

THE LOCHNERIZED FIRST AMENDMENT AND THE FDA:  
TOWARD A MORE DEMOCRATIC POLITICAL ECONOMYRESPONSE TO THE  
COLUMBIA LAW REVIEW'S 2018 SYMPOSIUM*Amy Kapczynski\**

## INTRODUCTION

*“[T]he majority has chosen the winners by turning the First Amendment into a sword, and using it against workaday economic and regulatory policy. Today is not the first time the Court has wielded the First Amendment in such an aggressive way. And it threatens not to be the last. Speech is everywhere—a part of every human activity (employment, health care, securities trading, you name it). For that reason, almost all economic and regulatory policy affects or touches speech. So the majority’s road runs long. And at every stop are black-robed rulers overriding citizens’ choices. The First Amendment was meant for better things.”*

*Janus v. AFSCME*, Justice Kagan, dissenting<sup>1</sup>

The “Lochnerization” of the First Amendment is without a doubt one of the most important developments in constitutional law in recent years.<sup>2</sup> This was so before the explosive end of the 2018 Term, and it is particularly evident after it.<sup>3</sup> As Justice Kagan laid bare on the same fateful

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\* Professor of Law, Yale Law School. I thank the organizers and participants of *Columbia Law Review’s* Symposium, “A First Amendment for All? Free Expression in an Age of Inequality,” for the rich conversation that prompted this Piece. Robert Post, Jed Purdy, and Sabeel Rahman gave invaluable comments on an early draft. I am also grateful to the interdisciplinary group involved in the Yale Collaboration for Research Integrity and Transparency, who have been central to my understanding of these issues.

1. *Janus v. Am. Fed’n of State, Cty., & Mun. Emps.*, Council 31, 138 S. Ct. 2448, 2501–02 (2018) (Kagan, J., dissenting) (citations omitted).

2. For academic discussions of the trend, see Robert Post & Amanda Shanor, Adam Smith’s First Amendment, 128 Harv. L. Rev. Forum 165, 167 (2015), [http://harvardlawreview.org/wp-content/uploads/2015/03/vol128\\_PostShanor2.pdf](http://harvardlawreview.org/wp-content/uploads/2015/03/vol128_PostShanor2.pdf) [<https://perma.cc/7CJM-YEAQ>] (observing “that the First Amendment has become a powerful engine of constitutional deregulation”); Jedediah Purdy, Neoliberal Constitutionalism: Lochnerism for a New Economy, 77 Law & Contemp. Probs., no. 4, 2014, at 195, 195 (describing First Amendment Lochnerization and its far-reaching implications).

3. See generally *Janus*, 138 S. Ct. 2448 (reversing long-standing precedent and declaring, on First Amendment grounds, that public sector unions may not require beneficiaries to pay dues for activities related to collective bargaining); Nat’l Inst. of Family & Life

day that Justice Kennedy announced his retirement, recent Supreme Court decisions have “weaponiz[ed]” the First Amendment, turning it into a powerful tool against a range of ordinary socioeconomic legislation.<sup>4</sup> There is little that can escape its reach, because we are creatures of speech, and governance and speech are inescapably intertwined.

There may be no edifice of public regulatory power more immediately threatened by this trend than the Food and Drug Administration (FDA). A key accomplishment of both the Progressive Era and the New Deal, the FDA is perhaps the most muscular of all federal agencies, and a key American instance of public power over market imperatives.<sup>5</sup> It also has enjoyed extraordinarily high levels of influence and public trust throughout its long history.<sup>6</sup>

Like many agencies, the FDA governs a great deal that is readily understood as speech, such as disclosures on food labels, warnings for tobacco, and advertisements for medicines and cosmetics.<sup>7</sup> But the core of its regulatory power runs much deeper and may seem far less obviously susceptible to the acid bath of contemporary free speech law. For example, the FDA is a gatekeeper for new pharmaceuticals, forbidding any person from “introduc[ing] into interstate commerce” any unapproved drug.<sup>8</sup> This sounds like it constructs governmental power over conduct and products, and it does. But it also can be construed as constraining speech. An introduction for sale, after all, is often accomplished through nothing more than speech, such as an offer for sale or advertisement. A “drug” is, by law, anything “intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease.”<sup>9</sup> Intended use is commonly construed via speech, such as advertisements or labels that

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*Advocates v. Becerra*, 138 S. Ct. 2361 (2018) (striking down, as inconsistent with the First Amendment, a California law requiring crisis pregnancy centers to inform women where to obtain comprehensive reproductive health services and requiring unlicensed facilities to reveal that status).

4. *Janus*, 138 S. Ct. at 2501 (Kagan, J., dissenting); see also *Becerra*, 138 S. Ct. at 2381–82 (Breyer, J., dissenting) (arguing that the majority’s decision will “invite courts . . . to apply an unpredictable First Amendment to ordinary social and economic regulation”); *Sorrell v. IMS Health Inc.*, 564 U.S. 552, 602–03 (2011) (Breyer, J., dissenting) (noting that the majority’s decision “open[ed] a Pandora’s Box of First Amendment challenges to many ordinary regulatory practices”).

5. See Daniel Carpenter, *Reputation and Power: Organizational Image and Pharmaceutical Regulation at the FDA* 24 (2010) (noting that “within the United States, the [FDA] exercises more forceful and more discretionary powers than do national agencies regulating other sectors of the national economy”).

6. *Id.* at 11 (describing this phenomenon of public trust particularly as applied to medicine, the FDA’s most intensive domain of regulation).

7. For a discussion of regulatory methods used by other agencies that similarly implicate speech, see Amanda Shanor, *The New Lochner*, 2016 *Wis. L. Rev.* 133, 166–71.

8. 21 U.S.C. § 355(a) (2012).

9. *Id.* § 321(g)(1).

suggest a particular use.<sup>10</sup> A company may market furniture oil as a cleaning product. But if it markets it as a remedy for cancer, the same substance becomes a “drug” for purposes of the FDA. The FDA is a critical and revealing example, then, of the astonishingly broad reach of a weaponized First Amendment.

As commercial speech protections have expanded, they have, in fact, begun markedly to encroach upon the FDA’s powers.<sup>11</sup> Courts, speaking in the name of the First Amendment, are “freeing” us from regulatory approaches that have worked for decades to inform us about the products we put in our bodies. How did we arrive here? And how might democratic prerogatives over the webs of commodity exchange upon which our lives today depend be rebuilt, particularly if the Court continues down its current path?

Part I offers a brief overview of the FDA. It traces the arc of the Agency’s construction in order to illuminate the importance of its work and to show the threat posed by recent First Amendment cases, particularly to the Agency’s oversight of drug and tobacco markets.

Part II explores how the First Amendment, long understood as a protector of democracy, has come to pose a threat to democratic authority over markets. Using several landmark commercial speech cases, I show that commercial speech protection today is built upon certain distinctive and contestable conceptions of the nature of markets, states, and subjects. Markets are cast as neutral domains that must be kept free from democratic interference; the state is suspect and the locus of capture rather than democratic will-formation; and subjects have unitary “interests” that allow no firm distinction between the realm of the political and the realm of the market. These ideas are not plucked from thin air. They are important components of the kind of market fundamentalist thought that gained prominence in the United States in the 1980s and thereafter, as has been elaborated in the literature on neoliberalism. The analysis here complements Professor Jed Purdy’s *Beyond the Bosses’ Constitution*<sup>12</sup> and similarly contributes to the emerging “law and political economy” literature.<sup>13</sup> Law and political economy approaches are grounded in the premise that the economy and political life are not fully separable but mutually shape and influence one another.<sup>14</sup> Law constructs markets, and

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10. 21 C.F.R. § 201.128 (2018) (defining “intended use” as being discernible from, inter alia, “labeling claims, advertising matter, or oral or written statements”).

11. See *infra* section I.B.

12. Jedediah Purdy, *Beyond the Bosses’ Constitution: The First Amendment and Class Entrenchment*, 118 *Colum. L. Rev.* 2161 (2018) [hereinafter Purdy, *Beyond the Bosses’ Constitution*].

13. For an introduction to the term and literature, see David Singh Grewal, Amy Kapczynski & Jedediah Purdy, *Law and Political Economy: Toward a Manifesto*, *Law & Political Econ.* (Nov. 6, 2017), <https://lpeblog.org/2017/11/06/law-and-political-economy-toward-a-manifesto/> [https://perma.cc/MZP6-FBCY].

14. See *id.*

the distribution of economic power (and “private” power more broadly) deeply shapes law. Political economy analysis seeks to illuminate this fact and to map the relationship between markets and political life as it is figured across a wide range of legal domains.<sup>15</sup>

Scholars elaborating political economy approaches to law also tend to engage a further question, one resonant with the aims of this Symposium: What new theories and institutions do we need to sustain and create a more genuinely democratic and equal society? Part III addresses this question as it appears in the FDA context. It shows that there is room within current doctrine to revive robust regulatory authority for the Agency. It also maps another way to rescue democratic prerogatives if courts continue down their current path: a pivot away from the model of private market regulation upon which the FDA’s approach is built.

If courts thrust us into a world with more limited authority over private markets, we must envision a much more substantial role for the public—in this case, for example, by expanding public funding for health research. This approach could mitigate the harm done by recent court decisions and have far-reaching benefits for what we might call health democracy or health justice. It is also an instance of a broader point: As a commitment to market supremacy advances inside of constitutional doctrine, democratic control over our economy and society will demand new public infrastructure that displaces or routes around an increasingly ungovernable private sector.<sup>16</sup>

Though beyond the ambition of this short contribution, an exploration of the political economy of current commercial speech law must eventually lead us also to reconsider its scope. Courts have long been confused about why our Constitution might protect speech acts in the marketplace. Current law reasons increasingly in a market-supremacist idiom, suggesting, outlandishly, that the First Amendment exists to protect market order from democratic governance.<sup>17</sup> Protections for commercial speech must serve rather than subvert our democracy. Delineating a new political economy of the First Amendment that helps achieve this aim is an important task for those who seek a future that is more democratic and equal than our present.

