

# DOES THE U.S. CONSTITUTION CONSTRAIN STATE PRODUCTS LIABILITY DOCTRINE?

Lars Noah\*

## ABSTRACT

*The time may have come to extend the U.S. Supreme Court's drive to constitutionalize the domain of speech torts into the field of products liability. This Article considers a pointed way of testing the viability of such a move: decisions recognizing an exception to the learned intermediary doctrine whenever manufacturers of prescription drugs or medical devices advertise directly to consumers, which seems to represent a fairly blatant violation of federal constitutional protections for commercial speech. Venturing into far more debatable territory, this Article then suggests that certain consumer goods closely connected to the exercise of fundamental rights—including but not limited to contraceptives—might deserve additional protection from the operation of well-established principles of strict products liability. If, however, that comes across as too radical an idea, then perhaps the longstanding constitutionalization of speech torts must remain distinctive, which also means that developments in the law of defamation can offer little assistance to those commentators who promote the notion that the Second Amendment should infiltrate the law of torts.*

## TABLE OF CONTENTS

INTRODUCTION.....	190
I.THE CURIOUS CASE OF PRESCRIPTION DRUG ADVERTISING TO CONSUMERS .....	194
A. <i>The U.S. Supreme Court Invalidates Restrictions on Such Advertising</i> .....	194
B. <i>State Courts Consider an Exception to the Learned Intermediary Doctrine</i> .....	200
C. <i>The Unappreciated Constitutional Flaws in This Doctrinal Modification</i> .....	206
II.THE NEXT STEP: SPECIAL IMMUNITIES FOR CONSTITUTIONALLY SACROSANCT PRODUCTS? .....	214
CONCLUSION .....	224

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\* Chesterfield Smith Eminent Scholar and Professor of Law, University of Florida; author, *Law, Medicine, and Medical Technology* (Foundation Press 4th ed. 2017).

## INTRODUCTION

A couple of years ago, a newcomer to the academy offered the startling claim that the Second Amendment's right to keep and bear arms might limit the reach of products liability doctrine against gun manufacturers.<sup>1</sup> For a variety of reasons, this provocative idea probably will never get put to the test, which makes it little more than an empty gesture: notwithstanding scholarly endorsement of novel claims against the industry,<sup>2</sup> the long history of failed litigation demonstrates that gun sellers routinely get away with murder without having to invoke the newfound constitutional rights of their purchasers to possess weapons.<sup>3</sup> On those rare occasions when a court adopted a novel theory of expansive gun manufacturer liability, the state's legislature acted quickly to shoot down the idea.<sup>4</sup> What, however, about the more general suggestion that the U.S. Constitution might impact the availability of products liability claims against the sellers of consumer goods?

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1. See Cody J. Jacobs, *The Second Amendment and Private Law*, 90 S. CAL. L. REV. 945, 986–89 (2017) (paying far more attention, however, to the nuances of how courts recently have interpreted the Second Amendment than to the variety of ways that products liability doctrine might burden the newly construed right to bear arms); see also *id.* at 982–86, 989–94 (making similar arguments in connection with other forms of tort liability related to the use of firearms). Actually, in an essay that Mr. Jacobs failed to reference (even while citing a different piece from that same symposium issue, see *id.* at 992 n.267), a seasoned torts scholar had floated essentially the same idea seventeen years earlier, before the Supreme Court uncovered a personal right to possess weapons. See Jerry J. Phillips, *The Relation of Constitutional and Tort Law to Gun Injuries and Deaths in the United States*, 32 CONN. L. REV. 1337, 1344, 1347 (2000).

2. See, e.g., Jean Macchiaroli Eggen & John G. Culhane, *Gun Torts: Defining a Cause of Action for Victims in Suits Against Gun Manufacturers*, 81 N.C. L. REV. 115, 176–210 (2002). See generally *SUING THE GUN INDUSTRY: A BATTLE AT THE CROSSROADS OF GUN CONTROL AND MASS TORTS* (Timothy D. Lyton ed., 2005).

3. See, e.g., *Hamilton v. Beretta U.S.A. Corp.*, 750 N.E.2d 1055, 1061–68 (N.Y. 2001); see also Patrick Luff, *Regulating Firearms Through Litigation*, 46 CONN. L. REV. 1581, 1583 (2014) (“[F]or now, at least, the use of litigation as a means of regulating these [social] costs has stalled.”); Lars Noah, *Platitudes About “Product Stewardship” in Torts: Continuing Drug Research and Education*, 15 MICH. TELECOMM. & TECH. L. REV. 359, 387 (2009) (referencing “novel (and largely unsuccessful) theories asserted against gun sellers”); cf. Andrew Jay McClurg, *The Second Amendment Right to Be Negligent*, 68 FLA. L. REV. 1, 4–10, 45–47 (2016) (asserting that owners and sellers of handguns already largely enjoy immunity from tort liability, with common law and statutory rules evidently influenced by the federal constitutional right to bear arms, and criticizing this situation); *id.* at 3 (arguing that “the United States has enshrined a de facto Second Amendment right to be negligent regarding many aspects of making, distributing, and possessing firearms”); *id.* at 29 (noting “the unstated infiltration of the Second Amendment in this area”).

4. See, e.g., *Kelley v. R.G. Indus., Inc.*, 497 A.2d 1143, 1159–62 (Md. 1985), *superseded by statute*, MD. CODE ANN. PUB. SAFETY § 5-402(b) (West 2018), *as recognized in* *Halliday v. Sturm, Ruger & Co.*, 792 A.2d 1145, 1156 (Md. 2002); see also Carl T. Bogus, *Pistols, Politics and Products Liability*, 59 U. CIN. L. REV. 1103, 1147–48 (1991) (discussing this legislative override); Elizabeth T. Crouse, Note, *Arming the Gun Industry: A Critique of Proposed Legislation Shielding the Gun Industry from Liability*, 88 MINN. L. REV. 1346, 1357–59 (2004) (summarizing several other state statutes); *infra* note 140 (noting more recent intervention by Congress); cf. *Ileto v. Glock Inc.*, 349 F.3d 1191, 1202 n.12 (9th Cir. 2003) (noting the repeal of a California statute that had barred certain claims against manufacturers); *Soto v. Bushmaster Firearms Int’l, LLC*, 202 A.3d 262, 325 (Conn. 2019) (allowing only unfair trade practice claims based on allegedly unlawful marketing of the assault rifle used in the Sandy Hook Elementary mass shooting).

Until the mid-twentieth century, tort litigation operated in a domain largely unaffected by federal constitutional law.<sup>5</sup> Now classic decisions of the U.S. Supreme Court gradually eroded this separation: more than half a century ago, protections for free speech began to intrude on the common law standards for defamation and related claims;<sup>6</sup> more than a quarter of a century ago, the Supremacy Clause began serving as the foundation for a defense of federal preemption against a range of tort claims;<sup>7</sup> and almost that much time has elapsed since the Court began using the Due Process Clause to rein in what it viewed as excessive punitive damage awards.<sup>8</sup> Do these decisions amount to narrowly confined intrusions,<sup>9</sup> or do they instead reflect part of a broader assault on state laws governing liability for injurious conduct?<sup>10</sup>

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5. Cf. John Fabian Witt, *The Long History of State Constitutions and American Tort Law*, 36 RUTGERS L.J. 1159, 1162 (2005) (“The current generation of state constitutional decisions reviewing tort reform legislation is merely the latest incarnation of what has been almost one and a half centuries of interaction between American constitutions at the state and *sometimes federal* levels, on one hand, and the law of torts, on the other.” (emphasis added)). For instance, more than a century ago, the U.S. Supreme Court rejected objections based on the Takings Clause to state statutes making railroads strictly liable when sparks from their locomotives triggered fires. *See id.* at 1174–75 (discussing *St. Louis & S.F. Ry. v. Mathews*, 165 U.S. 1 (1897)); *see also id.* at 1197 (“Perhaps courts ought to police a version of the constitutional causation requirement laid down in the railroad liability cases of the late nineteenth-century to ensure that [the expansion of] tort law does not impinge on constitutional takings limits.”).

6. *See, e.g.*, *N.Y. Times Co. v. Sullivan*, 376 U.S. 254, 264–65, 277–88, 292 (1964); *see also Masson v. New Yorker Magazine, Inc.*, 501 U.S. 496, 510 (1991) (“The First Amendment limits California’s libel law in various respects.”); David A. Anderson, *First Amendment Limitations on Tort Law*, 69 BROOK. L. REV. 755, 776 (2004) (explaining that “after twenty-five years and twenty-seven Supreme Court decisions, defamation law was effectively disabled, at least in the sphere of public affairs”); *id.* at 787–88 (summarizing these decisions); *id.* at 758 (“The constitutional limitations on defamation are so entrenched that it is hard to imagine the Court abandoning them.”); *infra* notes 106–114, 126–130 and accompanying text (elaborating on these decisions).

7. *See, e.g.*, *CSX Transp., Inc. v. Easterwood*, 507 U.S. 658, 664, 675 (1993); *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 518–30 (1992) (plurality opinion); *id.* at 544–46 (Scalia, J., concurring in part and dissenting in part); *see also* Lars Noah, *Reconceptualizing Federal Preemption of Tort Claims as the Government Standards Defense*, 37 WM. & MARY L. REV. 903, 904–25, 968–70, 978 (1996) (explaining that, before 1992, the Court consistently had rejected the notion that preemption would operate to limit liability); *infra* notes 12, 129, 177 (discussing some of the latest decisions).

8. *See, e.g.*, *Honda Motor Co. v. Oberg*, 512 U.S. 415, 420 (1994) (“Our recent cases have recognized that the Constitution imposes a substantive limit on the size of punitive damages awards.”); *id.* at 432 (invalidating an award on procedural due process grounds because the defendants could not challenge it as excessive on appeal).

9. In writing for a recent symposium, one commentator dismissed this snapshot of the Court’s handiwork as relatively inconsequential. *See* Thomas B. Colby, *The Constitutionalization of Torts?*, 65 DEPAUL L. REV. 357, 358 n.7 (2016) (“[The defamation cases] represent a much more narrow phenomenon: the imposition of constitutional limits on the substantive content of a particular branch of tort law, in the name of a particular substantive constitutional right.”); *id.* at 358 (“[E]xisting constitutional doctrine provides ample opportunities for the U.S. Supreme Court to make massive forays into the traditional territory of state tort law—virtually all of them through the operation of the Due Process Clause of the Fourteenth Amendment. . . . [But] the degree of constitutionalization of tort law generally is far short of what it could be . . . . Indeed, outside of the punitive damages arena, the Court has barely constitutionalized tort law at all.”); *id.* at 380 (“[T]he Court has taken virtually no steps to constitutionalize tort law beyond the realm of punitive damages—despite the ample opportunities and clearly illuminated doctrinal avenues to do so.”).

