 2015 before the FDA approved general use of the vaccine.<sup>20</sup>

Similarly, effective sunscreen ingredients are more widely available abroad than in the United States. The United States has 16 permitted ingredients, the EU has more than two dozen, and Japan has more than 40.<sup>21</sup> Sunscreens are widely recognized, and recommended by several government agencies, as an effective method to prevent skin cancer, a disease that afflicts 5 million Americans each year.<sup>22</sup> When Congress grew frustrated with the slow pace of FDA review of additional ingredients, it commanded the agency to make a decision by February 2015. The FDA did so—by rejecting all eight pending applications, asking for more data. To date, no manufacturer has found it worth the enormous costs of yet another study to demonstrate the safety and efficacy of ingredients that other countries have already approved.<sup>23</sup>

Or consider aspirin, a homely, familiar, and time-tested product included in millions of American medicine cabinets. Since 1985, the FDA has recognized that a daily aspirin regimen is an effective way to prevent a second heart attack.<sup>24</sup> Since 2002, the American Heart Association and the U.S. Preventative Services Task Force have recommended the same regimen to prevent a first heart attack.<sup>25</sup> Although the body of clinical evidence is persuasive to these expert organizations, they are not sufficient for the FDA. In 2014, it rejected an application for claims that aspirin can prevent a first heart attack, and it still refuses to permit such claims.<sup>26</sup> Because aspirin is widely available, many Americans can, and do, take a daily dose of aspirin, either on their own or following their doctor's advice. Nonetheless, the FDA continues to insist on the need for costly additional studies to prove even more conclusively what we already know.<sup>27</sup>

B.

### Sugar price supports: not so sweet

Some regulatory actions serve to artificially increase prices, particularly those of agricultural products. These are often defended as necessary to protect family farms and rural communities, especially from factors beyond farmers' control—like weather conditions—that can cause prices (and therefore revenues) to fluctuate widely.

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<sup>19</sup> Mark Flatten, *Studied to Death: FDA Overcaution Brings Deadly Consequences*, GOLDWATER INST. 13 (Nov. 2018), <https://goldwaterinstitute.org/wp-content/uploads/2018/11/Studied-to-Death-web.pdf>.

<sup>20</sup> *Id.*

<sup>21</sup> Marc S. Reisch, *After More Than A Decade, FDA Still Won't Allow New Sunscreens*, CHEM. & ENG'G NEWS (May 18, 2015), <https://cen.acs.org/content/cen/articles/93/i20/Decade-FDA-Still-Wont-Allow.html>; *Should You Buy Sunscreen from Europe or Japan Instead?*, FUTUREDERM (July 6, 2012), <https://www.futurederm.com/should-you-buy-sunscreen-from-europe-or-japan-instead/>.

<sup>22</sup> *Skin Cancer*, AM. ACAD. OF DERMATOLOGY, <https://www.aad.org/media/stats/conditions/skin-cancer>.

<sup>23</sup> Flatten, *supra* note 11, at 13.

<sup>24</sup> *Id.* at 7.

<sup>25</sup> *Id.*

<sup>26</sup> *Id.*

<sup>27</sup> *Id.*

One of the clearest examples of this regulatory activity is the U.S. sugar price support program, which uses three methods of artificially increasing prices for domestic sugar: guaranteed prices, domestic allotments, and import quotas. This program has been successful at keeping sugar prices high. Between 1982 and 2016, domestic U.S. prices averaged nearly double the world price: 29.28 cents vs 15.2 cents per pound.<sup>28</sup> The total cost of the program to sugar consumers is an estimated \$2.4 billion annually, with approximately \$1.4 billion going to sugar growers.<sup>29</sup> Like many price support programs, it continues to exist because of its relatively small cost to the typical sugar-using consumer (about \$10 per year) and, therefore, is not worth most people's attention. For sugar farms, however, the average benefit of roughly \$310,000 per year is worth significant lobbying expenditures to maintain the rules.<sup>30</sup>

Although the \$1.4 billion represents a loss for consumers and gain for producers, the \$1 billion difference in the total cost of the program is due to a reduction in U.S. economic output due to inefficient use of resources, such as shifting candy production overseas where sugar is cheaper. Without the program, overall economic activity in the country would be \$1 billion greater. The higher price reduces the ability of more sugar to be sold and consumed, reducing the number of jobs, investment, and other activity that would benefit more Americans.

### C. Out-of-date regulations reduce risk for no one

Once regulations are on the books, they are rarely evaluated to determine whether they are still needed or working as intended.<sup>31</sup> This can be a particular problem when regulations don't keep up with evolving technologies and business practices, as this next example illustrates.

Since at least the mid-19<sup>th</sup> century, people have attempted to find safe ways of transmitting money across long distances, eventually resulting in what became commonly known as "money orders." There was a persistent problem, however, that the companies that agreed to take and transmit cash would simply take a customer's money or might, through negligence, lose it by theft or other means. In order to protect money order customers, states began to pass laws requiring the licensing of companies that transmitted money.<sup>32</sup> These licenses were intended to assure the public that these companies could be trusted with holding their money.<sup>33</sup>

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<sup>28</sup> *Sugar and Sweeteners Yearbook Tables*, USDA, <https://www.ers.usda.gov/data-products/sugar-and-sweeteners-yearbook-tables/sugar-and-sweeteners-yearbook-tables/#World%20and%20U.S.%20Sugar%20and%20Corn%20Sweetener%20Prices>.

<sup>29</sup> Michael K. Wohlgenant, *Sugar Price Supports are Not So Sweet*, U.S. NEWS & WORLD REP. (Sept. 5, 2014), <https://www.aei.org/publication/sugar-price-supports-are-not-so-sweet/>.