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15. See *id.*

16. For accounts similarly suggesting that a more sustainable and just political economy requires attention to infrastructure, see K. Sabeel Rahman, *The New Utilities: Private Power, Social Infrastructure, and the Revival of the Public Utility Concept*, 39 *Cardozo L. Rev.* 1621, 1657–68 (2018) (financial sector infrastructure); *id.* at 1648–57, 1668–80 (communications infrastructure); David Singh Grewal, *Before Peer Production: Infrastructure Gaps and the Architecture of Openness in Synthetic Biology*, *Stan. Tech. L. Rev.*, Winter 2017, at 143, 150 (infrastructure for science and peer production); Jedediah Purdy, *The World We’ve Built*, *Dissent* (July 3, 2018), [https://www.dissentmagazine.org/online\\_articles/world-we-built-sovereign-nature-infrastructure-leviathan](https://www.dissentmagazine.org/online_articles/world-we-built-sovereign-nature-infrastructure-leviathan) [<https://perma.cc/57TZ-22BJ>] (environmental infrastructure).

17. See *infra* notes 141–149 (discussing the market-supremacist logic employed in *Sorrell v. IMS Health Inc.*, 564 U.S. 552 (2011)).

## I. THE FDA—THEN AND NOW

Whether in the United States or around the world, there are “few regulatory agencies of any sort . . . [that have] possessed or exercised the power held by the Food and Drug Administration.”<sup>18</sup> The FDA regulates food, supplements, cosmetics, drugs, medical devices, and tobacco, and its reach extends to more than one-fifth of all consumer products in the United States.<sup>19</sup> Its creation in the early twentieth century was a powerful refutation of the rhetoric of *laissez faire* that then prevailed.<sup>20</sup> New generations, usually responding to tragedy, repeatedly expanded the Agency’s power. In doing so, they made the Agency into a *bête noire* of leading neoliberal thinkers and the conservative legal movement, who have since the 1970s sought to radically curtail its authority.<sup>21</sup>

Much like the Progressive and New Deal eras that birthed it, the Agency, though, can be seen in two guises: as embodying and enacting a priority for public over market values, and as relatively modest and market-facilitating in its aims. Its modesty, in fact, is part of what makes the Agency so vulnerable to the weaponized First Amendment: Most of its powers can be readily described as operating centrally on and through speech. With this backdrop in view, we begin to see better the shape of the First Amendment challenge that looms.

A. *The Legislative Construction of Public Power*

The FDA was born in the Progressive era, the result of a long-brewing public awakening to the dysfunctions that accompanied modern commodity markets in food and drugs.<sup>22</sup> Toward the end of the nineteenth century, crusading investigators and government inquiries had called attention to the widespread tainting of the food supply, from bread adulterated with plaster of Paris<sup>23</sup> to “swill” milk that proved deadly to

18. Carpenter, *supra* note 5, at 18.

19. This figure is measured in terms of consumer value; FDA-regulated products account for approximately twenty cents of every dollar of annual spending by U.S. consumers. See Sheri Walker & Clark Nardinelli, Consumer Expenditure on FDA Regulated Products: 20 Cents of Every Dollar, U.S. FDA: FDA Voice (Nov. 1, 2016), <https://blogs.fda.gov/fdavoices/index.php/2016/11/consumer-expenditure-on-fda-regulated-products-20-cents-of-every-dollar/> [<https://perma.cc/46XJ-EUVV>].

20. On the legal debates over *laissez faire* during this period, see generally Barbara Fried, *The Progressive Assault on Laissez Faire* 15–28 (1998).

21. See *infra* note 65 and accompanying text (discussing Chicago School critiques of the FDA).

22. For discussions of the Progressive era and the early history of the FDA, see, e.g., Philip J. Hilts, *Protecting America’s Health: The FDA, Business, and One Hundred Years of Regulation* 35–55 (2004); Peter Temin, *Taking Your Medicine: Drug Regulation in the United States* 18–37 (1980); James Harvey Young, *Pure Food: Securing the Federal Food and Drugs Act of 1906*, at 146–73 (1989).

23. Young, *supra* note 22, at 32.

infants.<sup>24</sup> A dangerous market in “patent” medicines had also exploded.<sup>25</sup> These ostensible cures were different from the “formulary” medicines that preceded them in two key ways: Their ingredients were treated as proprietary and secret,<sup>26</sup> and they were directly advertised to the public, typically accompanied by grandiose claims that belied their significant harms.<sup>27</sup>

The legislative response to these dangers began at the state level, but the scale of the problem and the role that increasingly national markets played within it soon led to demands for a federal response.<sup>28</sup> In 1906, fueled by the publication of Upton Sinclair’s *The Jungle*, Congress passed the path-breaking Pure Food and Drugs Act.<sup>29</sup> For the first time, sellers had to disclose, as matter of national law, the presence of substances like alcohol and narcotics in drugs.<sup>30</sup> Drugs, in turn, were defined in a manner that honed in on their marketing: They comprised not only formulary drugs but also any substance that was intended to be used to cure or prevent disease.<sup>31</sup> The 1906 law also criminalized the adulteration of drugs and codified “misbranding” rules that required drug labels to be accurate.<sup>32</sup>

The law stood as a rebuttal to any aggressively laissez faire vision of American government, “establishing the principle that it was now the job of government not just to champion commerce but also to intervene when it got out of hand.”<sup>33</sup> But it also quickly proved inadequate. Court

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24. *Id.* at 36–39.

25. See Carpenter, *supra* note 5, at 77 (citing evidence of a meteoric expansion of the market over the nineteenth century, from just a few dozen advertised remedies in the early 1800s to tens of thousands a century later).

26. Formulary medicines were identified in compendia, which were developed by doctors over centuries and listed a small set of medicines, such as aspirin and morphine, along with their composition and techniques for manufacture. See Temin, *supra* note 22, at 24. Patent medicines, in contrast, were sold as proprietary, and were often little more than water, though some contained high (and undisclosed) levels of both alcohol and opioids. *Id.* at 25; see also Hiltz, *supra* note 22, at 24 (contrasting the secrecy of patent medicines with long-standing efforts to codify and “set universal formulas for each known remedy, [which] had advanced from the seventeenth century to the nineteenth, with little difficulty”).

27. See Carpenter, *supra* note 5, at 77–79 (describing the claims made, as well as the dangers, of these medicines); Temin, *supra* note 22, at 25–26 (discussing patent medicine advertising). As Philip Hiltz points out, advertising allowed patent medicines to emerge as “one of the first fully national markets.” Hiltz, *supra* note 22, at 23.

28. Temin, *supra* note 22, at 27.

29. Pure Food and Drugs Act, Pub. L. No. 59-384, 34 Stat. 768 (1906) (repealed 1938). On Sinclair’s role, see Hiltz, *supra* note 22, at 49–52.

30. Temin, *supra* note 22, at 30.

31. *Id.*

32. *Id.*

33. Hiltz, *supra* note 22, at xii.

decisions narrowed its reach,<sup>34</sup> and companies could skirt its requirements by making vague claims or separating advertising from labels.<sup>35</sup>

Reformers sought to expand the Agency's powers, but it took another public scandal to create the necessary legislative momentum. This time the culprit was "Elixir Sulfanilamide," a patent medicine contaminated with a highly toxic chemical that killed dozens of people.<sup>36</sup> In 1938, the Agency's powers were dramatically expanded in one of the last major legislative achievements of the New Deal.<sup>37</sup> Rather than simply mandating disclosures or penalizing fraud, the new law banned dangerous drugs from the marketplace outright.<sup>38</sup> A seller of any "new drug" had to demonstrate that it was safe and allow the Agency time to assess the relevant evidence *before* marketing.<sup>39</sup> At the same time, the federal government's authority expanded beyond labels to all drug advertising.<sup>40</sup>

The Agency accrued still more extensive powers in 1962, in the wake of the thalidomide crisis. Thalidomide was a drug widely used in Europe by pregnant women to treat morning sickness that proved extraordinarily toxic to fetuses.<sup>41</sup> The harm that it wreaked on children, some born without arms or legs, was documented in searing images that still today mark the public's consciousness of the risks of modern pharmaceuticals.<sup>42</sup> Thalidomide was never approved in the United States because of the tenacity of Frances Kelsey, an FDA reviewer who worked against the limits of the statute to prevent U.S. approval.<sup>43</sup> The tragedy, and Kelsey's ensuing celebrity, galvanized the public.<sup>44</sup> In 1962, Congress responded by granting the

34. In *United States v. Johnson*, the Supreme Court held that the prohibition on false and misleading statements on labels applied only to claims about the identity of the compound and not its therapeutic qualities. 221 U.S. 488, 497 (1911). The Court suggested that issues of therapeutic benefit could only be matters of opinion, given the state of scientific knowledge at the time. *Id.* at 498.

35. See Temin, *supra* note 22, at 30–31.

36. Carpenter, *supra* note 5, at 89–91.

37. See Charles O. Jackson, *Food and Drug Legislation in the New Deal*, at vii (1970).

38. See Temin, *supra* note 22, at 44.

39. See *id.*; Richard A. Merrill, *The Architecture of Government Regulation of Medical Products*, 82 Va. L. Rev. 1753, 1761–62 (1996) (discussing the introduction of premarket approval).

40. See Peter Barton Hutt, Richard A. Merrill & Lewis A. Grossman, *Food and Drug Law: Cases and Materials* 11 (4th ed. 2014). Initially, this power resided in the Federal Trade Commission rather than the FDA. See *id.*

41. Carpenter, *supra* note 5, at 238–40.

42. See Michael Winerip, *The Death and Afterlife of Thalidomide*, *N.Y. Times: Booming* (Sept. 23, 2013), <https://www.nytimes.com/2013/09/23/booming/the-death-and-afterlife-of-thalidomide.html> [<https://perma.cc/8UNH-Z85A>].

43. See Carpenter, *supra* note 5, at 217–26, 249–51 (discussing Kelsey's scrutiny of thalidomide's FDA application). Under the law at the time, drugs were automatically approved after sixty days if the Agency did not mount an objection. *Id.* at 254.