10. In a different contribution to that same recent symposium, a pair of commentators made rather more of both the defamation and preemption decisions (and less of the punitive damage cases). *See* John C.P. Goldberg & Benjamin C. Zipursky, *The Supreme Court’s Stealth Return to the Common Law of Torts*, 65 DEPAUL L. REV. 433, 437–43 (2016) (discussing defamation); *id.* at 444–55 (discussing preemption); *id.* at 436 & n.20, 443

Rather than plow that same ground and engage in debates about whether the U.S. Supreme Court has—or should have—involved itself in those particular subjects, this Article asks to what extent the Constitution might limit the substance of tort law in the heavily litigated context of defective products. If my titular question asked instead whether federal constitutional principles have constrained defamation doctrine, then the answer speaks for itself.<sup>11</sup> Moreover, if the question focused on the impact of the Supremacy Clause on products liability doctrine, then little doubt remains that federal preemption has become a central feature of such litigation even though the precise scope of this defense remains hotly contested.<sup>12</sup> Constitutional principles also have impacted collateral issues that may arise in tort litigation,<sup>13</sup> most notably the U.S. Supreme Court's growing willingness to deploy the Due Process Clause in order to regulate punitive damage awards.<sup>14</sup> Fears that vague jury instructions would invite arbitrary deprivations

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(noting the punitive damage decisions); *see also id.* at 435 (“[B]y the mid-1960s, the Court was actively making tort law, both directly and indirectly. In American tort law today, the Supreme Court is a major player.”); *id.* at 442 (“Regardless of whether the Supreme Court was correct to extend *Sullivan* as far as it did, . . . [i]t stands as an extraordinary example of how, notwithstanding *Erie* [*Railroad Co. v. Tompkins*, 304 U.S. 64 (1938)], the Court can become so deeply involved in tort cases that constitutional law displaces tort law.”); *id.* at 443 (anticipating and responding to objections that “[o]ur expressions of concern regarding the degree to which the Court has meddled with defamation law might seem overblown”).

11. *See infra* notes 106–114, 126–130 and accompanying text.

12. *See, e.g.*, *Merck Sharp & Dohme Corp. v. Albrecht*, 139 S. Ct. 1668, 1679–80 (2019); *Mut. Pharm. Co. v. Bartlett*, 570 U.S. 472, 490–93 (2013); *Kurns v. R.R. Friction Prods. Corp.*, 565 U.S. 625, 633–38 (2012); *see also* Mary J. Davis, *On Restating Products Liability Preemption*, 74 *BROOK. L. REV.* 759, 762 (2009) (criticizing “the current trend in preemption doctrine, toward increased preemption of state common law personal injury actions”); Goldberg & Zipursky, *supra* note 10, at 437 (referring to “the Court’s burgeoning preemption decisions, which, given their massive curtailment of liability for product-related injuries, raise particularly urgent issues of legitimacy”); *id.* at 448 (“*Cipollone* marked the first small step in what has since become an elaborate and, indeed, transformative use by the Court of the doctrine of federal preemption.”).

13. For instance, the Equal Protection Clause has begun to make a bit of headway against the tradition of calculating damages for lost earnings capacity on the basis of actuarial tables and labor statistics that differentiate by sex, race, and ethnicity. *See, e.g.*, *G.M.M. ex rel. Hernandez-Adams v. Kimpson*, 116 F. Supp. 3d 126, 152–54 (E.D.N.Y. 2015) (finding merit in equal protection and due process objections). *See generally* Kimberly A. Yuracko & Ronen Avraham, *Valuing Black Lives: A Constitutional Challenge to the Use of Race-Based Tables in Calculating Tort Damages*, 106 *CALIF. L. REV.* 325 (2018) (developing the equal protection arguments more fully). In contrast, the Free Exercise Clause has not helped tort victims escape the operation of the avoidable consequences rule. *See, e.g.*, *Munn v. Algee*, 924 F.2d 568, 573–75 (5th Cir. 1991) (holding that the victim had a duty to mitigate by accepting a blood transfusion even if, as a Jehovah’s Witness, she had a religious objection); *see also* *Shorter v. Drury*, 695 P.2d 116, 121–24 (Wash. 1985) (holding that a patient assumed the risk of death when she underwent a dilation and curettage procedure but, after internal bleeding occurred, refused to allow a blood transfusion on religious grounds); *cf.* Anne C. Loomis, Comment, *Thou Shalt Take Thy Victim as Thou Findest Him: Religious Conviction as a Pre-Existing State Not Subject to the Avoidable Consequences Doctrine*, 14 *GEO. MASON L. REV.* 473, 493–511 (2007) (criticizing this position).

14. *See, e.g.*, *Philip Morris USA v. Williams*, 549 U.S. 346, 353 (2007) (holding that procedural due process “forbids a State to use a punitive damages award to punish a defendant for injury that it inflicts upon nonparties”); *State Farm Mut. Auto. Ins. Co. v. Campbell*, 538 U.S. 408, 418–29 (2003) (invalidating an award as grossly excessive); *see also* Laura J. Hines & N. William Hines, *Constitutional Constraints on Punitive Damages: Clarity, Consistency, and the Outlier Dilemma*, 66 *HASTINGS L.J.* 1257, 1258–73 (2015) (summarizing the Supreme Court’s evolving approach); *id.* at 1315 (“One of the most fundamental areas of confusion among lower courts stems from the Court’s failure to explain how each guidepost interacts with the others.”); Benjamin J. McMichael & W. Kip Viscusi, *Taming Blockbuster Punitive Damages Awards*, 2019 *U. ILL. L. REV.* 171, 180–84, 206–18 (arguing that current constitutional limits fail to go far enough).

of property and violate rights of fair notice hardly represent features peculiar to punitive damages, however, which raises the possibility that due process might well constrain other central aspects of tort litigation such as the lack of any meaningful standards for awarding noneconomic damages.<sup>15</sup>

What about constitutional principles other than the unadorned form of due process and operating in domains beyond the law of defamation—might they also limit the substantive reach of state tort law? Lawsuits against gun manufacturers do not provide a good test for a pair of reasons: the relatively recent interpretation of the Second Amendment remains in a state of flux,<sup>16</sup> and the tort claims asserted in such cases often depend on fairly novel theories of liability that have not fared well.<sup>17</sup> This Article therefore examines the larger question in connection with more firmly established constitutional principles and products liability doctrines.

Twenty years ago, for instance, the New Jersey Supreme Court held that the “learned intermediary” doctrine, which limits the duty to warn when selling prescription drugs and devices, did not apply whenever manufacturers had engaged in direct-to-consumer advertising (DTCA). In *Perez v. Wyeth Laboratories Inc.*,<sup>18</sup> that court allowed patients alleging injuries from a long-acting contraceptive to pursue strict liability claims premised on the manufacturer’s failure to communicate any warnings

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15. See Colby, *supra* note 9, at 364–70; Lars Noah, *Comfortably Numb: Medicalizing (and Mitigating) Pain-and-Suffering Damages*, 42 U. MICH. J.L. REFORM 431, 442 & n.44 (2009); see also Mark Geistfeld, *Constitutional Tort Reform*, 38 LOY. L.A. L. REV. 1093, 1103–11 (2005) (pointing out that jury determinations about what constitutes reasonable care and the duty analysis undertaken by judges also suffer from similar unpredictability and may pose due process problems); *id.* at 1112 (“The constitutional concerns the Court has relied upon to justify due process constraints on punitive damages also justify constraining other areas of tort law . . . .”); *id.* at 1119 (“These rules [defining defective designs and warnings] govern the conduct of manufacturers in national product markets, and the vagueness and variability in the rules raise due process concerns that are not qualitatively different from those posed by punitive damages.”). Professor Geistfeld conceded that these relatively indeterminate standards would not ultimately fail a due process calculus; instead, he thought that extending such constitutional scrutiny would “serve the valuable role of forcing state courts and legislatures to identify more clearly the substantive objectives of tort liability.” *Id.* at 1115. As argued below, however, excessive judicial candor might imperil doctrinal choices for entirely different reasons. See *infra* notes 85, 125, 178 and accompanying text.

16. See *McDonald v. City of Chi.*, 561 U.S. 742, 791 (2010) (plurality opinion) (incorporating against the states the newly recognized constitutional limits on federal gun control measures based on an individual’s right to keep and bear arms for self-defense); *District of Columbia v. Heller*, 554 U.S. 570, 635 (2008) (striking down restrictions on handguns in Washington, D.C.); *N.Y. State Rifle & Pistol Ass’n v. City of New York*, 883 F.3d 45, 57–64 (2d Cir. 2018) (upholding a restriction on transporting handguns out of the city), *cert. granted*, 139 S. Ct. 939 (2019); see also Joseph Blocher & Darrell A.H. Miller, *What Is Gun Control? Direct Burdens, Incidental Burdens, and the Boundaries of the Second Amendment*, 83 U. CHI. L. REV. 295, 354 (2016) (“*Heller* and *McDonald* represent a bookend to the first generation of Second Amendment theorizing . . . .”); *id.* at 330 (“[A]s of yet, courts have identified few tools to determine when *incidental* burdens raise Second Amendment concerns.”); *id.* at 303–23 (asking whether generally applicable (i.e., “gun-neutral”) laws, including various potential tort claims against owners of weapons, might impermissibly burden this constitutional right); *cf. id.* at 301 n.33 (explaining that the recent recognition of an individual right to bear arms in the Second Amendment provides a “particularly useful object of study” precisely because it remains a “nascent doctrine”); *id.* at 324 (“[I]n part because it is so new, . . . the right to keep and bear arms presents a unique opportunity to explore these broad constitutional issues.”).

17. See *supra* notes 3–4 and accompanying text.

18. 734 A.2d 1245 (N.J. 1999).

directly to the recipients of this implanted product.<sup>19</sup> Although the decision attracted significant attention from courts and commentators,<sup>20</sup> essentially no one has ever suggested that the rule announced by the *Perez* court might run afoul of the U.S. Constitution. Section I of this Article develops just such an argument and concludes that it has genuine merit.

In Section II, this Article goes a step further and asks whether the sellers of certain products such as contraceptives might have grounds for immunity from some or all strict liability claims by virtue of their special constitutional status. If the First Amendment requires tolerating some defamatory falsehoods in order to avoid chilling valuable speech, then other fundamental rights might require tolerating the sale of certain injurious products lest manufacturers become spooked about supplying even nondefective versions that individuals have a right to use. If that argument seems far too radical, however, then gun sellers should fare no better in seeking to avoid tort law's reach.

### I. THE CURIOUS CASE OF PRESCRIPTION DRUG ADVERTISING TO CONSUMERS

As promotional efforts for prescription drugs, which historically targeted only physicians, increasingly sought to influence potential patients, the courts began to confront associated questions of both constitutional law and products liability doctrine. The parallel decisions in these separate legal domains have not yet, however, intersected with one another. After first summarizing the most pertinent First Amendment decisions of the U.S. Supreme Court and then discussing the different approaches of various state supreme courts when asked to modify tort law in light of the change in the pharmaceutical industry's marketing practices, this Section undertakes precisely such a synthesis. New Jersey's decision to deprive manufacturers of significant limitations on their liability solely because they have exercised their rights to engage in commercial speech strikes me as plainly unconstitutional, and the fact that this penalty originated with the state's high court rather than its legislature should make no difference. Whether this suggests a broader lesson must await Section II.

#### A. *The U.S. Supreme Court Invalidates Restrictions on Such Advertising*

Since the mid-1970s, the Supreme Court has recognized that advertising enjoys some of the First Amendment's guarantees for freedom of expression. In *Virginia State Board of Pharmacy v. Virginia Citizens Consumer Council, Inc.*,<sup>21</sup> the Court struck down one state's prohibition against the advertising of prescription drug prices. It decided that even speech merely proposing a transaction deserved some constitutional solicitude,

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19. See *id.* at 1255–57, 1263.