<sup>30</sup> Tim Worstall, *If US Sugar Tariffs Make Americans Poorer than Donald Trump's Tariffs Will Make Americans What?*, FORBES (Jan. 18, 2017), <https://www.forbes.com/sites/timworstall/2017/01/18/if-us-sugar-tariffs-make-americans-poorer-than-donald-trumps-tariffs-will-make-americans-what/#193b887e2ec4>.

<sup>31</sup> Dudley, S. (2017), "Retrospective evaluation of chemical regulations", *OECD Environment Working Papers*, No. 118, OECD Publishing, Paris, <https://doi.org/10.1787/368e41d7-en>.

<sup>32</sup> See Andrew Schouten, *Unlicensed Money Transmitting Businesses and Mens Rea Under the USA Patriot Act*, 39 MCGEORGE L. REV. 1097, 1104 (2008).

<sup>33</sup> *Id.*

Technology, however, has advanced and, today, it is no longer necessary for a company that transmits funds to actually obtain them from a customer. For instance, cryptocurrency, like Bitcoin, allows a service provider to offer money transmission services without taking custody of a customer's funds.<sup>34</sup> While a consumer will see a website interface that looks a lot like a bank portal, their money is not in an account held by a third party, but instead is held on their own computer under their personal control.

However, state laws continue to regulate entities that transmit money, despite the fact these entities, today, may never actually pose a risk to consumers of taking or losing the customer's funds. Thus, today, customers face the prospect of being required to pay a licensed company to transmit money that the company will never actually have in its possession.

### Intoxicating renewable fuels

In an effort to promote an alternative to fossil fuels, Congress authorized the Environmental Protection Agency (EPA) to establish a Renewable Fuels Standard (RFS).<sup>35</sup> This regulatory program forces consumers to burn ethanol by requiring a minimum amount of ethanol be added to conventional gasoline.<sup>36</sup> The program originally anticipated that new methods of producing "advanced biofuels" would be developed that were cost-effective and environmentally beneficial. That turned out to be a false promise; most of the ethanol is still produced by conventional methods from corn.<sup>37</sup> By artificially increasing the demand for corn, the regulations have put more land under intensive cultivation, which promotes the use of more fertilizer. This, in turn, aggravates water pollution, including the creation of so-called "dead zones" in the Gulf of Mexico.<sup>38</sup> Perhaps worse for consumers, the RFS requirements raise prices for food (such as corn-fed beef, and crops that compete with corn for acreage) as well as for fuel. The use of ethanol fuels can aggravate ozone and other conventional pollutants, and does not appear to reduce emissions of greenhouse gases.<sup>39</sup> Sold on the basis of helping the environment, the RFS, ironically, seems to have the opposite effect.

So why is the government forcing consumers to pay billions of dollars<sup>40</sup> for a program that damages the environment? Because corn producers and ethanol refiners greatly profit from these regulations. They will spend significant resources to ensure that the program survives and that the EPA uses its discretion to maximize their profits. Some EPA personnel might wish to put a stop to it, but no nominee to a position of responsibility at the EPA will be able to get confirmed without giving

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<sup>34</sup> See Will Warren, *What is a Decentralized Exchange?*, COIN CTR. (Oct. 10, 2018), <https://coincenter.org/entry/what-is-a-decentralized-exchange>.

<sup>35</sup> *Renewable Fuel Standard Program*, EPA, <https://www.epa.gov/renewable-fuel-standard-program>.

<sup>36</sup> There are similar requirements for biodiesel fuels, produced from other crops. See *Agriculture and Biofuels*, EPA, <https://www.epa.gov/agriculture/agriculture-and-biofuels>.

<sup>37</sup> RENEWABLE FUEL STANDARD: Program Unlikely to Meet Its Targets for Reducing Greenhouse Gas Emissions, U.S. GOV'T ACCOUNTABILITY OFFICE (Nov. 28, 2016), <https://www.gao.gov/products/GAO-17-94>.

<sup>38</sup> Vrinda Manglik, *Ethanol's Contribution to a Record-Breaking Dead Zone in the Gulf of Mexico*, SIERRA CLUB (Aug. 18, 2017), <https://www.sierraclub.org/compass/2017/08/ethanol-s-contribution-record-breaking-dead-zone-gulf-mexico>.

<sup>39</sup> Philip Rossetti, *The Renewable Fuel Standard's Policy Failures and Economic Burdens*, AM. ACTION FORUM (Apr. 19, 2018), <https://www.americanactionforum.org/research/renewable-fuel-standards-policy-failures-economic-burdens/>.

<sup>40</sup> *Id.*

assurances to farm-state Senators that the program will not be curtailed.<sup>41</sup> Further, it is difficult for any presidential candidate to survive the Iowa caucuses without pledging to support the Renewable Fuels Standard.

More recently, a new constituency has found a way to profit from the RFS standard. Refiners are required either to include a certain percentage of ethanol in the gasoline that they sell, or else to buy “RIN” credits from a seller who is able to use more ethanol than required. But small refiners have argued that they cannot afford to do either, and they have been able to obtain exemptions from the EPA.<sup>42</sup> They then are able to profit by being exempt from an expensive rule to which their larger competitors are subject. On top of that, the EPA discovered that when small refiners were granted an exemption, they would “short the market” in RINs, since they had advance knowledge that the RIN price would decline when the rest of the world heard about the exemption.<sup>43</sup> So now the farmers and the small refiners are engaged in a contest to tilt the RFS program to profit themselves; meanwhile consumers are stuck with the costs.