44. See *id.* at 238–60 (describing the public and governmental responses to the thalidomide crisis).

Agency substantially more extensive premarket review powers.<sup>45</sup> Now, marketers had to get the affirmative approval of the FDA and provide evidence not only of safety but also effectiveness.<sup>46</sup> The amendments also gave the Agency a significant new role in overseeing the testing and promotion of medicines.<sup>47</sup> In implementing these new powers, the Agency created the scientific apparatus that ushered in the modern era of drug R&D: the phased, randomized controlled trials that are now the gold standard for clinical research worldwide.<sup>48</sup>

For the last six decades, then, a company marketing a medicine has had to prove first to the FDA that the medicine actually works. The company also had to show—until recent First Amendment cases cast this system into doubt—that the drug worked for a particular purpose, and it could not promote the drug for unproven uses.<sup>49</sup> For example, a drug approved to treat severe pain in terminal cancer patients could not be legally promoted to treat individuals with chronic lower-back pain.<sup>50</sup> This is because the costs and benefits of drugs vary by use and can be established only via careful studies.<sup>51</sup> For example, an opioid might have fewer risks and more substantial benefits for terminally ill cancer patients than for individuals in mild pain.<sup>52</sup>

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45. Merrill, *supra* note 39, at 1764–65.

46. *Id.*; see also 21 U.S.C. § 355(a) (2012) (prohibiting the marketing of a new drug prior to FDA approval); *id.* § 355(d) (requiring drug sponsors to provide “substantial evidence” of a drug’s safety and effectiveness with respect to the specific use in the proposed labeling, and defining “substantial evidence” as “evidence consisting of adequate and well-controlled investigations, including clinical investigations”).

47. See Hutt, Merrill & Grossman, *supra* note 40, at 12; see also Merrill, *supra* note 39, at 1766–67 (describing the FDA’s expanded role in drug testing and approval).

48. See Carpenter, *supra* note 5, at 278–80, 292–95 (discussing the role of the FDA in trial standards); see also *id.* at 687 (noting the FDA’s global influence); Merrill, *supra* note 39, at 1777–82 (describing the FDA’s oversight of clinical trial design for pharmaceutical research and its development of requirements and guidelines for clinical trials).

49. See 21 U.S.C. § 321(g)(1) (defining “drugs” with reference to their “intended use”); 21 C.F.R. § 201.128 (2018) (defining “intended use”).

50. See William B. Schultz, Trump’s New FDA Commissioner Has a Huge Decision to Make, *Wash. Post* (May 16, 2017), [https://www.washingtonpost.com/opinions/trumps-new-fda-commissioner-has-a-huge-decision-to-make/2017/05/16/4ee187f8-3667-11e7-b412-62beef8121f7\\_story.html](https://www.washingtonpost.com/opinions/trumps-new-fda-commissioner-has-a-huge-decision-to-make/2017/05/16/4ee187f8-3667-11e7-b412-62beef8121f7_story.html) [<https://perma.cc/9R57-34DW>] (discussing rules against off-label promotion, and offering this example).

51. See Amy Kapczynski, Free Speech and Pharmaceutical Regulation—Fishy Business, 176 *JAMA Internal Med.* 295, 295–96 (2016) [hereinafter Kapczynski, *Fishy Business*] (“[D]rug[s] whose adverse effects may be acceptable when used to treat patients with serious illness[es] may cause more harm than benefit if used to treat healthier patients. Even a drug that is safe, but ineffective, can be harmful, for example if it is used instead of an effective intervention.”).

52. See *id.* at 295 (noting that drugs “prescribed for unproven indications can cause serious harm” and discussing Gabitril, a medication which can cause seizures when used off-label); see also Schultz, *supra* note 50 (noting the risks of marketing OxyContin, a “powerful opioid,” for mild pain).

The FDA has thus long exerted extraordinary control over what drug companies can say and, therefore, sell. As robust as these powers are, though, they can also be understood as quintessentially market-making, because they help generate reliable information for consumers. As I have described in previous work, unregulated markets cannot be expected to produce high quality, unbiased information about how medicines work.<sup>53</sup> Nor are markets alone able adequately to validate the scientific claims made about drugs.<sup>54</sup> The 1962 amendments were in fact the precondition for the possibility of the modern pharmaceutical industry, and the industry has grown enormously under its protective eye.<sup>55</sup>

For most of its history, the FDA had no similar oversight role for the tobacco industry, which metastasized into an extraordinarily lethal enterprise.<sup>56</sup> As the dangers of cigarettes became more publicly known, efforts to more closely regulate the industry gained strength. The FDA tried and failed to exert oversight over tobacco through its drug regulatory powers in the 1990s,<sup>57</sup> and Congress granted it expansive new authority over tobacco

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53. See Amy Kapczynski, *Dangerous Times: The FDA's Role in Information Production, Past and Future*, 102 *Minn. L. Rev.* 2357, 2358 (2018) [hereinafter Kapczynski, *Dangerous Times*] (“By controlling marketing, the FDA targets a distortion inherent to systems that rely on the profit motive and patents to generate clinical trial data: it encourages the creation of high-quality evidence about medicines that is not biased toward positive results.”).

54. *Id.* at 2358–59 (“Validation of the results of drug trials requires significant expertise, significant resources, and access to all of the relevant clinical trial data. While markets sometimes produce viable third-party certifiers, they cannot produce adequate third-party *validators*, absent major interventions that effectively turn third parties into . . . regulatory agencies.”); see also *id.* (noting that FDA drug reviews involve “hundreds of thousands of pages of data, and may require reviewers to rerun data analyses, to query companies for more information, and to closely scrutinize individual trial records”).

55. See Rebecca S. Eisenberg, *The Role of the FDA in Innovation Policy*, 13 *Mich. Telecomm. & Tech. L. Rev.* 345, 370–71 (2007) (suggesting that the FDA’s testing and approval process resolves several market failures, resulting in “increased public confidence” and preserved value for drug companies); Ariel Katz, *Pharmaceutical Lemons: Innovation and Regulation in the Drug Industry*, 14 *Mich. Telecomm. & Tech. L. Rev.* 1, 7 (2007) (“[R]ather than decreasing the expected returns to innovation, this aspect of the regulation . . . contributes to the value of new drugs and therefore may actually encourage innovation.”); see also Kapczynski, *Fishy Business*, *supra* note 51, at 296 (noting the FDA’s role in “foster[ing] the development of accurate and reliable information, and channel[ing] that information into settings where it can be rigorously evaluated”).

56. See U.S. Dep’t of Health & Human Servs., *The Health Consequences of Smoking—50 Years of Progress* 7 (2014), <https://www.surgeongeneral.gov/library/reports/50-years-of-progress/full-report.pdf> [<https://perma.cc/53FG-BXN3>] (reporting that smoking has resulted in the premature deaths of over 20 million Americans since 1964). Smoking continues to kill nearly half a million Americans each year. *Burden of Tobacco Use in the U.S.*, CDC, <https://www.cdc.gov/tobacco/campaign/tips/resources/data/cigarette-smoking-in-united-states.html> [<https://perma.cc/2ETE-FG7S>] (last updated Apr. 23, 2018).

57. In 1996, FDA Commissioner David Kessler sought to bring tobacco under the Agency’s authority, reasoning that nicotine met the statutory definition of a “drug” and that tobacco products were acting as delivery devices. See *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 125 (2000); see also Carpenter, *supra* note 5, at 744–45 (discussing Kessler’s attempts to regulate tobacco). Though this was a plausible reading of the statutory

products in 2009.<sup>58</sup> Aspects of this authority resemble the Agency's oversight over medicines and similarly turn critically on speech. A key provision of the new law, for example, requires the FDA to regulate so-called "modified risk tobacco products."<sup>59</sup> This was in response to decades of misleading marketing in which tobacco companies pushed "light," "low-tar," and "mild" cigarettes as healthier alternatives, though the companies knew that these cigarettes in fact had no demonstrable health benefits.<sup>60</sup> Citing this history, Congress required companies marketing products as having modified risk first to substantiate their claims to the FDA.<sup>61</sup> Makers of new products like "e-cigarettes"<sup>62</sup> therefore must provide substantiating evidence before they can market them in a manner that suggests that they have health benefits.<sup>63</sup>

As this brief history reflects, the FDA is the product of a national commitment to the view that markets must serve public values. As muscular as the Agency is, however, it can also be seen as fairly modest in its approach. Supporters have long described the Agency as aiming to make markets safe for consumers, for honest businessmen, and for virtuous competition.<sup>64</sup> Even where the Agency's power is at its height, in the realm

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text, the Supreme Court held that the Agency was acting inconsistently with Congressional intent. *Brown & Williamson*, 529 U.S. at 126.

58. See Family Smoking Prevention and Tobacco Control Act (TCA), Pub. L. No. 111-31, 123 Stat. 1776 (2009) (codified as amended in scattered sections of 5, 15, and 21 U.S.C.).

59. 21 U.S.C. § 387k (2012).

60. For example, companies marketed "light" cigarettes to dissuade smokers from quitting despite knowing that they did not meaningfully reduce smokers' risks. *United States v. Philip Morris USA Inc.*, 566 F.3d 1095, 1124 (D.C. Cir. 2009). They also "withheld and suppressed their extensive knowledge and understanding of nicotine-driven smoker compensation," by which smokers unknowingly take deeper puffs of weaker cigarettes. *Id.* at 1125 (internal quotation marks omitted) (quoting *United States v. Philip Morris USA, Inc.*, 449 F. Supp. 2d 1, 861 (D.D.C. 2006)); *Philip Morris*, 449 F. Supp. 2d at 860.

61. Marketers must show that the products: "(A) significantly reduce harm and the risk of tobacco-related disease to individual tobacco users; and (B) benefit the health of the population as a whole taking into account both users of tobacco products and persons who do not currently use tobacco products." 21 U.S.C. § 387k(g)(1); see also *id.* § 387k(b)(2)(A) (defining a modified risk product as one labeled, for example, as lower risk, having reduced levels of certain substances, or including the descriptor "light"); *id.* § 387k(g)(2) (providing limited discretion for the Secretary of Health and Human Services to exempt qualifying products upon certain findings).

62. E-cigarettes "are a diverse set of battery-powered devices that deliver a nicotine-containing aerosol to the user by heating a solution (called e-liquid) of humectants (propylene glycol and/or glycerin), nicotine, and flavorants." Gideon St. Helen & David L. Eaton, Public Health Consequences of e-Cigarette Use, 178 *JAMA Internal Med.* 984, 984 (2018).

63. See The Facts on the FDA's New Tobacco Rule, FDA, <https://www.fda.gov/ForConsumers/ConsumerUpdates/ucm506676.htm> [<https://perma.cc/V4L2-NWP5>] (last updated Nov. 9, 2017) (describing the FDA's expanded regulatory authority over e-cigarettes and other tobacco products).