20. See, e.g., Aaron D. Twerski, *Liability for Direct Advertising of Drugs to Consumers: An Idea Whose Time Has Not Come*, 33 HOFSTRA L. REV. 1149, 1150–51 (2005) (explaining that *Perez* seemed destined to become a landmark decision but, at least initially, failed to attract any imitators); see also *infra* notes 116–119 and accompanying text.

21. 425 U.S. 748 (1976); see also *Carey v. Population Servs. Int'l*, 431 U.S. 678, 700 (1977) (invalidating a state prohibition on advertising nonprescription contraceptives); *Bigelow v. Virginia*, 421 U.S. 809, 826 (1975) (invalidating a prohibition on newspaper advertisements by out-of-state abortion providers, noting that the “relationship of speech to the marketplace of products or of services does not make it valueless in the marketplace of ideas”).

explaining that the public's interest in the free flow of commercial information might be "as keen, if not keener by far" than its interest in political debate.<sup>22</sup> The lone dissenter forecasted with alarm that the majority's approach would prevent the government from prohibiting prescription drug advertising directed to consumers,<sup>23</sup> a promotional technique that would not become commonplace until two decades later.<sup>24</sup>

In *Virginia State Board*, the majority recognized that the "durab[ility]" and "hardiness" of commercial speech reduce the risk that regulation might chill it.<sup>25</sup> Coupled with the assumption that the disseminators of such expression could better verify its truthfulness, these attributes may "make it appropriate to require that a commercial message appear in such a form, or include such additional information, warnings, and disclaimers, as are necessary to prevent its being deceptive."<sup>26</sup> The Court expressed suspicion, however, about government efforts to achieve collateral goals through the suppression of truthful and nonmisleading information: "[T]he State's protectiveness of its citizens rests in large measure on the advantages of their being kept in ignorance."<sup>27</sup> As the Court has made clear in the decades since it initially extended the First Amendment to commercial speech, the government generally may not bar truthful and nondeceptive claims in pursuit of ends other than protecting consumers from potentially false or misleading information.<sup>28</sup>

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22. *Va. State Bd.*, 425 U.S. at 763; *see also id.* at 763–64 ("When drug prices vary as strikingly as they do, information as to who is charging what becomes more than a convenience. It could mean the alleviation of physical pain or the enjoyment of basic necessities."); Katie Thomas, *What Does a Drug Cost? It Depends on Where You Live*, SAN DIEGO UNION-TRIB., July 7, 2018, at C2 ("[P]rice variation is not just city by city—even pharmacies on the same block can sell drugs at vastly different prices.").

23. *See Va. State Bd.*, 425 U.S. at 781, 788–89 (Rehnquist, J., dissenting).

24. *See* Lars Noah, *Advertising Prescription Drugs to Consumers: Assessing the Regulatory and Liability Issues*, 32 GA. L. REV. 141, 141–43 (1997); *see also* Lisa M. Schwartz & Steven Woloshin, *Medical Marketing in the United States, 1997–2016*, 321 JAMA 80, 82 (2019) (noting that DTCA for prescription drugs had increased to \$6 billion annually); *infra* notes 54–59 and accompanying text (discussing the constitutionality of proposals to restrict such advertising).

25. *See Va. State Bd.*, 425 U.S. at 772 n.24.

26. *Id.*; *cf.* Alex Kozinski & Stuart Banner, *Who's Afraid of Commercial Speech?*, 76 VA. L. REV. 627, 634–52 (1990) (disputing these grounds for distinguishing commercial speech). Nonetheless, the Court subsequently recognized that even disclosure requirements might impermissibly discourage the exercise of rights to engage in commercial speech. *See Zauderer v. Office of Disciplinary Counsel*, 471 U.S. 626, 651 (1985) ("[U]njustified or unduly burdensome disclosure requirements might offend the First Amendment by chilling protected commercial speech.").

27. *See Va. State Bd.*, 425 U.S. at 769; *id.* at 770 ("It is precisely this kind of choice, between the dangers of suppressing information, and the dangers of its misuse if it is freely available, that the First Amendment makes for us.").

28. *See* Lars Noah, *Truth or Consequences?: Commercial Free Speech vs. Public Health Promotion (at the FDA)*, 21 HEALTH MATRIX 31, 37–51 (2011); *id.* at 67 (explaining that the Court's latest guidance "leaves outright prohibitions designed to dampen demand (or to serve other collateral purposes) vulnerable to constitutional invalidation, while more limited restrictions or disclosure requirements designed to guard against potentially misleading promotional messages would seem to survive"); *id.* at 67–68 ("[T]he First Amendment allows the government to guard against the dissemination of false or deceptive commercial speech but not much else.").

In *Central Hudson Gas & Electric Corporation v. Public Service Commission*,<sup>29</sup> the Court devised a four-part test for assessing constitutional objections to restrictions on advertising:

For commercial speech to come within [the First Amendment], it at least must concern lawful activity and not be misleading. Next, we ask whether the asserted governmental interest is substantial. If both inquiries yield positive answers, we must determine whether the regulation directly advances the governmental interest asserted, and whether it is not more extensive than is necessary to serve that interest.<sup>30</sup>

In other words, assuming that the advertising does not relate to some unlawful activity and is not inherently misleading, the government may restrict commercial speech only to achieve a substantial interest, and then only to the extent necessary. Although its subsequent decisions have applied this form of intermediate scrutiny with varying degrees of stringency, and individual justices have called for its replacement, the Supreme Court continues to claim allegiance to the *Central Hudson* test.<sup>31</sup>

In 2002, in *Thompson v. Western States Medical Center*,<sup>32</sup> a bare majority of the Court invalidated a congressional prohibition on advertising by pharmacists about compounded drugs.<sup>33</sup> Compounding generally refers to the extemporaneous preparation of pharmaceutical products to meet the special needs of patients unable to tolerate commercially available formulations.<sup>34</sup> Pharmacists have long engaged in such ad hoc customization of mass-produced drugs, and, though it technically would run afoul of the requirement that the U.S. Food and Drug Administration (FDA) first issue a license for

29. 447 U.S. 557 (1980).

30. *Central Hudson*, 447 U.S. at 566; see also *Bd. of Trs. v. Fox*, 492 U.S. 469, 477 (1989) (explaining that the framework is “substantially similar” to the test for time, place, and manner restrictions on core speech).

31. See Noah, *supra* note 28, at 50 & n.83, 53 & n.103. In contrast, when it considered objections to state laws that barred prescription data mining when it helps pharmaceutical salespeople refine the pitches that they make to physicians, the Court appeared to take a distinctive approach that promised even greater protections for commercial speech. In *Sorrell v. IMS Health Inc.*, 564 U.S. 552 (2011), the Court invalidated Vermont’s law on First Amendment grounds, emphasizing that the state had imposed a restriction on the creation and dissemination of information based on its content and speaker without adequate justification: “The State seeks to achieve its policy objectives through the indirect means of restraining certain speech by certain speakers—that is, by diminishing detailers’ ability to influence prescription decisions.” *Id.* at 577; see also *id.* at 578–79 (“Vermont may be displeased that detailers who use prescriber-identifying information are effective in promoting [more expensive and allegedly less safe] brand-name drugs. . . . The State may not burden the speech of others in order to tilt public debate in a preferred direction.”); *id.* at 571 (“[T]he outcome is the same whether a special commercial speech inquiry or a stricter form of judicial scrutiny is applied.”); *id.* at 579 (“The State nowhere contends that detailing is false or misleading. . . . Nor does the State argue that the provision challenged here will prevent false or misleading speech.”). Three dissenters objected to the majority’s use of heightened scrutiny to assess legislation that only indirectly affected commercial speech, noting that the FDA and other agencies routinely impose content- and speaker-based restrictions. See *id.* at 588–90, 592, 598 (Breyer, J., dissenting); *id.* at 588 (“[N]either of these categories—‘content-based’ nor ‘speaker-based’—has ever before justified greater scrutiny when regulatory activity affects commercial speech.”). See generally Leslie Kendrick, *Content Discrimination Revisited*, 98 VA. L. REV. 231 (2012) (offering a good overview of this central free speech principle, though entirely ignoring *IMS Health*).

32. 535 U.S. 357 (2002).

33. See *W. States Med. Ctr.*, 535 U.S. at 359, 377.

34. See *id.* at 360–61; see also Lars Noah, *The Coming Pharmacogenomics Revolution: Tailoring Drugs to Fit Patients’ Genetic Profiles*, 43 JURIMETRICS J. 1, 19–20 (2002).



a new drug, the agency historically has left the matter to professional regulation at the state level.<sup>35</sup> When pharmacies exceed the contours of traditional compounding, however, and begin to engage in veiled commercialization of unapproved new drugs, the FDA has taken enforcement action.<sup>36</sup>

In the Food and Drug Administration Modernization Act of 1997 (FDAMA),<sup>37</sup> Congress included a special set of provisions designed to facilitate legitimate forms of compounding.<sup>38</sup> Pharmacists would not have to comply with new drug approval requirements so long as, *inter alia*, they did not advertise the fact that they compounded particular drug products. Evidently not satisfied with their broader legislative victory, which had required accepting some compromises, a group of pharmacists challenged the advertising restriction as inconsistent with the First Amendment.

The majority opinion in *Western States* purported to apply the *Central Hudson* test.<sup>39</sup> Although Justice O'Connor characterized the law as imposing a *prohibition* on a type of speech,<sup>40</sup> violations of the FDAMA provision would not have led to prosecution—instead, deviations from that provision would have removed its special exemption from new drug approval requirements, and pharmacists then would face the threat of prosecution only if they distributed drugs in violation of much older provisions in the FDA's enabling statute.<sup>41</sup> In other words, pharmacists were as free as anyone else to advertise the availability of particular drugs so long as they first satisfied product licensing requirements, and it is the failure to do the latter rather than the desire to do the former that would have triggered the risk of federal prosecution.<sup>42</sup> At most, the challenged law posed an unconstitutional conditions problem insofar as it had predicated

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35. See *W. States Med. Ctr.*, 535 U.S. at 362.

36. See, e.g., *United States v. Sene X Eleemosynary Corp.*, 479 F. Supp. 970, 978–79 (S.D. Fla. 1979) (rejecting “practice of pharmacy” defense to misbranding charges associated with large-scale compounding); see also *Prof'ls & Patients for Customized Care v. Shalala*, 56 F.3d 592, 599 (5th Cir. 1995) (rejecting a procedural challenge to the FDA's enforcement guideline). In 2012, patients around the country received injections of a contaminated steroid sold by the New England Compounding Center. See Michael Muskal, *14 Arrested in Meningitis Outbreak; They Face Charges in the Deaths of 64 People Who Received Tainted Drugs in 2012*, L.A. TIMES, Dec. 18, 2014, at A15; see also Andrew Pollack, *In the Alchemist's Lab*, N.Y. TIMES, Aug. 15, 2014, at B1 (reporting that some “contend that profiteering is at least part of the reason for the proliferation of compound medicines”). The incident prompted Congress to enact additional controls. See Drug Quality and Security Act, Pub. L. No. 113-54, tit. I, 127 Stat. 587, 587–98 (2013) (codified in scattered sections of 21 U.S.C.). See generally Joanna Shepherd, *Regulatory Gaps in Drug Compounding: Implications for Patient Safety, Innovation, and Fraud*, 68 DEPAUL L. REV. 385 (2019).