### Air permit gridlock

In 1970, Congress enacted the Clean Air Act to “promote the public health and welfare and the productive capacity of [the Nation’s] population.”<sup>44</sup> Since its adoption, the United States has made great strides in improving air quality, reducing emissions of the six common pollutants that EPA has targeted – particulate matter, ozone, lead, carbon monoxide, nitrogen dioxide and sulfur dioxide – by about 75 percent while the U.S. gross domestic product has grown 275 percent.<sup>45</sup>

In 1977, Congress amended the Clean Air Act and, among other things, added EPA’s New Source Review (NSR) air permit program to ensure that modern pollution controls are designed into new major facilities; it also required that existing facilities undertaking significant modifications update their pollution control systems to current standards.<sup>46</sup> Unfortunately, over time, EPA expanded the complexity of the NSR program so that it became, perversely, a significant *impediment* to the modernization of existing factories and power plants – preventing, rather than encouraging, the development of more efficient, cleaner facilities.<sup>47</sup> Indeed, in the view of many experts, EPA’s NSR

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<sup>41</sup> For a similar story about the biodiesel component of the RFS standard, see Sofie E. Miller, *Crony Environmentalism*, CATO INST. (Spring 2013), <https://object.cato.org/sites/cato.org/files/serials/files/regulation/2013/3/v36n1-14.pdf#page=1>.

<sup>42</sup> See *Renewable Fuel Standard Exemptions for Small Refineries*, EPA, <https://www.epa.gov/renewable-fuel-standard-program/renewable-fuel-standard-exemptions-small-refineries>.

<sup>43</sup> Erin Voegelé, *EPA releases data on small refinery hardship waivers*, Biomass magazine, 9/20/18. Available at: <http://biomassmagazine.com/articles/15609/epa-releases-d>

<sup>44</sup> Clean Air Act Section 101(b), § 42 U.S.C. 7401(b).

<sup>45</sup> U.S. Environmental Protection Agency, “Our Nation’s Air: Air Quality Improves as America Grows” [https://gispub.epa.gov/air/trendsreport/2019/documentation/AirTrends\\_Flyer.pdf](https://gispub.epa.gov/air/trendsreport/2019/documentation/AirTrends_Flyer.pdf) (last checked July 26, 2019); see also U.S. Environmental Protection Agency, National Air Quality: Status and Trends of Key Air Pollutants <https://www.epa.gov/air-trends> (last checked July 26, 2019).

<sup>46</sup> Clean Air Act, 42 U.S.C. §§ 7470-7492, 7501-7515.

<sup>47</sup> See, e.g., Art Fraas et al., *EPA’s New Source Review Program: Time for Reform?*, 47 E.L.R. 10026 (Jan. 2017).

permit program, as it applies to existing sources, is the most unsuccessful and counterproductive of all the Clean Air Act programs.<sup>48</sup>

Although the NSR program is one of the primary regulatory tools for controlling emissions from new plants, it simply was not intended to be a key program for controlling emission from existing facilities.<sup>49</sup> If anything, the EPA’s approach to the NSR program too often delays or thwarts efficiency and air quality improvements at existing facilities. That is because the NSR requirements that EPA established for modified facilities are so stringent, costly, and slow that they discourage companies from upgrading their plants.<sup>50</sup> The NSR program is so complex that the basic issue of whether a company has made a “major modification” that will trigger NSR is discussed in several EPA regulations, over one thousand pages of guidance documents and Federal Register notices, and dozens of court cases.<sup>51</sup> In the end, the very things we should want companies to do – such as making their plants more efficient, reliable, safe, competitive, and clean – are thwarted.

In many cases, the modernization of existing plants, already subject to myriad other controls, is discouraged and beneficial projects using best controls are blocked simply because of unrealistic air quality modeling and assumptions that unnecessarily trigger the NSR process.<sup>52</sup> This problem has become more acute with EPA’s substantial tightening of its National Ambient Air Quality Standards (NAAQS), which in some areas now are close to background levels (i.e., levels of pollution from natural sources and transport of anthropogenic emissions from other areas, including from outside the U.S.). This leaves little or no “headroom” for states to permit new efficiency projects that can reduce emissions per unit of output -- even after the installation of the best available pollution control technology.<sup>53</sup> The problem has been seriously exacerbated by EPA policies and modeling tools that significantly over-predict impacts from facilities, especially when a series of unrealistic assumptions are compounded. Thus, it is imperative that modelling results reflect the reality of local air quality and actual exposure to emissions.

Recent initiatives aimed at reducing air permit gridlock may reduce some of these barriers to environmentally-sound modernization. These include efforts to expedite permit reviews and reduce regulatory burdens,<sup>54</sup> to make implementation of the NAAQS program more efficient and cost-effective,<sup>55</sup> to allow emissions increases and decreases to be “netted” (which expedites projects that

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<sup>48</sup> Testimony of Jeffrey R. Holmstead before the U.S. House Committee on Energy and Commerce, Subcommittee on the Environment, *Hearing on New Source Review Permitting Challenges for Manufacturing and Infrastructure* (Feb. 14, 2018).

<sup>49</sup> U.S. Environmental Protection Agency, *New Source Review: A Report to the President* (2002), at pp. 3-4.

<sup>50</sup> Art Fraas et al., *EPA’s New Source Review Program: Time for Reform?*, supra note 48.

<sup>51</sup> Testimony of Jeffrey R. Holmstead before the U.S. House Committee on Energy and Commerce, Subcommittee on the Environment, *Hearing on New Source Review Permitting Challenges for Manufacturing and Infrastructure* (Feb. 14, 2018), at p. 4.