64. For example, in urging approval of the 1938 Act, President Franklin D. Roosevelt described it in this way:

In such a situation as has grown up through our rising level of living and our multiplication of goods, consumers are prevented from choosing

of drugs and tobacco, it aims not to displace markets—for example by rendering public the process of researching or communicating about products—but rather to minimize the risks that come with delegating substantial authority to market actors. The model of the modern FDA assumes that private market actors will not only produce goods but also most of the evidence that we need to evaluate the worth of these goods. The FDA has long relied on an infrastructure of information provision and dissemination that is more private than public. In part for this reason, our system for understanding and controlling the risks of medicines and tobacco is extraordinarily vulnerable to the weaponized First Amendment.

#### B. *An Amendment Weaponized Against Regulatory Power*

As the FDA accrued regulatory power, it became a prominent target for free-market theorists and anti-regulatory activists. Milton Friedman and other Chicago School economists published influential critiques in the 1970s that took aim at the Agency’s approach to pharmaceuticals.<sup>65</sup> Right-wing advocacy groups also attacked the Agency in the courts. In the late 1990s, foreshadowing things to come, the Washington Legal Foundation (WLF) successfully used First Amendment arguments to pressure the Agency to permit drug companies to distribute reprints of journal articles about off-label uses.<sup>66</sup>

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intelligently, and producers are handicapped in any attempt to maintain higher standards. Only the scientific and disinterested activity of government can protect this honor of our producers and provide the possibility of discriminating choice to our consumers.

President Franklin D. Roosevelt, Message to Congress (Mar. 22, 1935), *in* Ruth deForest Lamb, *American Chamber of Horrors: The Truth About Food and Drugs* app. B at 332–33 (1936). This unprecedented expansion of agency power, he urged, was aimed at a “small minority of evaders and chiselers,” and would “provide a bulwark of consumer confidence throughout the business world.” *Id.* at 334.

65. For examples of these critiques, see generally Sam Peltzman, *An Evaluation of Consumer Protection Legislation: The 1962 Drug Amendments*, 81 *J. Pol. Econ.* 1049 (1973) (suggesting that the costs of the premarket approval process, measured by the forgone benefits of effective new medicines, exceed the benefits of avoiding ineffective medicines); Milton Friedman, *Frustrating Drug Advancement*, *Newsweek*, Jan. 8, 1973, at 49, reprinted in Milton Friedman, *There’s No Such Thing as a Free Lunch* 229–32 (1975) (discussing Peltzman’s article and suggesting that the 1962 amendments “should be repealed”). For a more recent critique, see generally Richard Epstein, *Overdose: How Excessive Government Regulation Stifles Pharmaceutical Innovation* (2006).

66. See *Wash. Legal Found. v. Friedman*, 13 F. Supp. 2d 51, 74 (D.D.C. 1998), appeal dismissed, vacated in part sub nom. *Wash. Legal Found. v. Henney*, 202 F.3d 331 (D.C. Cir. 2000); Richard C. Ascroft, Note, *Impact of the Washington Legal Foundation Cases on Pharmaceutical Manufacturer Practices in the United States*, 34 *Ind. L. Rev.* 95, 118 (2000) (describing the case and the role of First Amendment arguments). Around the same time, WLF also challenged aspects of the FDA’s approach to off-label promotion on First Amendment grounds, but developments rendered the case moot. See *Wash. Legal Found. v. Henney*, 202 F.3d at 336. WLF has been the organization most centrally involved in this litigation and has received funding from pharmaceutical industry and tobacco lobbying

In 1999, companies marketing dietary supplements also successfully invoked the First Amendment to force the FDA to significantly liberalize its regulation of these sometimes risky products.<sup>67</sup> The FDA's regulatory approach to supplements was structurally quite similar to its approach to pharmaceuticals: Companies wishing to market dietary supplements with health claims had first to show "significant scientific agreement" in support of those claims.<sup>68</sup> In both domains, the FDA's institutional approach delegated substantial authority to market actors, and relied upon a background assumption that was for decades uncontroversial: Free speech protections had no bearing on the ordinary activity of regulators seeking to shape markets and protect consumers.

Supplements companies argued, however, that they had a First Amendment right to market their wares in any way that the Agency could not affirmatively show to be false or misleading.<sup>69</sup> The D.C. Circuit agreed—mandating as a matter of constitutional law in the domain of supplements much the same strategy that Congress had judged inadequate for drugs in the 1930s. Disclaimers, the court felt, were adequate to protect consumers from being misled, and it remanded the case for factual determination.<sup>70</sup>

The blow to supplements regulation was substantial, particularly because courts proved ill-prepared to evaluate the relevant scientific evidence. On remand, the FDA objected that the scientific evidence did not support the health claims made by the manufacturer.<sup>71</sup> The district court reasoned, astonishingly, that "[t]he mere absence of significant affirmative evidence in support of a particular claim . . . does not translate into negative

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groups. See Washington Legal Foundation, DeSmog, <https://www.desmogblog.com/washington-legal-foundation> [<https://perma.cc/E9N2-G66R>] (last visited Aug. 27, 2018).

67. See *Pearson v. Shalala* (*Pearson I*), 164 F.3d 650, 661 (D.C. Cir. 1999); *Pearson v. Shalala* (*Pearson II*), 130 F. Supp. 2d 105, 120 (D.D.C. 2001). Recent evidence collected by the FDA suggests that supplements as a category are far from benign. An estimated 23,000 emergency visits and 2,154 hospitalizations each year can be attributed to supplements, a significant portion of these in young adults with cardiovascular symptoms after taking weight-loss or energy supplements. See Andrew I. Geller et al., *Emergency Department Visits for Adverse Events Related to Dietary Supplements*, 373 *New Eng. J. Med.* 1531, 1531 (2015).

68. *Pearson I*, 164 F.3d at 653. As the *Pearson I* court explained:

The FDA authorizes a claim only "when it determines, based on the totality of publicly available scientific evidence (including evidence from well-designed studies conducted in a manner which is consistent with generally recognized scientific procedures and principles), that there is significant scientific agreement among experts qualified by scientific training and experience to evaluate such claims, that the claim is supported by such evidence." The FDA's authorization comes by an informal rulemaking under the Administrative Procedure Act.

*Id.* at 652 (citation omitted) (quoting 21 C.F.R. § 101.14(c) (1998)).

69. See *id.* at 653–56.

70. See *id.* at 659–61.

71. *Pearson II*, 130 F. Supp. 2d. at 115 n.27.

evidence ‘against’ it.”<sup>72</sup> On this basis, it found the FDA’s refusal of the claim arbitrary and capricious.<sup>73</sup> Small wonder that dietary supplements have morphed into a multibillion-dollar industry that is “loosely regulated and plagued by accusations of adulteration and mislabeling.”<sup>74</sup>

The FDA seemed perilously close to losing its authority to regulate drugs but for a dangling footnote in the D.C. Circuit’s decision. That footnote asserted that “drugs . . . appear to be in an entirely different category [because] the potential harm presumably is much greater.”<sup>75</sup> What this had to do with the First Amendment went unexplained. But as the court anticipated, an analogous First Amendment challenge to the Agency’s drug regulatory powers soon followed. Without referring to, much less distinguishing, the supplements cases, the D.C. Circuit held in *Whitaker v. Thompson* that the same First Amendment logic simply did not apply to the FDA’s substantiation requirements for drugs.<sup>76</sup>

Enabled by shifting Supreme Court law, and supported avidly by groups like WLF, First Amendment challenges to the FDA’s power over drugs and tobacco have taken on new life in the federal courts today.<sup>77</sup> The firewall created by *Whitaker* crumbled in 2012, when the Second Circuit dealt the FDA’s authority to regulate medicines an extraordinary blow. In *United States v. Caronia*, the government charged a drug company detailer with promoting a drug approved for narcolepsy (and affixed

72. *Id.* at 115.

73. *Id.* The court also pointed to one study that purported to support the supplement marketer’s claim, but the FDA questioned its validity. *Id.* at 116.

74. Anahad O’Connor, GNC to Strengthen Supplement Quality Controls, *N.Y. Times: Well* (Mar. 30, 2015), <https://well.blogs.nytimes.com/2015/03/30/gnc-to-strengthen-supplement-quality-controls/> [<https://perma.cc/X4YK-QJAQ>]; see also Ziv Harel et al., The Frequency and Characteristics of Dietary Supplement Recalls in the United States, 173 *JAMA Internal Med.* 926, 927 (2013) (finding that dietary supplements accounted for more than half of FDA Class I drug recalls between 2004 and 2012); Donald M. Marcus & Arthur P. Grollman, Botanical Medicines: The Need for New Regulations, 347 *New Eng. J. Med.* 2073, 2073 (2002) (summarizing studies showing frequent adulteration and lack of standardization).

75. *Pearson I*, 164 F.3d at 656 n.6.

76. See 353 F.3d 947, 953 (D.C. Cir. 2004) (concluding that the Agency’s approach to drugs used speech only as evidence of a crime and so presented no First Amendment problem).

77. See, e.g., Brief of Washington Legal Foundation as Amicus Curiae in Support of Plaintiffs-Appellants, Urging Reversal, *Nicopure Labs, LLC v. FDA (Nicopure II)*, No. 17-5196 (D.C. Cir. filed Feb. 20, 2018), 2018 WL 994268 (arguing that the Modified Risk Tobacco Product Rule of the Tobacco Control Act violates the First Amendment); Amicus Curiae Brief of Washington Legal Foundation in Support of Appellant Alfred Caronia and Reversal, *United States v. Caronia*, 703 F.3d 149 (2d. Cir. 2012) (No. 09-5006), 2010 WL 6351496 (arguing that the FDA’s ban on off-label drug promotion violates the First Amendment). See generally Michael A. Walsh, The First Amendment and the Emerging Tort of “Off-Label Promotion” (Wash. Legal Found., Critical Legal Issues Working Paper No. 183, 2013), [http://www.wlf.org/upload/legalstudies/workingpaper/WalshWP2\\_4-13.pdf](http://www.wlf.org/upload/legalstudies/workingpaper/WalshWP2_4-13.pdf) [<https://perma.cc/46NK-65AM>] (demonstrating WLF’s commitment to deregulatory imperatives through First Amendment litigation).

with the FDA's most serious "black box" safety warning) for a range of off-label uses ranging from restless leg syndrome to insomnia.<sup>78</sup> A divided panel of the Second Circuit Court of Appeals concluded that the FDA's long-standing practice of prosecuting individuals for promoting drugs for unapproved uses violated the First Amendment.<sup>79</sup> The FDA could still, the court reasoned, preclude false and misleading statements by companies.<sup>80</sup> But as the dissent recognized, this ignores the obvious problem: How are we to know what claims are false and misleading in the absence of evidence generated in the premarket approval process?<sup>81</sup> The majority threw decades of regulatory practice overboard nonetheless, under the influence of the 2011 Supreme Court decision of *Sorrell v. IMS Health Inc.*<sup>82</sup>—a decision that dramatically swerved from the Court's previous approach to commercial speech.<sup>83</sup>

Prior to *Sorrell*, long-settled doctrine required commercial speech to be analyzed under the *Central Hudson* test—a form of intermediate scrutiny that permitted far more regulation of commercial than of political speech.<sup>84</sup> *Sorrell* suggested instead that more scrutiny of laws regulating commercial speech might be warranted, at least when the laws in question were "content- and speaker-based."<sup>85</sup> Reasoning from cases about political speech that had long been kept carefully distinct from those involving commercial speech, the Court suggested that *any* law that imposed content- and speaker-based distinctions on speech was immediately suspect.<sup>86</sup> As the dissent warned, this framing asked courts to begin to review and strike down vast amounts of regulatory conduct since it is

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78. 703 F.3d at 156–57, 171–72.