37. Pub. L. No. 105-115, § 127(a), 111 Stat. 2296, 2328 (codified at 21 U.S.C. § 353a (2018)).

38. See *W. States Med. Ctr.*, 535 U.S. at 364–65 (summarizing the operation of this provision).

39. See *id.* at 366; *id.* at 367–68 (“Although several Members of the Court have expressed doubts about the *Central Hudson* analysis and whether it should apply in particular cases, there is no need in this case to break new ground.” (citations omitted)).

40. See *id.* at 365 (explaining that the respondents “[f]ear[ed] that they would be prosecuted under FDAMA if they continued to distribute” promotional materials about specific compounded drugs); *id.* at 373 (wondering “why the Government believed *forbidding* advertising was a necessary as opposed to merely convenient means of achieving its interests” (emphasis added)).

41. See 21 U.S.C. §§ 331(d), 355(a). Thus, if a pharmacy advertised that it would soon begin compounding a particular drug but subsequently decided not to bother, then it violated no federal law. If it did compound the previously advertised product, then the pharmacy might face charges for selling an unapproved new drug, and the act of advertising would deprive it of an otherwise available defense under FDAMA.

42. See Noah, *supra* note 28, at 55 & n.111.

the availability of an exception to an existing legal requirement on the waiver of some First Amendment rights.<sup>43</sup>

The Court accepted the argument that the advertising restriction served substantial interests. On the one hand, the government wanted to guard against the use of unlicensed drugs that might endanger patients;<sup>44</sup> on the other hand, Congress sought to ensure that patients with special needs could access compounded drugs.<sup>45</sup> As a consequence, the government asserted an additional interest in finding a way of balancing these competing goals.<sup>46</sup> Then, after expressing some doubts under the third prong of the *Central Hudson* test, the majority assumed for the sake of argument that the advertising restriction would directly advance these weighty interests.<sup>47</sup> Nonetheless, the Court in *Western States* invalidated the law because it found that any number of non-speech-restrictive alternatives would serve the asserted interests equally well.<sup>48</sup>

Four members of the Supreme Court would have sustained the advertising restriction.<sup>49</sup> Justice Breyer's dissenting opinion viewed the provision as a congressional effort to guard against generating excess demand among patients—in the sense that many of them do not in fact have special needs that require access to a compounded drug—who then would ask their physicians to prescribe one of these unnecessary and potentially dangerous products.<sup>50</sup> Moreover, the dissent found the advertising restriction adequately tailored to serve this weighty public health purpose.<sup>51</sup> Under Breyer's analysis, it would not require much of an extra step to sustain the constitutionality of prohibitions on direct-to-consumer advertising of prescription drugs more generally.

43. See Mitchell N. Berman, *Commercial Speech and the Unconstitutional Conditions Doctrine: A Second Look at "The Greater Includes the Lesser,"* 55 VAND. L. REV. 693, 706–08, 726–39, 748–49, 769–71, 795–96 (2002); *id.* at 739–41 n.163 (defending the provision challenged in *Western States* just before the Court announced its contrary decision, adding that “an essential (if somewhat hidden) component of the government’s argument is that the regulation is not coercive and therefore does not infringe the First Amendment”).

44. See *W. States Med. Ctr.*, 535 U.S. at 368–69.

45. See *id.* at 369–70.

46. See *id.* at 370.

47. See *id.* at 371.

48. See *id.* at 372; see also *id.* at 373 (“If the First Amendment means anything, it means that regulating speech must be a last—not first—resort. Yet here it seems to have been the first strategy the Government thought to try.”). The majority’s application of the final prong of the *Central Hudson* test resembles the least restrictive means test normally reserved for strict scrutiny cases. See Lars Noah, *When Constitutional Tailoring Demands the Impossible: Unrealistic Scrutiny of Agencies?*, 85 GEO. WASH. L. REV. 1462, 1483 & n.79 (2017).

49. See *W. States Med. Ctr.*, 535 U.S. at 378, 390 (Breyer, J., dissenting); see also *id.* at 388 (“The Court, in my view, gives insufficient weight to the Government’s regulatory rationale, and too readily assumes the existence of practical alternatives. It thereby applies the commercial speech doctrine too strictly.”).

50. See *id.* at 379–85; *id.* at 380 (“Where an individual has a specific medical need for a specially tailored drug those risks [associated with the lack of premarket testing] are likely offset. But where an untested drug is a convenience, not a necessity, that offset is unlikely to be present.”); *id.* at 382 (“[I]ndividualized consideration is more likely present, and convenience alone is more likely absent, when demand for a compounding prescription originates with a doctor, not an advertisement. The [advertising] restrictions try . . . to diminish the likelihood that those who do not genuinely need untested compounded drugs will not receive them.”); *id.* at 383 (“There is considerable evidence that consumer oriented advertising will create strong consumer-driven demand for a particular drug. . . . And there is strong evidence that doctors will often respond affirmatively to a patient’s request for a specific drug that the patient has seen advertised.”).

51. See *id.* at 387–88.

After noting that the government never in fact asserted any such interest,<sup>52</sup> the majority offered a pointed rejoinder to this rationale: “Aside from the fact that this concern rests on the questionable assumption that doctors would prescribe unnecessary medications . . . , [it] amounts to a fear that people would make bad decisions if given truthful information about compounded drugs.”<sup>53</sup> Thus, the Court unmistakably reaffirmed the antipaternalism conception of the First Amendment first expressed in *Virginia State Board*, and it did so by invalidating for the first time a recently enacted congressional restriction on advertising, thereby showing little deference to the judgments of a coordinate branch of government.

In 2007, Congress considered bills that would have given the FDA the power to impose a moratorium on consumer advertising of certain new prescription drugs during their first two or three years on the market, when most unexpected adverse reactions come to light.<sup>54</sup> Although these proposals died on the Hill,<sup>55</sup> interest in the idea has not gone away.<sup>56</sup> In the wake of *Western States*, however, the constitutionality of such a law seems extremely doubtful.<sup>57</sup> As mentioned previously, the dissenting members in that

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52. See *id.* at 373–74 (majority opinion).

53. *Id.* at 374; see also *id.* (“We have previously rejected the notion that the Government has an interest in preventing the dissemination of truthful commercial information in order to prevent members of the public from making bad decisions with the information.”); *id.* at 376 (“[I]f it is appropriate for the statute to rely on doctors to refrain from prescribing compounded drugs to patients who do not need them, it is not clear why it would not also be appropriate to rely on doctors to refrain from prescribing compounded drugs to patients who do not need them in a world where advertising was permitted.”).

54. See Bruce Japsen, *Ads for New Drugs Spark Fight; Congress Ponders Possible Moratorium*, CHI. TRIB., Apr. 19, 2007, at C1; see also INST. OF MED., THE FUTURE OF DRUG SAFETY: PROMOTING AND PROTECTING THE HEALTH OF THE PUBLIC 171 (Alina Baciu et al. eds., 2007) (recommending such a moratorium). Testing conducted in pursuit of FDA approval cannot fully characterize the risks associated with a new drug. See Lars Noah, *Informed Consent and the Elusive Dichotomy Between Standard and Experimental Therapy*, 28 AM. J.L. & MED. 361, 394–96 (2002); see also Barry Meier, *Medicine Fueled by Marketing Intensified Trouble for Pain Pills*, N.Y. TIMES, Dec. 19, 2004, § 1, at 1 (reporting that aggressive DTCA fueled tremendous initial demand for COX-2 inhibitors, which later turned out to carry serious cardiac risks and only limited benefits).

55. See Anna Wilde Mathews & Stephanie Kang, *Media Industry Helped Drug Firms Fight Ad Restraints*, WALL ST. J., Sept. 21, 2007, at B1. Instead, Congress authorized the FDA to demand submission of TV advertisements forty-five days prior to broadcast so that it could review them. See Food and Drug Administration Amendments Act of 2007, Pub. L. No. 110-85, § 901(d), 121 Stat. 823, 939 (codified as amended at 21 U.S.C. § 353c (2018)); Draft Guidance for Industry on Direct-to-Consumer Television Advertisements—The Food and Drug Administration Amendments Act of 2007 Direct-to-Consumer Television Ad Pre-Dissemination Review Program, 77 Fed. Reg. 14,811, 14,812 (Mar. 13, 2012).

56. See Ceci Connolly, *With More Oversight on the Horizon, Drugmakers Work to Polish Image*, WASH. POST, Jan. 8, 2009, at A1; Natasha Singer, *Citing Risks, Lawmakers Seek to Curb Drug Commercials*, N.Y. TIMES, July 27, 2009, at B1; cf. *Merck & Co. v. HHS*, 385 F. Supp. 3d 81, 89–98 (D.D.C. 2019) (holding that the Centers for Medicare and Medicaid Services lacked the statutory authority to promulgate a rule requiring the disclosure of list prices in prescription drug advertisements broadcast on television).

57. See Mark I. Schwartz, *To Ban or Not to Ban—That Is the Question: The Constitutionality of a Moratorium on Consumer Drug Advertising*, 63 FOOD & DRUG L.J. 1, 8–27, 32–33 (2008); Miriam Shuchman, *Drug Risks and Free Speech—Can Congress Ban Consumer Drug Ads?*, 356 NEW ENG. J. MED. 2236, 2238 (2007) (reporting that “both liberal and conservative experts on the First Amendment view the proposed ban as likely to fail” in the courts); cf. David C. Vladeck, *The Difficult Case of Direct-to-Consumer Drug Advertising*, 41 LOY. L.A. L. REV. 259, 279–91 (2007) (canvassing the competing arguments, and concluding somewhat hopefully that certain DTCA restrictions might survive). But cf. Margaret Gilhooley, *Drug Safety and Commercial Speech: Television Advertisements and Reprints on Off-Label Uses*, 47 SAN DIEGO L. REV. 845,

case followed a line of reasoning that might have sustained a flat prohibition on DTCA.<sup>58</sup> Indeed, even for the dissenters, this would present a closer case: fears about the overuse of compounded drugs that had not undergone any premarket testing seem inapt for FDA-approved drugs that have survived such testing, while the benefits of the squelched information might strike these justices as somewhat weightier. In any event, their views failed to prevail (though partly because those in the majority did not believe that the government had invoked the demand-dampening rationale), and subsequent changes in the membership of the Court hardly portend a pro-government shift in the approach to commercial speech cases.<sup>59</sup>

*B. State Courts Consider an Exception to the Learned Intermediary Doctrine*

Traditionally, under the so-called learned intermediary rule, manufacturers satisfied their duty to warn of the hazards associated with prescription drugs or implanted medical devices by communicating risk information to physicians. Courts justified this rule on a number of grounds: physicians must make the judgment about whether to administer or prescribe a medication or use a device; manufacturers should not intrude on the doctor-patient relationship; physicians can better tailor their communication of important and complex information in ways understandable to their patients; and manufacturers lack practical means of conveying risk information directly to patients.<sup>60</sup> Although the absence of any separate duty to warn patients continues to provoke controversy,<sup>61</sup> this doctrine represents a durable feature of failure-to-warn litigation involving therapeutic products that remain accessible only through health care professionals.<sup>62</sup>

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868–76, 894–95 (2010) (defending the constitutionality of a targeted moratorium, though primarily on the strength of Justice Breyer’s dissenting opinion in *Western States*).