<sup>52</sup> Art Fraas et al., supra note 48.

<sup>53</sup> *Id.*

<sup>54</sup> Presidential Memorandum, *Streamlining Permitting and Reducing Regulatory Burdens for Domestic Manufacturing*, 82 Fed. Reg. 8667 (Jan. 30, 2017).

<sup>55</sup> *Presidential Memorandum for the Administrator of the Environmental Protection Agency* (April 12, 2018), <https://www.whitehouse.gov/presidential-actions/presidential-memorandum-administrator-environmental-protection-agency/>.

won't have significant emissions impacts<sup>56</sup>) to modernize emissions monitoring to anticipate ever-evolving technologies and better reflect actual public exposure,<sup>57</sup> and to better align a project's review to its significance, allowing unrelated investments at facilities to proceed more quickly.<sup>58</sup>

Reducing unnecessary delays, costs and other impediments to projects that will modernize manufacturing and power plants can benefit the environment as well as jobs, economic growth, and U.S. global competitiveness.

### Small businesses are particularly hurt by unreasonable regulation

Just as regulations like those previously mentioned can stifle innovation and growth – or worse, cause societal harm—regulations often pick winners and losers. And when it comes to regulations, small businesses bear a disproportionate amount of the regulatory burden.<sup>59</sup> Compliance costs, difficulty understanding regulatory requirements, and extra paperwork are the key drivers of the regulatory burdens on small business.<sup>60</sup> Understanding how to comply with regulations is a bigger problem for those firms with one to nine employees, since 72 percent of small business owners in that cohort try to figure out how to comply themselves, as opposed to assigning that responsibility to someone else.<sup>61</sup>

The uncertainty surrounding what regulations may be imposed next effectively acts as a “boot on the neck” of small business—negatively affecting a small business owner's ability to plan for future growth, including hiring new workers. Until recently, “government regulations and red tape” were listed as among the top three problems for small business owners, according to the National Federation of Independent Business (NFIB) monthly Small Business Economic Trends survey.<sup>62</sup> The NFIB's Small Business Problems and Priorities report ranked “regulations” second only behind

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<sup>56</sup> U.S. Environmental Protection Agency, Memorandum from EPA Administrator E. Scott Pruitt to Regional Administrators, titled “Project Emissions Accounting Under the New Source Review Preconstruction Permitting Program” (March 13, 2018); <https://www.epa.gov/nsr/project-emissions-accounting>

<sup>57</sup> U.S. Environmental Protection Agency, “Revised Policy On Exclusions from “Ambient Air,” Draft (Nov. 2018). [https://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=1&cad=rja&uact=8&ved=2ahUKEwj7z6WJ4NLjAhWCAZ0JHZkCDbYQFjAAegQIBRAC&url=https%3A%2F%2Fwww.epa.gov%2Fsites%2Fproduct%2Ffiles%2F2018-11%2Fdocuments%2Fdraft\\_ambient\\_air\\_guidance\\_110818.pdf&usq=AOvVaw1PNe9\\_ZHzA7T2gijqRGerf](https://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=1&cad=rja&uact=8&ved=2ahUKEwj7z6WJ4NLjAhWCAZ0JHZkCDbYQFjAAegQIBRAC&url=https%3A%2F%2Fwww.epa.gov%2Fsites%2Fproduct%2Ffiles%2F2018-11%2Fdocuments%2Fdraft_ambient_air_guidance_110818.pdf&usq=AOvVaw1PNe9_ZHzA7T2gijqRGerf)

<sup>58</sup> U.S. Environmental Protection Agency, “Prevention of Significant Deterioration (PSD) and Nonattainment New Source Review (NNSR): Aggregation; Reconsideration,” 83 Fed. Reg. 57324 (Nov. 15, 2018).

<sup>59</sup> *The State of Small Business in America 2016*, BABSON 1, 2, <https://www.babson.edu/media/babson/site-assets/content-assets/images/news/announcements/goldman-10ksb-report-2016.pdf>; Nicole V. Crain and W. Mark Crain, *The Cost of Federal Regulation to the U.S. Economy, Manufacturing and Small Business*, NAT'L ASS'N OF MFG. (September 10, 2014), <https://www.nam.org/Data-and-Reports/Cost-of-Federal-Regulations/Federal-Regulation-Full-Study.pdf>.

<sup>60</sup> *Id.*

<sup>61</sup> *Id.* at 10.

<sup>62</sup> *Small Business Economic Trends*, NFIB RESEARCH CTR., 18 (Apr. 2018), <https://www.nfib.com/assets/SBET-April-2018.pdf>.

taxes as the most pressing problem.<sup>63</sup> More recently, small business optimism has reached record levels in large part due to a more light-handed regulatory approach.<sup>64</sup>

For small companies, federal regulation can be the difference between success and failure. The more complicated the regulatory regime, the less likely it is a small business will be able to absorb the regulatory burden and survive. For example, following the enactment of the Dodd-Frank Act, which was meant to prevent banks from becoming “too big to fail,” the impact of regulations implementing that law has led to a dramatic reduction in community banks.<sup>65</sup>

### Regulatory Reform Success Stories

There are many instances where regulations cause more harm than they should. The remainder of III. this report examines circumstances and examples where regulations have been made to work better, and even encourage innovation and growth while achieving their regulatory goals.