79. *Id.* at 160; see also *id.* at 182 (Livingston, J., dissenting) (noting that the majority's opinion "calls into question a fundamental regime of federal regulation that has existed for more than a century").

80. *Id.* at 168 (majority opinion).

81. See *id.* at 177–80 (Livingston, J., dissenting) (concluding that the prohibition on off-label promotion "directly advances" the efficacy of the premarket approval process, which was introduced due to the concern that "doctors could not adequately evaluate frequently misleading claims by drug manufacturers without a body of objective, reliable information").

82. 564 U.S. 552 (2011).

83. See *Caronia*, 703 F.3d at 163 ("In applying [First Amendment] principles, we have a benefit not available to the district court: the Supreme Court's decision in *Sorrell v. IMS Health, Inc.* . . .").

84. See *Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n*, 447 U.S. 557, 563, 566 (1980) (holding that commercial speech may be regulated if it is false or misleading or relates to unlawful conduct, or if it advances a substantial government interest in direct fashion, and is not more extensive than necessary).

85. See *Sorrell*, 564 U.S. at 563, 571 (noting that the law in question "imposes a speaker- and content-based burden on protected expression, and that circumstance is sufficient to justify application of heightened scrutiny").

86. See *id.* at 571 (noting that "[i]n the ordinary case it is all but dispositive to conclude that a law is content-based and, in practice, viewpoint-discriminatory" (citing *R.A.V. v. City of St. Paul*, 505 U.S. 377, 382, 391–92 (1992))).

common for regulation to target particular content and particular speakers.<sup>87</sup> *Caronia* proved the dissenters all too prescient.

Shortly after *Caronia*, a district court dealt the Agency an even more significant defeat. In *Amarin Pharma, Inc. v. FDA*, citing the First Amendment, a Southern District of New York judge granted a company the right to market a drug approved for one narrow use to a vastly broader population, over the FDA's strenuous objection.<sup>88</sup> The Agency appealed neither case<sup>89</sup> and recently sought public comments on whether it should fundamentally revise its approach to off-label promotion.<sup>90</sup> Reports suggest that the FDA may be poised to voluntarily grant much more latitude to marketers, citing changing First Amendment law as the impetus.<sup>91</sup>

The FDA's authority over tobacco products is now similarly in doubt. As soon as the FDA made clear that it considered e-cigarettes within its regulatory scope in 2016, no fewer than nine First Amendment lawsuits were filed spanning five federal circuits.<sup>92</sup> A key circuit court decision on the matter is poised to come in *Nicopure Labs, LLC v. FDA*, currently pending in the D.C. Circuit.<sup>93</sup> Appellant-Manufacturers—again supported

87. See *id.* at 587–92 (Breyer, J., dissenting) (suggesting that the court “has embarked upon an unprecedented task—a task that threatens significant judicial interference with widely accepted regulatory activity”).

88. See 119 F. Supp. 3d 196, 198, 237 (S.D.N.Y. 2015) (granting the company preliminary relief and declaring certain marketing statements to be truthful and nonmisleading, over FDA objection).

89. See Katie Thomas, F.D.A. Deal Allows Amarin to Promote Drug for Off-Label Use, *N.Y. Times* (Mar. 8, 2016), <https://www.nytimes.com/2016/03/09/business/fda-deal-allows-amarin-to-promote-drug-for-off-label-use.html> (on file with the *Columbia Law Review*).

90. Notice of Public Hearing and Request for Comments, Manufacturer Communications Regarding Unapproved Uses of Approved or Cleared Medical Products, 81 Fed. Reg. 60299 (Sept. 1, 2016).

91. See, e.g., David Pittman, Pharma Considerations Loom in Spending Bill, *Politico: Prescription Pulse* (Mar. 19, 2018), <https://www.politico.com/newsletters/prescription-pulse/2018/03/19/pharma-considerations-loom-in-spending-bill-142047> [<https://perma.cc/Y9A9-TZCG>] (reporting on a First Amendment Working Group evaluating the issue at the FDA and concluding that “Commissioner Scott Gottlieb is likely to move toward the drug industry’s position—more freedom to communicate off-label information”).

92. See FDA Deeming Rule, Pub. Health & Tobacco Pol’y Ctr., <http://tobaccopolicycenter.org/tobacco-control/recent-cases/fda-deeming-rule/> [<https://perma.cc/CM5T-6FA3>] (last visited Aug. 27, 2018) (compiling cases filed in the U.S. District Court for the District of Columbia; U.S. District Courts in Florida and Alabama; U.S. District Court for the Southern District of West Virginia; U.S. District Court for the District of Minnesota; and U.S. District Court for the Central District of California).

93. See Notice of Appeal, *Nicopure II*, No. 17-5196 (D.C. Cir. filed Aug. 31, 2017). The district court rejected plaintiffs’ First Amendment claim on the grounds that distribution of e-cigarettes and vaping devices was *conduct* rather than First Amendment protected speech. See *Nicopure Labs, LLC v. FDA*, 266 F. Supp. 3d 360, 415 (D.D.C. 2017). The lower court further held that even if this distribution were to be speech, its regulation passes muster under the First Amendment by advancing a substantial governmental interest of limiting youth exposure to tobacco. See *id.* at 415–16.

by groups like WLF<sup>94</sup>—argue that Congress’s and the FDA’s evidentiary requirements for modified-risk tobacco products violate the First Amendment.<sup>95</sup> The FDA, in response, argues that its premarket review power for modified-risk tobacco products is similar to its premarket review power for drugs and so should survive under the D.C. Circuit’s *Whitaker* decision.<sup>96</sup> Further, the FDA contends that the power should survive *Central Hudson* because “it is narrowly tailored to serve the government’s substantial interest in ensuring that statements about such products are complete, accurate, and relate to the product’s overall risk.”<sup>97</sup>

These cases pose significant risks to public health, whether from more extensive (and less well-understood) off-label uses of drugs or more extensive (and less well-understood) uses of electronic and conventional cigarettes.<sup>98</sup> And consider this: If it is unconstitutional for the FDA to require approval before allowing marketing of new *uses* of drugs, can it possibly be constitutional for the FDA to require premarket approval of *any* new drug? Why can’t companies market any new elixir as a cure for cancer, until the FDA comes to court and shows their claims to be false or misleading? We are on the road to a dangerous new world.

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94. See Litigation, Wash. Legal Found., <https://www.wlf.org/litigation/> [https://perma.cc/5HWW-VPPP] (last visited Aug. 27, 2018) (listing cases supported or litigated by WLF).

95. For example, they contend that this is so because the requirements apply when manufacturers make certain claims (e.g., “no tar”) and apply only to manufacturers. See Opening Brief of Appellants at 23–24, *Nicopure II*, No. 17-5196 (filed Feb. 12, 2018).

96. See Brief for Appellees at 27–29, *Nicopure II*, No. 17-5196 (filed May 2, 2018).

97. *Id.* at 3.

98. Evidence suggests that medicines used off-label come with substantially greater risks. See Tewodros Egualé et al., Association of Off-Label Drug Use and Adverse Drug Events in an Adult Population, 176 *JAMA Internal Med.* 55, 61 (2016). E-cigarettes seem to incorporate fewer toxic substances than conventional cigarettes, but their long-term health effects for individuals are not yet known, and their public health effects are uncertain. An excellent source on the topic is the recent consensus study report by a committee of the National Academy of Science, Engineering, and Medicine. See Nat’l Acad. of Sci., Eng’g & Med., *Public Health Consequences of E-Cigarettes* (Kathleen Stratton et al. eds., 2018). The report concluded that while e-cigarettes contain “fewer numbers and lower levels of most toxicants than does smoke from combustible tobacco cigarettes,” exposure to nicotine levels vary widely, and “the absolute risks of the products cannot be unambiguously determined at this time,” particularly over the long-term. *Id.* at 1. The review also concluded that “[t]he net public health effect, harm or benefit, of e-cigarettes depends on three factors: their effect on youth initiation of combustible tobacco products, their effect on adult cessation of combustible tobacco products, and their intrinsic toxicity.” *Id.* The population-level implications depend substantially on issues about which there is currently very little evidence—such as whether they will help adult smokers quit in the long-term better than other available approaches. *Id.* Crucially, if e-cigarettes do not help lead adult smokers to quit—a matter about which there is little evidence—“e-cigarette use could cause considerable harm to public health in the short and long-term due both to the inherent harms of exposure to e-cigarette toxicants and to the harms related to subsequent combustible tobacco use by those who begin using e-cigarettes in their youth.” *Id.*; see also *id.* at 10 (finding that there is “insufficient evidence from randomized controlled trials about the effectiveness of e-cigarettes as cessation aids compared with no treatment or to Food and Drug Administration-approved smoking cessation treatments”).

How did this come to pass? To understand it, we must reckon with the contemporary political economy of the First Amendment: with the right relation between markets and democratic governance put into play in recent decisions, and the vision of markets, subjects, and state that animate their reasoning and that follow in their wake. Reckoning with it requires first seeing how these ideas have worked their way into doctrine, and then moving outside of doctrine to consider the contours of a new political economy of drug and tobacco research, one with more robustly public infrastructure at its core.