58. See *W. States Med. Ctr.*, 535 U.S. at 379–85 (Breyer, J., dissenting); see also *Va. State Bd. of Pharmacy v. Va. Citizens Consumer Council*, 425 U.S. 748, 788–89 (1976) (Rehnquist, J., dissenting) (warning that constitutional protection for price advertising by pharmacists would prevent the government from banning DTCA).

59. See Schwartz, *supra* note 57, at 27–32; Adam Liptak, *How Free Speech Was Weaponized by Conservatives*, N.Y. TIMES, July 1, 2018, at A1 (adding that the 1976 decision in *Virginia State Board* represented “a transformative ruling by the Supreme Court”); see also *supra* note 31 (discussing the Court’s 2011 decision in *IMS Health*).

60. See Noah, *supra* note 24, at 170; see also *id.* at 155–61 (elaborating on these rationales with copious citations to the case law and commentary available more than twenty years ago); Lars Noah, *This Is Your Products Liability Restatement on Drugs*, 74 BROOK. L. REV. 839, 890–97 (2009) (revisiting these rationales with updated citations and further analysis); *id.* at 912 (noting the application of the learned intermediary rule to certain medical devices). The last (practical) concern has become far less significant as pharmacists increasingly print out and attach patient information sheets at the time of dispensing, though these generally do not originate with drug manufacturers. See Jonathan D. Rockoff, *Prescription Leaflets Lack Key Safety Data*, WALL ST. J., Dec. 17, 2008, at D3.

61. See Noah, *supra* note 24, at 180 (“In the past, the learned intermediary rule protected manufacturers of prescription drugs from tort liability if they conveyed an adequate warning to physicians. Some commentators have argued that the rule no longer serves a legitimate purpose and should be eliminated altogether or at least reduced in scope by recognizing a number of new exceptions.”); Noah, *supra* note 60, at 894 (“The learned intermediary doctrine has attracted its share of critics who argue, among other things, that the defense reflects an anachronistic and excessively paternalistic model of the physician-patient relationship and fails to take into account changes in the delivery of health care services.”).

62. See *In re Zimmer, NexGen Knee Implant Prods. Liab. Litig.*, 884 F.3d 746, 752 (7th Cir. 2018) (concluding that “there is good reason to think that given the opportunity, the Wisconsin Supreme Court would

The learned intermediary rule has important consequences for litigation. For a couple of reasons, plaintiffs tend to encounter greater difficulties in getting a failure-to-warn case involving a prescription product before a jury.<sup>63</sup> First, unlike a consumer-directed warning to which jurors can apply their own experience, plaintiffs typically have to produce expert testimony to support an inadequacy claim.<sup>64</sup> Second, even if plaintiffs find experts willing to quibble about the labeling of a prescription drug or device,<sup>65</sup> their treating physicians often testify that they understood the warnings provided by the company.<sup>66</sup> In some cases, plaintiffs succeed in convincing juries that the professional labeling for a prescription product suffered from some inadequacy and thereby caused their injuries,<sup>67</sup> but the rule continues to present a formidable obstacle to recovery in such cases.

Mass immunizations represented the classic exception to the learned intermediary doctrine: when vaccines get administered in such a program, no health care professional makes any sort of an individualized medical decision or engages in a dialogue with the patient.<sup>68</sup> A few courts extended this exception to other products, such as prescription

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join the vast majority of state supreme courts and adopt the learned-intermediary doctrine”); Diane Schmauder Kane, Annotation, *Construction and Application of Learned-Intermediary Doctrine*, 57 A.L.R.5th 1, § 2.5 (1998 & 2018 Supp.) (collecting approximately one hundred decisions from just the last decade).

63. See, e.g., *Ackermann v. Wyeth Pharm.*, 526 F.3d 203, 209–14 (5th Cir. 2008); *Ziliak v. AstraZeneca LP*, 324 F.3d 518, 521 (7th Cir. 2003); *Stahl v. Novartis Pharm. Corp.*, 283 F.3d 254, 264–72 (5th Cir. 2002); *Estate of LaMontagne v. Bristol-Myers Squibb*, 111 P.3d 857, 862–65, 865 n.19 (Wash. Ct. App. 2005).

64. See, e.g., *Montagnon v. Pfizer, Inc.*, 584 F. Supp. 2d 459, 462–63 (D. Conn. 2008) (osteoporosis warning for Depo-Provera<sup>®</sup> injectable contraceptive); *Colville v. Pharmacia & Upjohn Co.*, 565 F. Supp. 2d 1314, 1321 (N.D. Fla. 2008) (same); *Upjohn Co. v. MacMurdo*, 562 So. 2d 680, 683 (Fla. 1990) (“[T]he adequacy or inadequacy of the warning to inform a physician must, except in the more obvious situations, be proved by expert testimony.”); *Wyeth Labs., Inc. v. Fortenberry*, 530 So. 2d 688, 692 (Miss. 1988) (“The adequacy of a warning addressed to the medical community may fall into the category of issues requiring expert testimony.”).

65. See, e.g., *Thom v. Bristol-Myers Squibb Co.*, 353 F.3d 848, 853–54 (10th Cir. 2003) (holding that the adequacy of a warning presented a question for the jury where the package insert was “equivocal” in referring to reports of an adverse effect as “rare” and only “temporally associated” but for which a “causal relationship . . . has not been established”); *Janssen Pharm., Inc. v. Bailey*, 878 So. 2d 31, 55–59 (Miss. 2004) (noting that the plaintiffs had argued “that Propulsid became a victim of label fatigue” by virtue of the five revisions to the package insert—sometimes accompanied by “Dear Doctor” letters—issued over the course of five years to convey increasingly alarming risk information, and concluding that this presented a question for the factfinder).

66. See, e.g., *Hall v. Merck, Sharp & Dohme*, 774 F. Supp. 604, 606–07 (D. Kan. 1991); *Wooten v. Johnson & Johnson Prods. Inc.*, 635 F. Supp. 799, 802–04 (N.D. Ill. 1986). Alternatively, treating physicians may testify that they had learned of the information from other sources, which would mean that any failure to warn did not cause the patient’s injury. See *Ellis v. C.R. Bard, Inc.*, 311 F.3d 1272, 1283 n.8 (11th Cir. 2002); *Miller v. Pfizer Inc.*, 196 F. Supp. 2d 1095, 1126–30 (D. Kan. 2002), *aff’d*, 356 F.3d 1326 (10th Cir. 2004); *Harden v. Danek Med., Inc.*, 985 S.W.2d 449, 451–52 (Tenn. Ct. App. 1998).

67. See, e.g., *McNeil v. Wyeth*, 462 F.3d 364, 368–72 (5th Cir. 2006); *Bennett v. Madakasira*, 821 So. 2d 794, 806–07 (Miss. 2002); see also *Hyman & Armstrong, P.S.C. v. Gunderson*, 279 S.W.3d 93, 111–12, 121–22 (Ky. 2008) (diluted by overpromotion).

68. See, e.g., *Plummer v. Lederle Labs.*, 819 F.2d 349, 356 (2d Cir. 1987) (“If the drug is given under clinic-type conditions the manufacturer is obligated to warn consumers directly.”); *Stanback v. Parke, Davis & Co.*, 657 F.2d 642, 647 (4th Cir. 1981) (limiting this exception to massive, nationwide immunization programs where it would have been foreseeable by the manufacturer that the “vaccines would be dispensed without a

contraceptives, for which physicians may play a reduced role in helping patients to select among available options.<sup>69</sup> Courts occasionally have crafted still other exceptions on an ad hoc basis.<sup>70</sup>

When it appeared two decades ago, the *Products Liability Restatement* grudgingly endorsed the learned intermediary doctrine in its special rules governing sellers of prescription drugs and medical devices.<sup>71</sup> An accompanying comment explained that the blackletter formulation attempted to capture the mass immunization exception, discussed the debate about possible exceptions where the FDA mandated the distribution of patient package inserts (PPIs) or manufacturers had engaged in DTCA, but left to developing case law the adoption of these or still other exceptions.<sup>72</sup> Just as this volume of the *Third Restatement of Torts* made its debut, I elaborated on the curious twists and turns that had occurred during the drafting process in relation to the learned intermediary doctrine,<sup>73</sup> before explaining at length some of the flaws in proposals to recognize the advertising exception.<sup>74</sup>

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physician's consideration of individual needs and circumstances"); *Allison v. Merck & Co.*, 878 P.2d 948, 958 n.16 (Nev. 1994).

69. See, e.g., *Hill v. Searle Labs.*, 884 F.2d 1064, 1071 (8th Cir. 1989) (predicting, in a case involving an intrauterine device (IUD), that Arkansas would recognize such an exception); *Odgers v. Ortho Pharm. Corp.*, 609 F. Supp. 867, 878–79 (E.D. Mich. 1985) (oral contraceptives); *MacDonald v. Ortho Pharm. Corp.*, 475 N.E.2d 65, 69–70 (Mass. 1985) (same); see also *Niedner v. Ortho-McNeil Pharm., Inc.*, 58 N.E.3d 1080, 1084–85 (Mass. App. Ct. 2016) (hormonal contraceptive patch). But see *In re Norplant Contraceptive Prods. Liab. Litig.*, 955 F. Supp. 700, 704–05, 704 n.18 (E.D. Tex. 1997) (collecting cases that reject this exception), *aff'd*, 165 F.3d 374 (5th Cir. 1999); *West v. Searle & Co.*, 806 S.W.2d 608, 614 (Ark. 1991) (“[A]pplication of the learned intermediary rule is appropriate in the case of oral contraceptives.”).

70. See, e.g., *Nichols v. McNeilab, Inc.*, 850 F. Supp. 562, 564–65 (E.D. Mich. 1993) (holding that the learned intermediary doctrine would not defeat a claim alleging failure to provide notification of a drug recall prompted by safety concerns, distinguishing this from the risk information conveyed to patients at the time that a drug is initially prescribed); see also *Lars Noah, Doctors on the Take: Aligning Tort Law to Address Drug Company Payments to Prescribers*, 66 BUFF. L. REV. 855, 892–907 (2018) (recommending a novel exception to the learned intermediary doctrine when physicians receive compensation from manufacturers). But see, e.g., *Vitanza v. Upjohn Co.*, 778 A.2d 829, 846–47 (Conn. 2001) (declining to adopt an exception in the case of prescription drug samples).

71. See RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 6(d) (AM. LAW INST. 1998).

72. See *id.* § 6 cmt. e. Just before formal publication of this volume, one state court declined to apply the doctrine whenever a drug manufacturer had supplied PPIs. See *Edwards v. Basel Pharm.*, 933 P.2d 298, 301 (Okla. 1997). Nonetheless, this exception remains a distinctly minority position. See, e.g., *Yates v. Ortho-McNeil-Janssen Pharm., Inc.*, 808 F.3d 281, 292–93 (6th Cir. 2015); *Martin v. Ortho Pharm. Corp.*, 661 N.E.2d 352, 356 (Ill. 1996); see also *Humes v. Clinton*, 792 P.2d 1032, 1042–43 (Kan. 1990) (ordering summary judgment to an IUD manufacturer where the physician had neglected to hand out the company's PPI in favor of a homemade leaflet).