As shown above, government regulation can make things worse. Rule-writers may lack information, even if they are wholly benevolent, because decentralized processes, like markets, are usually best at providing the self-correcting mechanisms that produce good information. And regulators cannot always be depended on to act in the public interest. Their regulatory decisions may be distorted by interest groups or even their own interests, including the desire to create a larger bureaucracy or provide better outside options for themselves when they leave government<sup>66</sup>.

Thus, it is important to remember that competition, rather than government regulation, can often provide a better “fix” when markets are imperfect. Take the example of protecting consumers against low-quality goods. Observers have sometimes argued that government regulation of quality is necessary when quality is difficult to evaluate, because consumers may be misled and not be compensated if they are cheated.<sup>67</sup> But, as shown in the ride-sharing example below, markets can create other mechanisms to protect consumers.

Whatever their particular mission, government regulators need to be mindful that competition is often the most effective regulator of our economy. While we do have other legitimate regulatory goals that require licenses, rules, and inspectors, we need to be very careful that, in pursuing those goals, we do not displace the competition that governs the larger marketplace.<sup>68</sup>

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<sup>63</sup> Holly Wade, *Small Business Problems and Priorities*, NFIB RESEARCH FOUND., 17, (Aug. 2016), <https://www.nfib.com/assets/NFIB-Problems-and-Priorities-2016.pdf>.

<sup>64</sup> National Federation of Independent Businesses, *Small Business Optimism Roars Back, Rivaling Historic Highs*, <https://www.nfib.com/content/press-release/economy/small-business-optimism-roars-back-rivaling-historic-highs/>

<sup>65</sup> Marshall Lux & Robert Greene, *The State and Fate of Community Banking* (M-RCBG Assoc. Working Paper Series No. 37, Harv. Kennedy Bus. Sch. Mossavar-Rahmani Ctr. for Bus. & Gov't, 2015), <https://www.hks.harvard.edu/centers/mrcbg/publications/awp/awp37>.

<sup>66</sup> See Wilson, James q. *Bureaucracy*, Basic Books Classics, New York, NY, 1990.

<sup>67</sup> See Beales et al., *supra* note 3.

<sup>68</sup> Brian Mannix, *The Tension between Optimization and Competition in Rulemaking: The Case of Proposed Fuel-Efficiency Standards for Trucks*, GEORGE WASHINGTON COLUMBIAN COLL. OF ARTS AND SCI. (Oct. 8, 2015), <https://regulatorystudies.columbian.gwu.edu/tension-between-optimization-and-competition-rulemaking-case-proposed-fuel-efficiency-standards>.

Competition can also improve the regulatory system itself. Instead of making the nation the locus of regulation, we can choose to rely on states. This decentralization creates competition between regulatory authorities. It is sometimes said that such competition leads to a race to the bottom, but that is often not the case. Many scholars of corporate law believe that competition in the regulation of the corporate form has led to a race to the top.<sup>69</sup> To cite one example, Delaware is the home of most corporations because it has the most efficient corporate law. Even in the case of pollution, states and localities have very good incentives to regulate to provide clean waterways and other pollution-free amenities to attract businesses and people.<sup>70</sup>

The point here is not to argue that centralized regulation is never necessary, but to provide a reminder that even when markets are imperfect, competitive processes can complement and sometimes outperform regulation. Regulations that may have made sense when originally imposed can benefit from evaluation given the dramatic changes in society and technology over the last few decades. Revisiting the need for regulation and the way regulations are designed can encourage competition and innovation that yield significant gains for consumers, workers and business owners. The examples of successful efforts at regulatory reform below suggest that gains from further reforms can be great.

### The success of economic deregulation in the 1970s and 1980s

#### A.

U.S. regulatory policy significantly evolved over the last century.<sup>71</sup> The regulatory agencies formed before and during the New Deal generally issued “economic regulations.” That is, they regulated a broad array of activities within particular industries using economic controls such as price ceilings or floors, quantity restrictions, and service parameters.<sup>72</sup> For instance, the Interstate Commerce Commission set the price a farmer had to pay the railroad to get his grain shipped from Des Moines to Chicago. Economic regulation is often justified by concerns of “market power” or “natural monopoly”—where a market can be served at lowest cost with a single supplier.<sup>73</sup>

These regulatory agencies were established as independent commissions to avoid political influence,<sup>74</sup> but observers began to be concerned that these agencies were “captured” by the industries they regulated.<sup>75</sup> By the early 1970s, scholarship in the fields of economics, antitrust, and

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<sup>69</sup> See, e.g., Frank H. Easterbrook & Daniel R. Fischel, *The Economic Structure of Corporate Law* (1991).

<sup>70</sup> See Richard L. Revesz, *Rehabilitating Interstate Competition: Rethinking the “Race-to-the-Bottom” Rationale for Federal Environmental Regulation*, NYU Law Review, December 1992. Available at: [https://its.law.nyu.edu/faculty/profiles/representiveFiles/revesz/%20-rehabilitatinginter\\_98BEA5C8-1B21-6206-60C2DA65DA66BF1C.pdf](https://its.law.nyu.edu/faculty/profiles/representiveFiles/revesz/%20-rehabilitatinginter_98BEA5C8-1B21-6206-60C2DA65DA66BF1C.pdf) Also

see Jonathan H. Adler, *Interstate Competition and the Race to the Top*, Case Western Reserve University Faculty Publications (2012), at: [https://scholarlycommons.law.case.edu/faculty\\_publications/23](https://scholarlycommons.law.case.edu/faculty_publications/23)

<sup>71</sup> See Susan Dudley, *Improving Regulatory Accountability*, 69 CASE W. RES. L. REV. 1027, 1032–33 (2015).