## II. THE POLITICAL ECONOMY OF COMMERCIAL SPEECH

We are all accustomed to reading cases for their holdings and rationale, but decisions also embody deeper worldviews.<sup>99</sup> The conceptions of markets, states, and subjects on display in key Supreme Court commercial speech cases reflect logics that are profoundly marked by the era in which they emerged. Most critically, they are shaped by the imaginary of neoliberalism—a powerful set of interlinked arguments that have had substantial influence in the United States, and transnationally, over the last several decades.<sup>100</sup>

The history of neoliberalism is commonly traced back to the 1947 founding of F.A. Hayek’s Mont Pèlerin Society.<sup>101</sup> But it was in the 1970s and 1980s, under the influence of thinkers like Milton Friedman<sup>102</sup> and James Buchanan,<sup>103</sup> that neoliberal thought came to prominence. One mark of this prominence is the world-changing shifts in governance made in its image, including the Reagan and Thatcher revolutions, structural adjustment and the “Washington Consensus” at the IMF and World Bank, and the “shock-therapy” transitions in post-Communist countries.<sup>104</sup>

In Professor David Harvey’s influential description, neoliberalism is the view that “human well-being can best be advanced by liberating

99. See, e.g., Purdy, *Beyond the Bosses’ Constitution*, *supra* note 12, at 2174–75 (suggesting that the Supreme Court’s characterizations of capitalist democracy embody “a worldview, . . . a way of organizing institutions and events into certain patterns of salience, highlighting certain priorities and dangers and discounting others”).

100. On acceptance of the term, including by some of its proponents, see Quinn Slobodian, *Globalists: The End of Empire and the Birth of Neoliberalism* 2–3 (2018). For a piece explaining the term in a manner especially attuned to law and legal scholarship, see generally David Grewal & Jedediah Purdy, *Introduction: Law and Neoliberalism*, 77 *Law & Contemp. Probs.*, no. 4, 2014, at 1, 1.

101. See, e.g., Angus Burgin, *The Great Persuasion* 104–05 (2012).

102. *Id.* at 154.

103. See Nancy MacLean, *Democracy in Chains* 135–37 (2017).

104. See, e.g., Adam Tooze, *Neoliberalism’s World Order*, *Dissent* (Summer 2018), <https://www.dissentmagazine.org/article/neoliberalism-world-order-review-quinn-slobodian-globalists> [<https://perma.cc/BEJ7-E37C>]; see also Naomi Klein, *The Shock Doctrine: The Rise of Disaster Capitalism* 7–13 (2007) (discussing neoliberalism’s role in affecting large-scale post-disaster reforms).

individual entrepreneurial freedoms and skills within an institutional framework characterized by strong private property rights, free markets, and free trade.”<sup>105</sup> Sutured together here are visions of the proper role and relationship of markets, of the state, and of the human subject. Markets are spaces of neutrality and of justice that must be “free” from political interference and given maximum scope to order human affairs.<sup>106</sup> The social is dissolved in favor of preference-maximizing individuals whose preferences are best satisfied via voluntary transactions in markets.<sup>107</sup> The state, in turn, is modeled as just one among many market actors.<sup>108</sup> Politics is simply the process of interest-group competition, rather than a domain where we develop public aims or express public will.<sup>109</sup> Indeed, the state is an object of suspicion, because its status as sovereign gives it the qualities of a monopolist, protected from market discipline and the virtue-enhancing rigors of competition.<sup>110</sup> Freedom, in this analysis, is found in the marketplace when properly protected from public interference.<sup>111</sup> As political theorist Wendy Brown puts it, “The guarantee of equality through the rule of law and participation in popular sovereignty is replaced with a market formulation of winners and losers. Liberty itself is narrowed to market conduct, divested of associations with mastering the conditions of life, existential freedom, or securing the rule of the demos.”<sup>112</sup>

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105. David Harvey, *A Brief History of Neoliberalism 2* (2007); see also Grewal & Purdy, *supra* note 100, at 1 (referring to neoliberalism as “the revival of the doctrines of classical economic liberalism, also called *laissez-faire*, in politics, ideas, and law”).

106. See Wendy Brown, *Undoing the Demos: Neoliberalism’s Stealth Revolution 17* (2015) (arguing that neoliberalism insists on the “‘economization’ of political life and of other heretofore noneconomic spheres and activities”); Harvey, *supra* note 105, at 3 (“[S]ocial good will be maximized by maximizing the reach and frequency of market transactions . . .”).

107. As Margaret Thatcher famously said, “There is no such thing as society.” Interview by Douglas Keay with Margaret Thatcher, Prime Minister, U.K. (Sept. 23, 1987), <https://www.margaretthatcher.org/document/106689> [<https://perma.cc/U9AN-VWQC>]; see also Brown, *supra* note 106, at 39 (“[*Homo oeconomicus* approaches everything as a market and knows only market conduct; it cannot think public purposes or common problems in a distinctly political way.”).

108. For key works in this genre, see generally James M. Buchanan & Gordon Tullock, *The Calculus of Consent* (1962); Mancur Olson, *The Logic Of Collective Action* (1965).

109. See, e.g., Friedrich A. von Hayek, *Whither Democracy?*, in *The Essence of Hayek* 352, 357 (Chiaki Nishiyama & Kurt R. Leube eds., 1984) (describing unfettered democracy as “not based on agreement of opinions, but . . . [on] aggregations of special interests mutually assisting each other”).

110. See, e.g., William A. Niskanen, *Bureaucracy and Representative Government 31* (1971) (characterizing government agencies as monopolists and monopsonists).

111. See Friedrich A. von Hayek, *Principles of a Liberal Social Order*, in *The Essence of Hayek*, *supra* note 109, at 363, 366 (describing “the order of the market” as a central means of reconciling divergent human purposes for mutual benefit, and thus as central to free society).

112. Brown, *supra* note 106, at 41.

As legal realists and critical legal scholars showed long ago, of course, there is no such thing as a self-regulating market, nor is there any economic domain that is separable and cordoned off from politics.<sup>113</sup> This is in part because government is a condition of modern market ordering. Government creates and enforces rights to property and contract and establishes and underwrites the financial system and social infrastructures that make modern market society possible.<sup>114</sup> But, equally as important, it is because the ideal of market supremacy is also in deep tension with the project of democracy.<sup>115</sup> If markets are to be given free rein, they also must be protected from the political power of the majority. The neoliberal project must be a project of governance because it must hem in democratic powers to shape markets and to make choices about distribution.<sup>116</sup>

The best understanding of neoliberalism, then, identifies it not as a utopian economic theory but as a fundamentally *political* project, one that redefines the tools and contours of economic and social management—putting some on the side of free markets and others in the domain of impermissible regulation—in order to achieve practical ends, chief among them the opportunity to accumulate by those empowered to wield capital.<sup>117</sup> Newer histories of neoliberal thought thus emphasize its demand for a world “kept safe from mass demands for social justice and redistributive equality by the guardians of the economic constitution.”<sup>118</sup> Neoliberalism does not, in fact, demand minimal state interference.<sup>119</sup> Rather, it

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113. For discussions of the interrelationship between law, power, and distributive consequences, see generally Robert Hale, *Freedom Through Law: Public Control of Private Governing Power* (1952); Duncan Kennedy, *The Stakes of Law, or Hale and Foucault!*, 15 *Legal Stud. F.* 327 (1991).

114. See, e.g., Hale, *supra* note 113, at 10–12 (discussing the government’s construction and enforcement of contract and property rights). This is, in part, what political economist Karl Polanyi meant when he said “laissez faire was planned.” See Karl Polanyi, *The Great Transformation* 141 (Octagon Books 1980) (1944).

115. See Grewal & Purdy, *supra* note 100, at 3 (“[The] contest . . . between capitalist imperatives and democratic demands . . . is persistent because of pressures that capitalist markets make on the legal and political order—pressures not just for familiar protections of property and contract, but also for a favorable return on investment and managerial authority . . .”).

116. See Slobodian, *supra* note 100, at 2 (“[T]he neoliberal project focused on designing institutions—not to liberate markets but to encase them, to inoculate capitalism against the threat of democracy . . .”); see also MacLean, *supra* note 103, at 1–12, 61–73 (describing Buchanan’s thought, and public choice theory, as aiming to discredit government and hem in the power of majorities, and linking it to historical thought and political developments in the United States that protect racial hierarchy and states’ rights).

117. See Slobodian, *supra* note 100, at 19 (suggesting that neoliberalism’s aim in “re-embedding” the market was “to prevent state projects of egalitarian redistribution and [to] secure competition”).

118. *Id.* at 16.

119. It is notable, too, that neoliberalism has taken hold contemporaneously with the elaboration of a vast carceral and surveillance state, especially in the United States. For theories of the relation between the two, see generally, for example, Bernard E. Harcourt,

offers a distinctive picture of the legitimate ends to which the state can be put. It demands a state that can protect profit-making from majoritarian wishes and that can insinuate forms of market order into domains of human life previously characterized by nonmarket logics.

That neoliberal thought should find a comfortable home inside of constitutional jurisprudence is, in this sense, not a surprise. If markets are to be protected from majorities, some sovereign entity must step in to limit majority power, to insist on a “market freedom” that is also an instance of governmental control. Sheltered from the more immediate democratic will-formation facilitated by legislatures, courts may even be privileged institutions for neoliberal reforms.

Commercial speech law, in fact, takes shape in constitutional law during the period of the ascendancy of neoliberal thought and politics. It is the 1976 case of *Virginia Pharmacy* that first brings commercial speech under the protection of the First Amendment.<sup>120</sup> Plaintiffs had challenged a Virginia law that forbade pharmacists to advertise the prices of prescription drugs, arguing that this impinged upon the pharmacist’s right to speak.<sup>121</sup> But the Court had never before held that speech that “does ‘no more than propose a commercial transaction’” was entitled to Constitutional protection.<sup>122</sup>

How did the Court justify the extension of the First Amendment, long understood as committed to the protection of political speech or speech on matters of public concern, to purely commercial speech? By way of an analogy that dissolves any distinctive status of the political: The “consumer’s interest in the free flow of commercial information,” the Court declares, “may be as keen, if not keener by far, than his interest in the day’s most urgent political debate.”<sup>123</sup> The founding conceit of the doctrine, then, is one that dissolves politics into homogenous “interests,” with no distinction between our interests as citizens and our interests as consumers.