73. See *Noah*, *supra* note 24, at 161–68.

74. See *id.* at 168–79; see also *id.* at 173 (“Proponents of an advertising exception cannot rebut the two central rationales underlying the learned intermediary doctrine: patients cannot lawfully purchase a prescription drug without receiving authorization from a physician, and physicians are far better situated than manufacturers to communicate with patients.”); *id.* at 180 (concluding that “no persuasive case exists for recognizing an advertising exception”). In an essay that he published eight years after my critique of their handiwork on this issue, one of the two reporters for the *Products Liability Restatement* expressed an apparent change of heart. See *Twerski*, *supra* note 20, at 1150–53.

Not long thereafter, in *Perez v. Wyeth Laboratories Inc.*,<sup>75</sup> the New Jersey Supreme Court decided to adopt the DTCA exception. The case involved Norplant® (levonorgestrel), an implantable, long-acting contraceptive product.<sup>76</sup> The consolidated lawsuits claimed that the manufacturer had failed to warn patients of a litany of alleged side effects of use and complications associated with removal of the product.<sup>77</sup> The trial judge dismissed the complaints,<sup>78</sup> but the state supreme court reversed. After taking apparent comfort in the fact that the *Products Liability Restatement* had left the question to developing case law,<sup>79</sup> the majority concluded that DTCA undermined most of the rationales thought to justify the learned intermediary rule.<sup>80</sup>

Although direct advertising has plainly altered the dynamic between patients and their physicians when considering the use of a drug promoted in this fashion,<sup>81</sup> the dissent emphasized that, at least with respect to Norplant (a hybrid drug-device product requiring surgical implantation), doctors would continue playing a central role.<sup>82</sup> The majority also failed to explain how DTCA vitiated fears that supplying detailed warnings directly to patients might prompt them to discontinue needed treatments,<sup>83</sup> much less how a

75. 734 A.2d 1245 (N.J. 1999).

76. See *id.* at 1247, 1251; see also Allan J. Coukell & Julia A. Balfour, *Levonorgestrel Subdermal Implants: A Review of Contraceptive Efficacy and Acceptability*, 55 *DRUGS* 861, 881–83 (1998); Gina Kolata, *Will the Lawyers Kill Off Norplant?*, N.Y. TIMES, May 28, 1995, § 3, at 1. A couple of weeks after the court's decision, the defendant offered to settle more than thirty-six thousand claims for the "relatively modest sum" of \$50 million in total. See Gardiner Harris & Robert Langreth, *After Setbacks, American Home Plans Remedies*, WALL ST. J., Aug. 31, 1999, at B1; cf. *In re Norplant Contraceptive Prods. Liab. Litig.*, 215 F. Supp. 2d 795, 802 (E.D. Tex. 2002) (noting that almost three thousand plaintiffs failed to accept their settlement offers). The manufacturer no longer sells this product. See Erin Allday, *FDA Approves New Contraceptive Injected in Arm: Norplant-Like Device Used in Europe Will Be Available in '07*, S.F. CHRON., July 19, 2006, at A2 (reporting that Norplant was withdrawn in 2002); see also Jerome F. Strauss III & Michael Kafriksen, *Waiting for the Second Coming: Contraceptive Research Is Seriously in Need of Revitalization.*, 432 *NATURE* 43, 44 (2004) ("Despite the favourable rulings, defending the product was a significant financial burden for Wyeth.").

77. See *Perez*, 734 A.2d at 1248.

78. See *id.* at 1249.

79. See *id.* at 1253. The lone dissenter countered that a state statute had codified the learned intermediary doctrine without countenancing any exceptions. See *id.* at 1264–67 (Pollock, J., dissenting); *id.* at 1267 ("Given the statutory basis for the learned intermediary doctrine in New Jersey, recourse to the *Restatement* . . . is gratuitous."). The majority, however, found ambiguity in the state legislation. See *id.* at 1253–54 (majority opinion).

80. See *id.* at 1255–57, 1263. In the course of its opinion, the majority quoted several passages from my earlier article on the subject, see *id.* at 1251–52, 1255–56, 1258, but evidently failed to notice that I had concluded that the exception made no sense, citing instead a student note published in the *William Mitchell Law Review* as supporting its ultimate conclusion, see *id.* at 1256. Indeed, immediately after quoting my summary of the rationales underlying the learned intermediary rule, the majority offered a brief synopsis that blatantly mischaracterized some of these before explaining that at least three of the four became inapplicable when manufacturers engage in DTCA. See *id.* at 1255–56. As the dissent briefly explained, all four of the rationales remained pertinent. See *id.* at 1269 (Pollock, J., dissenting).

81. See Noah, *supra* note 60, at 897–98 n.257.

82. See *Perez*, 734 A.2d at 1267–68 (Pollock, J., dissenting).

83. See Noah, *supra* note 60, at 898 n.260 ("Extensive warnings conveyed directly by pharmaceutical manufacturers might make patients lose trust in their physicians or discontinue necessary drug therapies because of undue anxiety about the reported side effects that the physician felt did not deserve mention . . ."); *id.* ("[A]dvertisements emphasize benefits and come before the patient visits a physician, while PPIs emphasize risks and reach patients only upon drug dispensing.").

manufacturer might do so in a way that laypersons could comprehend.<sup>84</sup> Evidently the majority thought that Norplant, like some of the other examples that it had cited, did not qualify as a therapeutically important product,<sup>85</sup> echoing suggestions made by some commentators that another exception to the learned intermediary doctrine should apply to “lifestyle” drugs and devices, whether or not directly advertised to consumers.<sup>86</sup>

The majority opinion repeatedly suggested that Wyeth should not enjoy protection from liability for failing to warn patients directly when it had aimed misleading advertisements at them,<sup>87</sup> but it conceded that this characterization assumed that the plaintiffs would manage to prove their allegations at trial,<sup>88</sup> and it hastened to add that compliance with FDA requirements would entitle the defendants to a presumption of adequacy.<sup>89</sup> In fact, the plaintiffs apparently had not seen any of the allegedly misleading ads,<sup>90</sup> and they did not seek clearer risk information in advertisements that they may not

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84. See *id.* at 898 n.261.

85. See *Perez*, 734 A.2d at 1257 (“Further, when one considers that many of these ‘life-style’ drugs or elective treatments cause significant side effects without any curative effect, increased consumer protection becomes imperative, because these drugs are, by definition, not medically necessary.”). Elsewhere in the opinion, the majority painted an unflattering picture of DTCA, citing advertisements involving entirely different pharmaceutical products indicated for the treatment of allergies, baldness, erectile dysfunction, and excess weight. See *id.* at 1247, 1251–53, 1260, 1264. It also discussed changes in health care delivery that made it more difficult for physicians to spend time having meaningful discussions with their (increasingly pushy) patients. See *id.* at 1247, 1255, 1260; see also *id.* at 1262 n.6 (discussing Internet prescribing). The dissent admonished the majority for going beyond the confines of the record developed in the Norplant cases before the court. See *id.* at 1268 (Pollock, J., dissenting) (“Through the incorporation of presumed facts, the majority has created a phantom record . . .”).

86. See Timothy S. Hall, *Reimagining the Learned Intermediary Rule for the New Pharmaceutical Marketplace*, 35 SETON HALL L. REV. 193, 197 & n.10, 229–30, 237, 243, 250 (2004) (arguing that the “lifestyle” use of a drug should count as a factor against application of the learned intermediary rule); Susan A. Casey, Comment, *Laying an Old Doctrine to Rest: Challenging the Wisdom of the Learned Intermediary Doctrine*, 19 WM. MITCHELL L. REV. 931, 952–55 (1993) (arguing that an advertising exception should exist at least with regard to elective prescription drugs and medical devices, such as acne treatments and breast implants, promoted to consumers for cosmetic purposes); Kathy A. King-Cameron, Comment, *Carving Another Exception to the Learned Intermediary Doctrine: Application of the Learned Intermediary Doctrine in Silicone Breast Implant Litigation*, 68 TUL. L. REV. 937, 969–70 (1994) (mammary prostheses). For a critique of the suggestion that such a distinct category exists, see Noah, *supra* note 3, at 381–84.

87. See, e.g., *Perez*, 734 A.2d at 1257 (“It is one thing not to inform a patient about the potential side effects of a product; it is another thing to misinform the patient by deliberately withholding potential side effects while marketing the product as an efficacious solution to a serious health problem.”); *id.* (“The question is whether the absence of an independent duty to warn patients gives the manufacturer the right to misrepresent to the public the product’s safety.”); *id.* at 1261 (declining to “insulate the manufacturer who has engaged in deceptive trade practices”); *id.* at 1264 (“[W]e must decide if a pharmaceutical manufacturer is free to engage in deceptive advertising to consumers. . . . [The learned intermediary rule] does not confer on pharmaceutical manufacturers a license to mislead or deceive consumers when those manufacturers elect to exercise their right to advertise their product directly to such consumers.”).

88. See *id.* at 1247–48; *id.* at 1263 (“acknowledg[ing] that the procedural posture of this case casts defendant’s product in an unfair light”). The DTCA exception did not, however, apply only in cases of deceptive promotional campaigns.

89. See *id.* at 1259, 1263. As I explained a decade later, this represented a largely meaningless concession given the nature of the applicable FDA requirements. See Noah, *supra* note 60, at 901–02.

90. See *Perez*, 734 A.2d at 1260; *id.* at 1268 (Pollock, J., dissenting); cf. *In re Norplant Contraceptive Prods. Liab. Litig.*, 955 F. Supp. 700, 707–08, 708 n.44 (E.D. Tex. 1997) (declining to address arguments in



have seen (or remembered); instead, they wanted print warnings to accompany the drugs when later dispensed or provided to them. As a consequence, manufacturers wishing to engage in DTCA would have to shoulder the onerous burden of supplying comprehensive PPIs.<sup>91</sup>

Direct advertising encourages active participation by patients in prescribing decisions, a favorable development that courts should not reward by expanding the tort duties of drug manufacturers and, because consumer-directed warnings inevitably would fall short, discouraging such advertising in the future.<sup>92</sup> Although the FDA increasingly switches drugs to over-the-counter (OTC) status,<sup>93</sup> products that continue to require prescription labeling reflect the agency's judgment that professional intervention remains necessary to ensure their safe use.<sup>94</sup> To the extent that DTCA exaggerates the benefits or downplays the hazards of prescription drugs and devices, which may well prompt consumers to demand inappropriate therapeutic products, misrepresentation claims against manufacturers might have merit,<sup>95</sup> but health care professionals also have an obligation to stand their ground.<sup>96</sup> Advertising naturally emphasizes product benefits, but even this may provide valuable information in the prescription drug context if consumers otherwise would leave bothersome conditions untreated. Whether or not such policy arguments persuade the growing chorus of DTCA critics, overlaying commercial speech principles might give them additional traction.<sup>97</sup>

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favor of an exception because the plaintiffs had not seen any of the advertisements), *aff'd*, 165 F.3d 374, 379 (5th Cir. 1999).

91. See Noah, *supra* note 24, at 175 (“[P]harmaceutical manufacturers would have to find a way of disseminating [PPIs], ensure that these inserts contained references to all possible side effects in nontechnical language, and, in the unlikely event that they managed to design such an unassailable warning, hope that a jury would not decide that continued advertising to consumers diluted the effectiveness of that warning.”).