<sup>72</sup> See MURRAY L. WEIDENBAUM, BUSINESS AND GOVERNMENT IN THE GLOBAL MARKETPLACE 23–41 (6th ed. 1999) (discussing the development and rationale of U.S. regulation).

<sup>73</sup> See W. KIP VISCUSI, JOHN M. VERNON & JOSEPH E. HARRINGTON JR., ECONOMICS OF REGULATION AND ANTITRUST 356–57 (Mass. Inst. Tech. 3d ed. 2000) (1992) (discussing the regulation of natural monopolies).

<sup>74</sup> See *Humphrey’s Ex’r v. United States*, 295 U.S. 602, 625 (1935) (noting that Congress created the Federal Trade Commission as an independent agency because “it was essential that the commission should not be open to the suspicion of partisan direction”).

<sup>75</sup> George J. Stigler, *The Theory of Economic Regulation*, 2 BELL J. ECON. & MGMT. SCI. 3, 3 (1971).

law generally supported the idea that regulation of private sector prices, entry, and exit tended to keep prices higher than necessary to the benefit of regulated industries and at the expense of consumers. Academics, officials in the Ford, Carter, and Reagan Administrations, and members of Congress linked this knowledge to the problem of inflation by showing that eliminating economic regulations and fostering competition would better control prices.<sup>76</sup> Bipartisan efforts across all three branches of government eventually led to the abolition of whole agencies such as the Civil Aeronautics Board and the Interstate Commerce Commission, and removal of unnecessary regulation in several previously regulated industries, with resulting improvements in innovation and consumer welfare.<sup>77</sup>

The transportation and telecommunications deregulation that took place in the 1970s and 1980s is generally regarded as a success, having lowered consumer prices and increased choices. Deregulation and consumer choice have aligned service quality with customer preferences. Competitive markets have generated real gains—and not just reallocated benefits—for consumers and society as a whole, and markets have evolved in beneficial ways that were not anticipated before deregulation.<sup>78</sup> The deregulation of transportation and telecommunications is estimated to have provided tens of billions of dollars per year in consumer benefits.<sup>79</sup> Before deregulation, government rules for the telephone system made cell phones—and even just cordless phones installed in the home—against the law.

## B. Reforming energy regulations

Another area that has benefited from regulatory reform is energy markets. Americans have benefited from having a wide range of energy resources available to fuel our economy and from technological innovations that continuously improve the efficiency with which we produce and use energy. But the two oil embargoes of the 1970s were traumatic because they took place when the economy's dependence on imported oil was near its peak.<sup>80</sup> They prompted a series of interventions, beginning with President Nixon's "Project Independence," to regulate energy markets to achieve "energy independence," which sounded politically attractive.<sup>81</sup>

Project Independence failed to reduce our dependence on foreign oil. Similarly, President Nixon's imposition of price controls failed to bring down the price of oil products.<sup>82</sup> Instead, oil price controls led to manipulation and corruption, as small refiners and other special interests used them to obtain

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<sup>76</sup> Susan E. Dudley, *Alfred Kahn 1917–2010*, GEORGE WASHINGTON COLUMBIAN COLL. OF ARTS AND SCI. (Jan. 3, 2011), <https://regulatorystudies.columbian.gwu.edu/tribute-alfred-kahn-1917-2010>.

<sup>77</sup> MARTHA DERTHICK & PAUL J. QUIRK, *THE POLITICS OF DEREGULATION* 5 (1985); ICC Termination Act of 1995, Pub. L. No. 104–88, § 101, 109 Stat. 803, 804 (1995).

<sup>78</sup> Clifford Winston, *U.S. Industry Adjustment to Economic Deregulation*, 12 J. Econ. Persp., 89, 89–90, 97 (1998).

<sup>79</sup> Robert W. Crandall, *Extending Deregulation*, BROOKINGS INST., [https://www.brookings.edu/wp-content/uploads/2016/06/PB\\_Deregulation\\_Crandall.pdf](https://www.brookings.edu/wp-content/uploads/2016/06/PB_Deregulation_Crandall.pdf).

<sup>80</sup> Samantha Gross, *The 1967 War and the "Oil Weapon"*, BROOKINGS INST. (June 5, 2017), <https://www.brookings.edu/blog/markaz/2017/06/05/the-1967-war-and-the-oil-weapon/>.

<sup>81</sup> Neil De Marchi, *Energy Policy Under Nixon: Mainly Putting Out Fires*, in *ENERGY POLICY IN PERSPECTIVE: TODAY'S PROBLEMS, YESTERDAY'S SOLUTIONS* 395, 409 (Craufurd D. Goodwin, William J. Barber, James L. Chochnane, Neil D. Marchi, Joseph A. Yager eds., The Brookings Institution 1981).

<sup>82</sup> Gene Healy, *Remembering Nixon's Wage and Price Controls*, CATO INST. (Aug. 16, 2011), <https://www.cato.org/publications/commentary/remembering-nixons-wage-price-controls>.

subsidies.<sup>83</sup> Prices to consumers rose steadily throughout the Nixon, Ford, and Carter administrations, and queues—sometimes hours long—made buying gasoline a real challenge.