We must incorporate commercial speech into our constitutional order, the Court further suggested, as an inexorable extension of our commitment to free markets:

So long as we preserve a predominantly free enterprise economy, the allocation of our resources in large measure will be made through numerous private economic decisions. It is a matter of public interest that those decisions, in the aggregate, be intelligent and well informed. To this end, the free flow of

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The Illusion of Free Markets: Punishment and the Myth of Natural Order (2012); Loïc J. D. Wacquant, *Punishing the Poor: The Neoliberal Government of Social Insecurity* (2009).

120. *Va. State Bd. of Pharmacy v. Va. Citizens Consumer Council, Inc.*, 425 U.S. 748 (1976).

121. *Id.* at 749–50.

122. *Id.* at 762 (quoting *Pittsburgh Press Co. v. Human Relations Comm’n*, 413 U.S. 376, 385 (1973)).

123. *Id.* at 763.

commercial information is indispensable. And if it is indispensable to the proper allocation of resources in a free enterprise system, it is also indispensable to the formation of intelligent opinions as to how that system ought to be regulated or altered. Therefore, even if the First Amendment were thought to be primarily an instrument to enlighten public decisionmaking in a democracy, we could not say that the free flow of information does not serve that goal.<sup>124</sup>

The Court invokes here a background “free enterprise economy” that has become so natural, so American, that it takes on a quasi-constitutional status. We have markets, and therefore information must flow to inform private decisions in order that the “public interest”—here again, reduced to efficiency—be served. The influence of Chicago School thinking is palpable.

In concluding that the advertisement of prices warranted constitutional protection, the Court also selected a distinctive image of the subject of its concern. The state had defended its law as a means to help maintain professionalism among pharmacists. The Court rejected this justification—the idea, we might say, that the state has an interest in calling forth certain kinds of nonmarket subjects—and insisted instead on the primacy of market-rational, self-interest-maximizing man: We should assume, the Court insisted, “that . . . information is not in itself harmful, that people will perceive their own best interests if only they are well enough informed, and that the best means to that end is to open the channels of communication rather than to close them.”<sup>125</sup>

There is also a distinctive, if submerged, picture of the state here. If the free flow of commercial information is of such importance to the public and to the functioning of our “free enterprise economy,” we might ask, why would majorities restrict it? It makes sense that majorities might outlaw unpopular political speech. But why would majorities deny themselves the information needed to make good economic decisions? What do the people have against a good bargain? Legislatures must, it seems, not be enacting the will of a majority. Rather, they must be following the will of “interest groups,” in Chicago and Virginia School parlance.

Relying in this way on key aspects of the neoliberal imaginary, the Court cast the First Amendment, for the first time, as having an interest in “the free flow of commercial information” about “who is producing and selling what product, for what reason, and at what price.”<sup>126</sup> Note, also, the ambiguity in the key passage cited above: Does the First Amendment protect commercial speech because it elevates the aim of “proper allocation of resources in a free enterprise system” to a constitutional value?<sup>127</sup> Or does it protect commercial speech because—and when—such speech

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124. *Id.* at 765 (footnote omitted) (citations omitted).

125. *Id.* at 770.

126. *Id.* at 765.

127. See *id.*

is indispensable to the formation of public opinions about the governance of markets.<sup>128</sup> The latter is surely the better reading of the holding—if not the full gestalt—of the excerpt above, and is consistent with far more regulation of commercial speech than is the former view.

Choosing the latter view in cases that followed, the Court constructed a hierarchy: It permitted far more regulation of commercial than political speech based on an understanding of core differences between the two.<sup>129</sup> Commercial speech was “a hardy breed of expression,”<sup>130</sup> one that did not merit the protection of overbreadth doctrine or the doctrine of prior restraints.<sup>131</sup> Commercial speech could be regulated by content (indeed, was *defined* via its content) and received protection only if it was not false or misleading.<sup>132</sup> Even true and nonmisleading commercial speech could be regulated under the *Central Hudson* test, if the state had a substantial interest and the law directly advanced that interest.<sup>133</sup>

Then came *Sorrell v. IMS Health Inc.*<sup>134</sup> As described above, *Sorrell* created a powerful new weapon against ordinary commercial regulations when it transposed the Court’s hostility to laws that single out particular *political* content or *political* speakers onto laws that single out particular *commercial* content or *commercial* speakers.<sup>135</sup> The move was unprecedented,<sup>136</sup> and extraordinarily disruptive. Regulators often do and must regulate according to content and viewpoint, as the dissenters pointed out with many examples. Cosmetic companies might be required to substantiate the claim that a “product contains ‘cleansing grains that scrub away dirt and excess oil’” while “opponents of cosmetics use need not substantiate their claims.”<sup>137</sup> Salesmen might be allowed to access credit databases to run credit checks but not to search for new customers.<sup>138</sup> Or, the FDA might forbid drug companies to promote drugs for unapproved uses, though academic researchers may recommend for or against the same uses.<sup>139</sup>

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128. See *id.*

129. *Bd. of Trs. of the State Univ. of N.Y. v. Fox*, 492 U.S. 469, 477 (1989) (“[C]ommercial speech [enjoys] a limited measure of protection, commensurate with its subordinate position in the scale of First Amendment values,’ and is subject to ‘modes of regulation that might be impermissible in the realm of noncommercial expression.’” (second alteration in original) (quoting *Ohralik v. Ohio State Bar Ass’n*, 436 U.S. 447, 456 (1978))).

130. *Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm’n*, 447 U.S. 557, 564 n.6 (1980).

131. See *id.* at 565 n.8, 571 n.13.

132. See *id.* at 563–64, 564 n.6.

133. *Id.* at 564.

134. 564 U.S. 552 (2011).

135. See *supra* notes 84–87 and accompanying text.

136. *Sorrell*, 564 U.S. at 588 (Breyer, J., dissenting) (“[N]either of these categories—‘content-based’ nor ‘speaker-based’—has ever before justified greater scrutiny when regulatory activity affects commercial speech.”).

137. *Id.* at 589–90.

138. *Id.* at 587.

139. *Id.* at 590.

The dissent warned of precisely the invasion of regulatory prerogative that is now upon us.<sup>140</sup> How can the decision be justified? Centrally, the majority in *Sorrell* reasons via the logic of nondiscrimination—with the victim of alleged discrimination market actors themselves.<sup>141</sup>

The state law under challenge in *Sorrell* barred pharmacies from selling prescribing data to data vendors without affirmative consent from doctors.<sup>142</sup> The legislature’s aim was to protect doctors from “harassment” by pharmaceutical company detailers, who made frequent visits to urge them to purchase more or different medicines.<sup>143</sup> Companies also disproportionately promote expensive medicines;<sup>144</sup> by diminishing detailing, the state hoped to “improv[e] public health and reduc[e] healthcare costs.”<sup>145</sup> Academic researchers and nonprofit groups that engaged in “counter-detailing” were exempted from the law because they did not pose these same problems.<sup>146</sup>

The majority, however, saw this disparity not as a response to a marketplace structured by forces that give profit-seeking actors particular incentives and advantages. Rather, they described the state as interfering in a marketplace that was by definition a space of neutrality, and doing so with a discriminatory purpose: the “disfavor[ing] of specific speakers, namely pharmaceutical marketers.”<sup>147</sup> The state here appears not as the representative of public will but as a coercive monopolist, seeking to “burden the speech of others in order to tilt public debate in a preferred direction.”<sup>148</sup>

The embrace of a market-supremacist logic that chooses markets over majorities is now complete. It is a *market* here—in the exchange of data—that is being protected; no one is speaking to the public. Gone is the logic in *Virginia Pharmacy* that tethered commercial speech protection to the value of democratic politics by linking the exchange of information in the marketplace to the “formation of intelligent opinions.”<sup>149</sup> The First Amendment’s role here is to protect markets from the public. Protecting markets, in turn, requires that we integrate institutions governed at least in part on a different logic—here, the doctor’s office—ever more fully to logic of the marketplace.

*Sorrell* was a triumph for the brand of neoliberal thought that seeks to shield market actors and structures from democratic power. And, as

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140. *Id.* at 589–91.

141. See *id.* at 564–65 (majority opinion).

142. *Id.* at 557.

143. See *id.* at 572, 575.

144. *Id.* at 560–61, 580.

145. *Id.* at 572.

146. *Id.* at 559–60.

147. *Id.* at 564.

148. *Id.* at 578–79.

149. *Va. State Bd. of Pharmacy v. Va. Citizens Consumer Council, Inc.*, 425 U.S. 748, 765 (1976).

the dissenters predicted, cases like *Caronia* and *Nicopure* have inevitably followed. What can be done in response?

### III. TOWARD A MORE EQUAL AND DEMOCRATIC POLITICAL ECONOMY OF COMMERCIAL SPEECH

#### A. *Modern Commercial Speech Law Permits Information-Forcing and Prior Restraints*

A better approach to cases like *Caronia* and *Nicopure* is possible, even inside of the four corners of First Amendment doctrine as we know it today. *Sorrell* invited, but did not demand, heightened constitutional protection for content- or speaker-based commercial speech. Its holding turned on an application of *Central Hudson*,<sup>150</sup> and a decisive return to the *Central Hudson* approach would lead courts to uphold the regulatory structures at stake in both *Caronia* and *Nicopure*. As *Central Hudson* makes clear, commercial speech is protected because it serves an “informational function” for listeners.<sup>151</sup> The FDA’s substantiation requirements for both pharmaceuticals and tobacco are designed to protect the public by *informing* it: Companies are permitted to market if they produce evidence. There is nothing discriminatory, moreover, about applying the schemes to companies but not to doctors or other third parties. It is logical, and well within the government’s prerogative, to determine that companies are better situated to produce the knowledge in question.<sup>152</sup> The FDA’s regulatory approaches to medicines and tobacco, as described earlier, can be understood as informing consumers, and so are in no real tension with modern commercial speech law.

Particularly when dangerous products are concerned, there also should be—and always has been—room for prior restraints against commercial speech.<sup>153</sup> There is also room, and precedent, for judicial humility about courts’ scientific capacities.<sup>154</sup> Such humility should lead judges away from interpretations of constitutional doctrine that require them to

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150. See *Sorrell*, 564 U.S. at 571–72.