92. See Charles J. Walsh et al., *The Learned Intermediary Doctrine: The Correct Prescription for Drug Labeling*, 48 RUTGERS L. REV. 821, 881 (1996) (“Ironically, preservation of this brightline [learned intermediary] rule would help create the conditions necessary for improved communications between pharmaceutical manufacturers and patients.”); *id.* at 880 (“[T]ruthful direct-to-consumer advertising will provide the consumer with useful information without eroding the paramount role of the prescribing physician. In any event, there is little evidence that direct-to-consumer advertising has harmed consumers or foisted medically inappropriate therapies upon them.”).

93. See Lars Noah, *Reversal of Fortune: Moving Pharmaceuticals from Over-the-Counter to Prescription Status?*, 63 VILL. L. REV. 355, 356 & n.8 (2018).

94. See Peter Temin, *The Origin of Compulsory Drug Prescriptions*, 22 J.L. & ECON. 91, 103 (1979) (“[T]he FDA assumed that adequate directions for laymen could not be written for some drugs.”). A number of reasons may exist for prescription labeling, such as the difficulty with self-diagnosis, a product's margin of safety, and the extent to which dosages need to be carefully titrated for each patient. See Lars Noah, *Treat Yourself: Is Self-Medication the Prescription for What Ails American Health Care?*, 19 HARV. J.L. & TECH. 359, 366–68, 375 (2006).

95. See *infra* notes 120, 123 and accompanying text.

96. See Thomas L. Hafemeister & Richard M. Gulbrandsen, Jr., *The Fiduciary Obligation of Physicians to “Just Say No” if an “Informed” Patient Demands Services That Are Not Medically Indicated*, 39 SETON HALL L. REV. 335, 362–67, 373–74, 380–84 (2009); Michelle D. Ehrlich, Note, *Doctors Can “Just Say No”: The Constitutionality of Consumer-Directed Advertising of Prescription Drugs*, 12 HASTINGS COMM. & ENT. L.J. 535, 550, 553–55 (1990) (“[T]he physician—and not the patient/consumer—makes the ultimate decision of what drug a patient will purchase.”).

97. In my prior work, I presented precisely such policy arguments and briefly drew a parallel to the constitutional analysis solely in an attempt to bolster them. See Noah, *supra* note 60, at 904 (“As the United States Supreme Court has observed repeatedly in deciding commercial speech cases, some information is better

C. *The Unappreciated Constitutional Flaws in This Doctrinal Modification*

As previously explained, in *Thompson v. Western States Medical Center*,<sup>98</sup> the U.S. Supreme Court held unconstitutional federal legislation that granted compounding pharmacists an exception from burdensome product licensure requirements so long as they did not engage in any advertising of these drug products.<sup>99</sup> In *Perez v. Wyeth Laboratories Inc.*,<sup>100</sup> the New Jersey Supreme Court adopted a rule that operated in a parallel fashion: it continued to recognize the learned intermediary doctrine, which gave manufacturers of prescription drugs and devices the benefit of an exception from the otherwise burdensome duty in products liability to convey adequate warnings to consumers, so long as they had not advertised directly to potential patients.<sup>101</sup> The fact that this DTCA exception burdens commercial speech does not end the constitutional inquiry, of course, but the tort rule announced in New Jersey looks no more defensible than the act of Congress invalidated under the heightened scrutiny applied in *Western States*, and the fact that it emanated from the state's high court rather than its legislature should make no difference in the analysis.<sup>102</sup>

Only one scholarly article has suggested that the DTCA exception might pose a constitutional problem, and it did so largely as an afterthought.<sup>103</sup> Offering the first published commentary in the wake of *Perez*, and without the benefit of the decision three years later in *Western States*, the authors feared that this exception might “chill” commercial speech,<sup>104</sup> but they entirely failed to discuss the possibility that the analysis used in assessing direct regulations might apply differently when evaluating the permissible reach of tort doctrine.<sup>105</sup> Although I share these authors' sense that

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than none.”). As the next Part suggests, like-minded judges and commentators might have recourse to a less timid approach.

98. 535 U.S. 357 (2002).

99. See *supra* notes 41–48 and accompanying text.

100. 734 A.2d 1245 (N.J. 1999).

101. See *supra* notes 75–90 and accompanying text; see also *In re Norplant Contraceptive Prods. Liab. Litig.*, 215 F. Supp. 2d 795, 816 (E.D. Tex. 2002) (“*Perez* essentially declines to afford drug manufacturers the benefit of using the learned intermediary doctrine as a shield from liability if they attempt to influence consumers via advertising.”); Twerski, *supra* note 20, at 1153 (“Without the learned intermediary rule, direct advertising failure-to-warn cases are likely to constitute an expansive and expensive category of liability.”).

102. See Frank I. Michelman, *The Bill of Rights, the Common Law, and the Freedom-Friendly State*, 58 U. MIAMI L. REV. 401, 403–04 (2003) (arguing that *N.Y. Times Co. v. Sullivan*, 376 U.S. 254 (1964), “open[ed] the doors wide to judicial inspection of the common law for consistency with the Bill of Rights . . . and there is no way logically—conceptually—to push them shut”); *id.* at 417 (suggesting “that common law ought to be no less subject than statute law to judicial inspection for consonance with the requirements of a constitutional bill of rights”). See generally Alexandra B. Klass, *Tort Experiments in the Laboratories of Democracy*, 50 WM. & MARY L. REV. 1501, 1575 (2009) (discussing the involvement of state legislatures as well as courts in expanding and contracting tort law); *id.* at 1536 (“States will continue to struggle with where to increase and decrease tort rights to respond to the needs of their citizens, the business community, and technological and social advances.”).

103. See Jack B. Harrison & Mina J. Jefferson, “[S]ome [A]ccurate [I]nformation Is [B]etter than [N]o [I]nformation [A]t [A]ll”: Arguments Against an Exception to the Learned Intermediary Doctrine Based on Direct-to-Consumer Advertising, 78 OR. L. REV. 605, 619 (1999) (listing it as the last of five arguments against recognizing this exception); *id.* at 633–38 (elaborating on the constitutional objections).

104. See *id.* at 637–38; see also *id.* at 612–13 (offering only a brief summary of the *Perez* decision).

105. Separately, they lodged an objection premised on “coerced speech” principles, see *id.* at 634–37, but this in no way would apply solely to the DTCA exception. Indeed, if taken seriously, this argument might throw

New Jersey's high court ran afoul of the First Amendment, this only becomes clear upon comparing what has happened in the context of defamation and related claims.

More than half a century ago, the U.S. Supreme Court began the process of using the First and Fourteenth Amendments to modify state law governing so-called speech torts.<sup>106</sup> In a famous 1964 decision, it held that public officials could recover for defamation only upon a showing of actual malice.<sup>107</sup> The Court soon expanded the category of plaintiffs subject to this heightened standard to include public figures as well,<sup>108</sup> and it later superimposed the actual malice standard on intentional infliction of emotional distress claims.<sup>109</sup> In addition, public figures would have to prove actual malice by clear and convincing evidence,<sup>110</sup> and reviewing courts could not show their typical deference to the factfinder on these issues.<sup>111</sup> Even entirely private figures may have to surmount this heightened pleading requirement when the allegedly tortious

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into doubt the duty to warn health care professionals under the learned intermediary doctrine or, more broadly, the failure-to-warn claims that play such a central role in products liability litigation for the entire range of consumer goods. See Lars Noah, *The Imperative to Warn: Disentangling the "Right to Know" from the "Need to Know" About Consumer Product Hazards*, 11 YALE J. ON REG. 293, 343–50, 375–78, 382–83 (1994).

106. See David A. Anderson, *Tortious Speech*, 47 WASH. & LEE L. REV. 71, 71 (1990) (“The one tort that has been fully subjected to this [First Amendment] scrutiny, libel, has been transformed into a half-tort, half-constitutional hybrid that is almost universally viewed as unsatisfactory.”); *id.* at 101 (“One of the unfortunate consequences of prescribing constitutional rules is that it stunts the growth of state law. This has happened in defamation, where constitutional requirements have left the states little room or incentive to experiment with their own solutions to the speech-tort conflict.”). See generally David S. Han, *Rethinking Speech-Tort Remedies*, 2014 WIS. L. REV. 1135.

107. See *N.Y. Times Co. v. Sullivan*, 376 U.S. 254, 279–80 (1964); see also *St. Amant v. Thompson*, 390 U.S. 727, 730–33 (1968) (elaborating on the actual malice standard); *Rosenblatt v. Baer*, 383 U.S. 75, 82–83 (1966) (explaining that the challenged statement must be “of and concerning”—i.e., make “specific reference” to—the plaintiff); *Goldberg & Zipursky*, *supra* note 10, at 437 (“The modern Supreme Court’s deepest and most widely accepted foray into tort law began in 1964 with *Sullivan*.”).

108. See *Curtis Publ’g Co. v. Butts*, 388 U.S. 130, 155 (1967) (plurality opinion); *cf.* *Bose Corp. v. Consumers Union, Inc.*, 466 U.S. 485, 492 & n.8, 513–14 (1984) (assuming without deciding that the actual malice standard should apply to a product disparagement claim by a manufacturer of loudspeakers, treated as a public figure, against the publisher of *Consumer Reports*); *Vascular Sols., Inc. v. Marine Polymer Techs., Inc.*, 590 F.3d 56, 59 (1st Cir. 2009) (per curiam) (explaining that the question not answered in *Bose* remains unsettled).

109. See *Hustler Magazine, Inc. v. Falwell*, 485 U.S. 46, 56 (1988).

110. See *Gertz v. Robert Welch, Inc.*, 418 U.S. 323, 342 (1974); see also *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 252–57 (1986) (holding that, when ruling on a motion for summary judgment in a public figure defamation case, the trial judge must overlay this more demanding evidentiary standard).

111. See *Harte-Hanks Commc’ns, Inc. v. Connaughton*, 491 U.S. 657, 688–93 (1989); Susan M. Gilles, *Taking First Amendment Procedure Seriously: An Analysis of Process in Libel Litigation*, 58 OHIO ST. L.J. 1753, 1771–74, 1776–79, 1791–92 (1998); see also *id.* at 1755–56, 1761–66, 1770–71 (discussing other procedural accommodations).

speech affects a matter of public concern,<sup>112</sup> at least when they seek to recover presumed or punitive damages.<sup>113</sup>

If nothing else, this constitutional makeover of the common law related to tortious speech demonstrates that judicial pronouncements about doctrines used to resolve private disputes qualify as state action.<sup>114</sup> For the most part, these decisions focused on the need to give high-value speech necessary breathing room. As the Supreme Court has steadily brought commercial speech closer to the First Amendment's core,<sup>115</sup> doctrinal choices made by state courts to punish advertisers seemingly have become fair game for serious constitutional inquiry.