President Carter recognized the problem and promised to remove price and allocation controls from crude oil and its various products, but he did so very gradually so as not to aggravate inflation.<sup>84</sup> When President Reagan took office in 1981, he removed Carter's timetable and the regulations by issuing Executive Order 12287.<sup>85</sup> The result was that gasoline queues became just a bad memory, prices for gasoline and heating oil dropped dramatically, and U.S. production began to recover.<sup>86</sup> Deregulation accomplished U.S. energy policy objectives far better than any of the regulatory programs had. In more recent years, deregulated oil markets have encouraged innovations like fracking, which have dramatically increased U.S. production and recoverable reserves.<sup>87</sup>

### Getting the lead out

The renewable fuels fiasco described above is reminiscent of the EPA's regulation of lead in gasoline during the 1970s and early 1980s. Tetraethyl lead was used to boost the octane rating of gasoline. When catalytic converters were mandated for new vehicles, unleaded gasoline was introduced in order to avoid the problem of lead fouling the catalyst. But older vehicles continued to use the less-expensive leaded gasoline. The EPA granted waivers to small refiners, allowing them to put as much as five times the amount of lead in their gasoline than large refiners were permitted to use.<sup>88</sup> Small refiners (then, as now, often owned by billionaires) became one of the most powerful lobbying groups in Washington in order to preserve this and other subsidies.

In 1982, the EPA adopted a better regulatory approach. It put all gasoline refiners and importers on the same lead standard and introduced flexibility by allowing them to trade with each other so that no one refiner faced a rigid cap.<sup>89</sup> Like RINs, lead credits were traded; but, unlike RINs, there were no exceptions. This effectively ended the lead subsidy, at around the same time that oil deregulation ended yet another set of subsidies for small refiners at the expense of consumers. In the next few years, more than half of all the refineries in the country were closed, without a significant loss of refining capacity,

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<sup>83</sup> See Jerry Taylor & Peter Van Doren, *Economic Amnesia: The Case against Oil Price Controls and Windfall Profit Taxes*, CATO INST. (Jan. 12, 2006), <https://object.cato.org/pubs/pas/pa561.pdf>.

<sup>84</sup> *Id.*

<sup>85</sup> Ronald Reagan, *Statement on Signing Executive Order 12287, Providing for the Decontrol of Crude Oil and Refined Petroleum Products*, (Jan. 28, 1981), [http://www.theccwr.org/wp-content/uploads/2016/02/CCWR\\_ReaganResolve\\_Appendix5.pdf](http://www.theccwr.org/wp-content/uploads/2016/02/CCWR_ReaganResolve_Appendix5.pdf).

<sup>86</sup> Brian Domitrovic, *Want Gasoline Prices to Decline? Do As Ronald Reagan Did*, FORBES (Apr. 10, 2012), <https://www.forbes.com/sites/briandomitrovic/2012/04/10/want-gasoline-prices-to-decline-do-as-ronald-reagan-did/#18859f37678c>.

<sup>87</sup> Liz Hampton, *U.S. Oil Industry Set to Break Record, Upend Global Trade*, REUTERS (Jan. 16, 2018), <https://www.reuters.com/article/us-usa-oil-record-shale-analysis/u-s-oil-industry-set-to-break-record-upend-global-trade-idUSKBN1F50HV>.

<sup>88</sup> Lisa Heinzerling, Frank Ackerman & Rachel Massey, *Applying Cost-Benefit to Past Decisions: Was Environmental Protection Ever a Good Idea?*, 57 ADMIN. L. REV. 155, 166 (2005).

<sup>89</sup> *Id.*

nor damage to competition in the industry.<sup>90</sup> Those small refiners had served no economic purpose at all, and they existed only in order to profit by exploiting loopholes in the oil price controls and in the EPA's lead phasedown regulations.

By 1984, when the EPA had evidence that the lead in gasoline was poisoning children, the agency was able to begin removing lead altogether from fuel—and now there was no opposition because the lead subsidies by then had been removed. Once the EPA banned leaded fuels, other countries quickly followed suit—resulting in global benefits estimated to exceed two trillion dollars per year.<sup>91</sup>

### Even baby steps in the drug approval process can save lives

The emergence of AIDS in the 1980s made plain to everyone that there are very real costs of delaying approval of new drugs for serious and life-threatening diseases. The FDA's first, tentative steps were taken in 1987, under considerable pressure from the Office of Information and Regulatory Affairs, with the authorization of a new category of pharmaceuticals, "Treatment Investigational New Drugs."<sup>92</sup> Although probably used too infrequently, the idea behind this program was to make promising drugs that were still under development available to patients who needed them, even if they were not participating in clinical trials. In 1988, the FDA added provisions to its drug approval process regulations recognizing the need for broad flexibility and the different risk-benefit threshold facing patients with serious and life-threatening diseases.<sup>93</sup> And in 1992, Congress approved the use of user fees for new drug approvals to speed drug approvals at the FDA.<sup>94</sup>

These changes led to substantial improvements. A comprehensive study of all drugs approved from 1979 to 2002 concluded that the reduced approval times due to user fees saved the equivalent of an extra 180,000 to 310,000 years of life.<sup>95</sup> As discussed above, there are numerous instances where federal restrictions on the availability of new drugs continue to put patients' lives at risk, and there is undoubtedly room—and large potential benefits—for continued improvement. The recently passed "Right to Try Act" takes another step in the right direction. This legislation creates an alternative channel to get drugs to patients who need them, allowing terminally ill patients access to potentially life-saving drugs that have not yet received full FDA approval.<sup>96</sup> Because full approval can take years,

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<sup>90</sup> Data on the number and capacity of U.S. petroleum refineries is reported by the Department of Energy's Energy Information Administration. See: [https://www.eia.gov/dnav/pet/PET\\_PNP\\_CAP1\\_DCU\\_NUS\\_A.html](https://www.eia.gov/dnav/pet/PET_PNP_CAP1_DCU_NUS_A.html)

<sup>91</sup> Peter L. Tsai & Thomas H. Hatfield, *Global Benefits From the Phaseout of Leaded Fuel*, 74 J. ENVTL. HEALTH 1, 8–15 (December 2011).