151. *Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm’n*, 447 U.S. 557, 563 (1980); see also Robert Post, *The Constitutional Status of Commercial Speech*, 48 *UCLA L. Rev.* 1, 11–15 (2000) (discussing the informational role of commercial speech protection and noting its “audience oriented” nature).

152. See Kapczynski, *Fishy Business*, *supra* note 51, at 295–96 (making these points and showing their relevance to *Central Hudson*).

153. See, e.g., Brief of Amici Curiae First Amendment Scholars in Support of Appellee at 4–8, *Nicopure II*, No. 17-5196 (D.C. Cir. filed May 9, 2018) (providing support for the argument that prior restraints have always been acceptable where commercial speech is concerned).

154. See, e.g., *Nat. Res. Def. Council v. EPA*, 824 F.2d 1211, 1216 (D.C. Cir. 1987) (noting that it is generally “not for the judicial branch to undertake comparative evaluations of conflicting scientific evidence”).

play the role of expert regulator.<sup>155</sup> Finally, because the FDA's approaches to pharmaceutical and tobacco regulation aim centrally at the regulation of material commodities, they can be construed as not implicating commercial speech at all but merely using speech to establish the requisite intent, that of violating federal law by selling an unapproved substance.<sup>156</sup>

A more democratic First Amendment, and one still recognizable in current doctrine, would also admit that history and experience can help us distinguish between settings in which governments are likely to abuse their powers and settings in which governments are likely to be necessary to give effect to collective judgments about how we wish to live and order our values. Historical experience and empirical evidence can and should inform courts' understandings of the markets and regulators in question. Where evidence shows—as in the examples of drug detailing and evidence production about medicines and tobacco—that markets exhibit patterned forms of power and disempowerment, First Amendment analysis can and should take this into account. The question, as Professor Purdy puts it, is “what kind of interaction a democratic republic should build between economic and political power, and for what reasons.”<sup>157</sup> The answers are necessarily particular and derived from experience, rather than abstract and rooted in ungrounded assertions of market neutrality.

#### B. *Rebuilding Public Infrastructure*

What, however, if the courts continue down their current path? The question brings us beyond doctrine to what we, at the Symposium, began to call questions of “infrastructure.”<sup>158</sup> In a democracy, our shared infrastructure must respond to public needs and priority setting. The odd thing about applying this insight in this context is that, because the First Amendment has wandered so far, the infrastructure we must consider—infrastructure for health research—has little obvious connection to the First Amendment. But if courts take from the public the regulatory sticks needed to incentivize information production by private market actors, we will have little choice but to reassess our infrastructure for health

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155. See Kapczynski, *Fishy Business*, supra note 51, at 295 (describing how courts must stand in for FDA regulators under the approach taken in *Amarin*).

156. See *Whitaker v. Thompson*, 353 F.3d 947, 953 (D.C. Cir. 2004) (relying on this argument to uphold FDA's authority over unapproved medicines); see also Kapczynski, *Fishy Business*, supra note 51, at 295 (explaining how the logic of *Whitaker* applies in the off-label context).

157. Purdy, *Beyond the Bosses' Constitution*, supra note 12, at 2163.

158. Infrastructure, conventionally understood, constitutes the basic facilities that are needed for democratic life and to meet public needs. Speech, like travel, requires infrastructure—inputs to many different outputs, developed with a view of what we all require to collectively govern our democracy and lives. For a similar definition of infrastructure, see Brett M. Frischmann, *Infrastructure: The Social Value of Shared Resources* 61 (2012).

research and insist on a much more substantial role for public funding and public priority setting.

The model of information production that the FDA currently facilitates allocates enormous responsibility to the private sector. Private companies are expected to conduct the studies that inform us whether their products work. This system was never ideal: It generates serious conflicts of interest and works against transparent access to information.<sup>159</sup> Relying on private sector research also has broader implications for the price and nature of the products that are developed.<sup>160</sup> Investing more in public funding for research could redress these problems and also serve to make health research more egalitarian.<sup>161</sup>

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159. See Kapczynski, *Dangerous Times*, supra note 53, at 2363–65, 2371–72 (discussing companies’ “high powered incentives” to avoid negative information and the “awkward fit” between transparency and the profit-motivated system for evidence development).

160. High-quality scientific research is expensive, particularly for products like pharmaceuticals, and patent law and other exclusive rights have been expanded over the decades to permit industry actors to recoup these costs. See Amy Kapczynski & Talha Syed, *The Continuum of Excludability and the Limits of Patents*, 122 *Yale L.J.* 1900, 1904 (2013). But that has generated market power that has led to astronomical price increases. As I’ve shown in previous work with Professor Talha Syed, relying on exclusive rights to incentivize research also distorts research, because not all kinds of innovations are similarly susceptible to exclusion. See *id.* at 1916–21. Even under the most expansive possible patent law, for example, patents on tangible goods like medicines will be far easier to exclude than patents on talking cures, exercise regimes, or natural substances. See *id.* at 1935–37. And the profit motive will not incentivize the production of information that makes a product look bad—meaning that markets under conditions of exclusive rights are likely to produce systematically biased information. See *id.* at 1925–26. Regulation can correct for this, but likely not perfectly. Finally, market driven R&D systems prioritize according to not just willingness but ability to pay and so will tend to benefit those with more resources. See Amy Kapczynski, *The Cost of Price: Why and How to Get Beyond Intellectual Property Internalism*, 59 *UCLA L. Rev.* 970, 999–1000 (2012). Profit-driven R&D systems, for example, will neglect medicines needed predominantly by the poor (such as treatments for tropical diseases). Assuming risk aversion and discounting, profit-maximizers will also neglect interventions for high-risk but low-probability events like influenza pandemics. See Amy Kapczynski, *Order Without Intellectual Property Law: Open Science in Influenza*, 102 *Cornell L. Rev.* 1539, 1559–60 (2017) [hereinafter Kapczynski, *Order Without Intellectual Property Law*].

161. There are many ways to do this, from direct and mediated government funding for research to prizes or other financial rewards that work in a more decentralized fashion. For discussions of alternatives to the patent system, see generally Dean Baker, *Ctr. for Econ. & Policy Research*, *Financing Drug Research: What Are the Issues?* (2004), [http://www.cepr.net/documents/publications/intellectual\\_property\\_2004\\_09.pdf](http://www.cepr.net/documents/publications/intellectual_property_2004_09.pdf) [<https://perma.cc/8KCY-9DUR>]; James Love & Tim Hubbard, *Prizes for Innovation of New Medicines and Vaccines*, 18 *Annals Health L.* 155 (2009). There are many kinds of research—epidemiological work, basic science R&D, and drug development for neglected diseases, for example—that have never been well-rewarded in markets and that have long been conducted, if at all, via government funding. See generally Kapczynski, *Order Without Intellectual Property Law*, supra note 160, at 1558–61 (summarizing the literature showing that markets will neglect such research, and offering examples of government conducting it instead, in the field of influenza).

Publicly funding research could also mitigate the damage done if courts undermine the regulatory “stick” that the FDA has used to date to encourage balanced evidence production by marketers.<sup>162</sup> If, for example, the FDA cannot require companies to provide evidence before marketing drugs off-label, then the public can fund research to determine whether off-label uses are warranted—and pay for this research via the cost-savings that will result from more appropriate prescribing.

This is an example, in the end, of a broader point. As the First Amendment emerges as a tool to insulate free market actors from regulation, it will increase the stakes of a turn to the public. Just as the judicial attack on the ACA has fueled calls for Medicare for all,<sup>163</sup> attacks on the state’s power to regulate the market may, and should, fuel demands for a more robust public role and less reliance on increasingly ungovernable private actors.

### C. *Reconsidering Commercial Speech Protection*

Finally, considering the political economy of commercial free speech law should also lead us to revisit the proper justification for constitutional protection for commercial speech, and so the proper scope of that protection. Courts have come startlingly close, in recent cases, to declaring the purpose of commercial speech protection to be the enforcement of ideals christened in *Mont Pèlerin* and further developed in Chicago and Virginia—most prominently, the notion that markets are free by definition, and that the freedom that the First Amendment commits us to is the freedom *of markets* to be protected from popular political will. The First Amendment has long been understood as centrally aimed at protecting “free political discussion to the end that government may be responsive to the will of the people.”<sup>164</sup> The view that it commits us to free market supremacy has no serious constitutional argument in its favor and subverts a keystone of genuine democracy: the power of majorities to determine when and how to embed markets in public values.

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162. See generally Ian Ayres & Amy Kapczynski, *Innovation Sticks: The Limited Case for Penalizing Failures to Innovate*, 82 U. Chi. L. Rev. 1781 (2015) (introducing the idea of innovation “sticks” and discussing the role of penalties in inducing innovation and the production of new information).

163. See Paul Waldman, *The Next Big Thing for Democrats: Medicare For All*, Wash. Post (Apr. 19, 2018), <https://www.washingtonpost.com/blogs/plum-line/wp/2018/04/19/the-next-big-thing-for-democrats-medicare-for-all/> [<https://perma.cc/LX9M-XGXV>]. A direct expansion of public insurance would, of course, sidestep both the Spending Clause and Commerce Clause challenges raised in *National Federation of Independent Business v. Sebelius*, because Congress would not be regulating private actors or conditioning spending. See generally 567 U.S. 519 (2012).

164. *Stromberg v. California*, 283 U.S. 359, 369 (1931).

## CONCLUSION

Fundamentally, *we* govern markets; we are governed *by* democratic politics.<sup>165</sup> This is a distinction that must have constitutional salience, or we will lose our democracy to the antidemocratic imperatives of laissez faire. Any protections for commercial speech must serve rather than subvert our democracy. For this view to prevail in the Courts, progressives must, of course, accumulate the political power to shape appointments, and the intellectual and political power to build a discursive alternative to market-supremacist thought. The way will not be easy. But it is the only path to returning the First Amendment, that “guardian of our democracy,”<sup>166</sup> to the better things for which it, and we, were meant.

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165. A similar point is made by Professors Amanda Shanor and Robert Post:

When we engage in public discourse, the First Amendment accords us the privileges of “rulers” who exercise the prerogatives of self-determination. We are given the freedom and autonomy to speak as we will. But when we engage in commercial speech, we are not participating in democratic self-determination; we are instead transacting business in the marketplace. We are accordingly communicating as “subjects” who are “ruled.”

Post & Shanor, *supra* note 2, at 171–72.

166. *Brown v. Hartlage*, 456 U.S. 45, 60 (1982).