<sup>92</sup> Kathleen M. O'Connor, *OMB Involvement in FDA Drug Regulations: Regulating the Regulators*, 38 CATHOLIC UNIV. L. REV. 175, 175-212 (1988).

<sup>93</sup> Erin E. Kepplinger, *FDA's Expedited Approval Mechanisms for New Drug Products*, 34 Biotechnology L. Report 15, 15-37 (2015).

<sup>94</sup> Janet Woodcock & Suzanne Junod, *PDUFA Lays the Foundation: Launching Into the Era of User Fee Acts*, U.S. FDA, <https://www.fda.gov/files/about%20fda/published/PDUFA-Lays-the-Foundation--Launching-Into-the-Era-of-User-Fee-Acts.pdf>.

<sup>95</sup> T.J. Philipson et al., *Assessing the Safety and Efficacy of the FDA: The Case of the Prescription Drug User Fee Acts*, (NBER working paper 11724, October 2005).

<sup>96</sup> President Donald J. Trump to Sign Right to Try Legislation Fulfilling the Promise He Made to Expand Healthcare Options for Terminal Americans, WHITE HOUSE (MAY 30, 2018), <https://www.whitehouse.gov/briefings->

for some patients, Right to Try may be the difference between life and death. Speeding the approval process for all drugs would provide even greater benefits.

### New technologies can lyft us above regulations and provide uber-benefits

Today we take for granted that if we want a ride across town, we can call an Uber or Lyft. But it was just a few short years ago that taxis were the only game in town. Taxis were regulated and licensed by cities to address an information problem: when you hail a cab on the street, you know nothing about the driver, the car, or the prices you might be charged.<sup>97</sup>

To try to ensure quality, licensing requires certain minimum standards from taxi cars and drivers. The rates that can be charged are also regulated so there are no surprises. But these policies have significant downsides. Since all cabs look and charge the same, there's no incentive for a driver to provide better service than the bare minimum required. Cities also limit the number of taxis they license, often at the behest of the existing cab owners, which limits competition and keeps prices artificially high.<sup>98</sup>

Uber and Lyft show us that not only is regulation unnecessary to address information problems; it is far worse than employing technology and markets in novel ways.<sup>99</sup> Ride-sharing apps avoid an information asymmetry by letting passengers rate drivers and their cars, so that when you hail a car on your phone, you can see the quality of the car and driver before you get in the car. Low-quality drivers are pushed out of the market, which means all drivers have an incentive to provide the best possible service.<sup>100</sup>

Prices aren't fixed in ride-sharing apps. Instead they are dynamic, responding to the demand for rides and the supply of drivers available.<sup>101</sup> When you call a car with your smartphone, you are quoted a price before you agree to hail it. Sometimes it is less than the regulated rates for taxis, which is great for consumers. Sometimes it is more, and counterintuitively that's also good for consumers. It is more when there is more demand, such as during rush hour or when there is bad weather. In such circumstances, given their fixed numbers, it is nearly impossible to hail a licensed taxi. Higher fares when there's more demand incentivizes more drivers to hit the streets, and that means that if you really need a car when it's raining, you now have the choice to pay a bit more and get a ride.

We can use technology rather than regulation to address information asymmetries in other markets, too. Thanks to Airbnb and other home listing services, we now have more choices to book a room

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[statements/president-donald-j-trump-sign-right-try-legislation-fulfilling-promise-made-expand-healthcare-options-terminal-americans/](#)

<sup>97</sup> See, e.g., Mark W. Frankena & Paul A. Pautler, *An Economic Analysis of Taxicab Regulation*, FED. TRADE COMM'N (May 1984), <https://www.ftc.gov/sites/default/files/documents/reports/economic-analysis-taxicab-regulation/233832.pdf>.

<sup>98</sup> See Jason Snead, *Taxicab Medallion Systems: Time for a Change*, HERITAGE FOUND. (DEC. 10, 2015), <https://www.heritage.org/transportation/report/taxicab-medallion-systems-time-change>.

<sup>99</sup> See, e.g., Alex Tabarrok & Tyler Cowen, *The End of Asymmetric Information?*, CATO UNBOUND (Apr. 6, 2015), <https://www.cato-unbound.org/2015/04/06/alex-tabarrok-tyler-cowen/end-asymmetric-information>.

<sup>100</sup> Id.

<sup>101</sup> See, e.g., Bill Gurley, *A Deeper Look at Uber's Dynamic Pricing Model, Above the Crowd* (Mar. 11, 2014), <http://abovethecrowd.com/2014/03/11/a-deeper-look-at-ubers-dynamic-pricing-model>.

than just hotels. But there's more that can be done. Services like Angie's List do a better job than regulation at ensuring consumers have access to high-quality plumbers, electricians, and other tradespeople. Consumers will benefit from a combination of technology and markets that can be applied to just about every licensed service and profession.

## Conclusion

As the examples in the first section of this paper illustrate, even well-intentioned regulations can have perverse outcomes that end up slowing economic growth, benefiting the advantaged, and harming those they are intended to protect. But it need not be that way. Regulatory reforms—such as those illustrated in the above examples of price deregulation and streamlining drug approvals—can unleash virtuous competition and innovation to the benefit of all.

A regulatory system that focuses on core problems that can only be resolved by the federal government, and that respects individual choice and competition, can unleash the entrepreneurial spirit that made the United States welcoming and prosperous, and lead to a stronger, more resilient, and more inclusive economy.