Contrast the approach in *Perez* with the subsequent decisions of two other state high courts. First, after echoing the New Jersey court's plain disdain for DTCA, West Virginia decided to reject the learned intermediary doctrine altogether.<sup>116</sup> Federal district courts sitting in that state have, however, offered starkly different readings of the decision; one viewed it as such a strong objection to the idea of limiting the duty of prescription drug manufacturers that it refused to follow normal choice-of-law principles that pointed to applying the law of another state to a case because to do so would have offended public policy,<sup>117</sup> while a different federal judge read the West Virginia decision as a plurality

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112. See *Snyder v. Phelps*, 562 U.S. 443, 454–61 (2011) (affirming the reversal of a \$5 million judgment for the father of a deceased soldier for intentional infliction of emotional distress and intrusion upon seclusion claims against members of the Westboro Baptist Church for an outrageous protest in the vicinity of his son's funeral); *Phila. Newspapers, Inc. v. Hepps*, 475 U.S. 767, 776–78 (1986) (holding that private plaintiffs also must carry the burden of proving falsity of speech when it involves a matter of public concern); see also *Hutchinson v. Proxmire*, 443 U.S. 111, 134–36 (1979) (trying to define the line between public and private figures); cf. *Milkovich v. Lorain Journal Co.*, 497 U.S. 1, 18–22 (1990) (rejecting the notion that statements of opinion should separately enjoy constitutional immunity from suit). See generally Mark Strasser, *What's It to You: The First Amendment and Matters of Public Concern*, 77 MO. L. REV. 1083 (2012) (criticizing this distinction).

113. See *Gertz*, 418 U.S. at 349–50 (holding that a non-public figure could recover such damages only upon a showing of actual malice); see also *Dun & Bradstreet, Inc. v. Greenmoss Builders, Inc.*, 472 U.S. 749, 759–63 (1985) (plurality opinion) (holding that presumed and punitive damages for errors in a credit report do not require proof of actual malice because it does not involve a matter of public concern).

114. See *N.Y. Times Co. v. Sullivan*, 376 U.S. 254, 265 (1964); *id.* at 277 (“What a State may not constitutionally bring about by means of a criminal statute is likewise beyond the reach of its civil law of libel.”); see also *Hepps*, 475 U.S. at 777 (reiterating this point, though recognizing that “a suit by a private party is obviously quite different from the government’s direct enforcement of its own laws”); Anderson, *supra* note 6, at 766–70, 804 (discussing this distinction); Cristina Carmody Tilley, *Tort, Speech, and the Dubious Alchemy of State Action*, 17 U. PA. J. CONST. L. 1117, 1139–43, 1180–81 (2015) (criticizing this aspect of *Sullivan*). See generally Lillian BeVier & John Harrison, *The State Action Principle and Its Critics*, 96 VA. L. REV. 1767 (2010) (defending the Court’s broader state action doctrine).

115. See *supra* Part I.A.; see also Noah, *supra* note 48, at 1468–69, 1481–83, 1483 n.79.

116. See *State ex rel. Johnson & Johnson Corp. v. Karl*, 647 S.E.2d 899, 907–14 (W. Va. 2007); see also *Rimbert v. Eli Lilly & Co.*, 577 F. Supp. 2d 1174, 1214–24 (D.N.M. 2008) (predicting that the New Mexico courts would reject the doctrine in its entirety). See generally Victor E. Schwartz et al., *Marketing Pharmaceutical Products in the Twenty-First Century: An Analysis of the Continued Viability of Traditional Principles of Law in the Age of Direct-to-Consumer Advertising*, 32 HARV. J.L. & PUB. POL’Y 333, 355–69, 386–87 (2009); Kyle T. Fogt, Note, *The Road Less Traveled: West Virginia’s Rejection of the Learned Intermediary Doctrine in the Age of Direct-to-Consumer Advertising*, 34 J. CORP. L. 587 (2009).

117. See *Vitatoe v. Mylan Pharm., Inc.*, 696 F. Supp. 2d 599, 608–10 (N.D. W. Va. 2010) (refusing to apply Louisiana’s learned intermediary doctrine to a failure-to-warn claim arising out of a prescription drug injury that had occurred there because it would offend the policy of the forum state).

whose narrowest ground for decision favored an exception only in cases of DTCA.<sup>118</sup> At the other extreme from West Virginia's complete rejection of the doctrine, the Arizona Supreme Court recently declined an invitation to follow the lead of *Perez*,<sup>119</sup> though it did allow the plaintiffs to assert misrepresentation claims without facing the obstacle of the learned intermediary rule.<sup>120</sup>

If a court rejects the doctrine outright, then it imposes no greater duty to warn on companies that engage in DTCA than those that do not.<sup>121</sup> Although the baseline may differ from the norm in other states,<sup>122</sup> this position does not single out only those drug manufacturers that advertise (or sell contraceptive products). If, instead, a court allows

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118. See *Tyree v. Bos. Sci. Corp.*, 56 F. Supp. 3d 826, 829–33 (S.D. W. Va. 2014) (declining to apply *Karl* to the manufacturer of an implanted medical device that had not engaged in DTCA). The court's explanation struck me as doubly puzzling: (1) the two separate "concurring" opinions in *Karl* never suggested that they had only concurred in the judgment, and point 3 of the court's official syllabus hardly equivocated about its holding; and (2) only the dissenting opinion had voiced a preference for a DTCA exception. In any event, a couple of years later the state legislature announced its "intention . . . to adopt and allow the development of a learned intermediary doctrine as a defense in cases based upon claims of inadequate warning or instruction for prescription drugs or medical devices," W. VA. CODE ANN. § 55-7-30(b) (West 2018), which plainly abrogated the broader holding in *Karl* at least as applied to future cases, see *J.C. ex rel. Michelle C. v. Pfizer, Inc.*, 814 S.E.2d 234, 238 n.9 (W. Va. 2018), though apparently without foreclosing the possibility that the West Virginia courts eventually might recognize a DTCA exception.

119. See *Watts v. Medicis Pharm. Corp.*, 365 P.3d 944, 950–51 (Ariz. 2016) (explaining that this exception "has been adopted only in New Jersey").

120. See *id.* at 953 (allowing a misrepresentation claim under the state's Consumer Fraud Act). *But see* *Miller v. Pfizer Inc.*, 196 F. Supp. 2d 1095, 1121–23 (D. Kan. 2002) (applying the learned intermediary rule to misrepresentation claims), *aff'd*, 356 F.3d 1326 (10th Cir. 2004).

121. Thus, my argument differs from possible due process objections to broad doctrinal modifications. See *Colby*, *supra* note 9, at 373 (discussing the extent to which "the constitutional right to present every available defense" recognized in the Supreme Court's latest punitive damages decision might constrain "a state's ability to cut back on the defenses available to defendants as a matter of substantive tort law"); *id.* at 376 ("The Court could even hold that due process imposes constitutional limits not just on a state's alteration or application of its procedural rules, but also on its substantive rules—its ability to abolish certain traditional defenses from its substantive tort law."). In his discussion, see *id.*, Professor Colby quoted *Munn v. Illinois*, 94 U.S. 113, 134 (1876) ("Rights of property which have been created by the common law cannot be taken away without due process; but the law itself, as a rule of conduct, may be changed at the will, or even at the whim, of the legislature, unless prevented by constitutional limitations."), but then he suggested that the last clause of this passage might include limits imposed by the very same notions of due process. A more natural (and less circular) reading would look to possible constitutional limitations springing from elsewhere, such as free speech rights, even if incorporated against the states through the Fourteenth Amendment's Due Process Clause (or its adjacent protection of "privileges or immunities"). See U.S. CONST. amend. XIV, § 1. In any event, it seems unlikely that the Court will extend its recent decisions beyond the context of punitive damages. See *Colby*, *supra* note 9, at 380–91.

122. Several courts have declined to follow *Perez* when asked to recognize a DTCA exception. See *In re Meridia Prods. Liab. Litig.*, 328 F. Supp. 2d 791, 812 n.19 (N.D. Ohio 2004), *aff'd*, 447 F.3d 861 (6th Cir. 2006); *In re Norplant Contraceptive Prods. Liab. Litig.*, 215 F. Supp. 2d 795, 812 (E.D. Tex. 2002) ("New Jersey law is in direct conflict with the law of every other jurisdiction in the United States."); see also *Banner v. Hoffmann-La Roche Inc.*, 891 A.2d 1229, 1236–37 (N.J. Super. Ct. App. Div. 2006) (declining to apply the exception where a drug manufacturer simply had provided brochures for physicians to give to their patients); *Centocor, Inc. v. Hamilton*, 372 S.W.3d 140, 162–64 (Tex. 2012) (declining to decide, however, "whether Texas law should recognize a DTC advertising exception when a prescription drug manufacturer distributes intentionally misleading information directly to patients or prospective patients" or adopt "any of the other exceptions to the learned intermediary doctrine"); Twerski, *supra* note 20, at 1151 ("[S]even years have passed [since *Perez*] and nothing has happened.").

misrepresentation claims when consumers have seen and relied upon allegedly deceptive drug advertisements, then it could justify visiting a special burden on companies that engage in DTCA as necessary to discourage false or misleading claims,<sup>123</sup> which apparently represents the sole legitimate grounds for restricting commercial speech.<sup>124</sup> In contrast, the DTCA exception in *Perez*, which imposes special burdens on companies when they advertise—whether or not the advertisements contained any misleading claims, and, even if they had, whether or not the plaintiffs saw and relied upon them—plainly singles out for unfavorable treatment defendants that engage in commercial speech simply because some of the judges in that state have no use for the practice.<sup>125</sup> Thus, even though negative views about DTCA (or contraceptive products) may well permit different doctrinal positions, crafting an exception to the learned intermediary doctrine seems to represent the least defensible choice of all.

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123. A subsidiary question might arise based on the standard of liability for misrepresentations—i.e., intentional (fraudulent), merely negligent, or entirely innocent. See Jerry J. Phillips, *Product Misrepresentation and the First Amendment*, 18 IDAHO L. REV. 395, 400–10 (1982). In line with the view that a strict liability standard applies to product defect actions, consumers may bring claims against sellers even for innocent misrepresentations. See *Hawkinson v. A.H. Robins Co.*, 595 F. Supp. 1290, 1309–10 (D. Colo. 1984); *Crocker v. Winthrop Labs.*, 514 S.W.2d 429, 433 (Tex. 1974) (allowing a claim to proceed against the seller of a prescription analgesic drug for misrepresenting it as nonaddictive); see also RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 9 (AM. LAW INST. 1998); Lars Noah, *Adding Insult to Injury: Paying for Harms Caused by a Competitor's Copycat Product*, 45 TORT TRIAL & INS. PRAC. L.J. 673, 674–75, 684–95 (2010) (criticizing the expansive use of misrepresentation claims against brand-name drug manufacturers for injuries caused by generic versions sold by other companies). Perhaps such an unforgiving standard would pose too great a burden on commercial speech. Cf. *Gertz v. Robert Welch, Inc.*, 418 U.S. 323, 347 (1974) (holding that the Constitution forbids imposing “liability without fault” on a publisher in a defamation action brought by a private figure); *id.* at 340 (“[A] rule of strict liability that compels a publisher or broadcaster to guarantee the accuracy of his factual assertions may lead to intolerable self-censorship.”); *id.* at 347 n.10 (calling this “[o]ur caveat against strict liability”).

124. See *supra* notes 28, 53 and accompanying text. The contraceptive exception may survive heightened scrutiny on other grounds: the FDA already mandates the distribution of PPIs for such products, and enforcing this requirement through tort litigation ensures that patients receive what the federal government has promised them. When, however, the PPI satisfies those FDA requirements, allowing a court to question the adequacy of the warnings does visit an additional burden on companies supplying this market. Furthermore, the agency has mandated patient labeling for dozens of other prescription products, and a few courts have crafted an exception to the learned intermediary doctrine to cover such cases, see *supra* note 72, making it harder to justify a contraceptive-only exception on this basis.

125. See *supra* note 85 and accompanying text; see also Noah, *supra* note 24, at 170 (“[P]roponents of an advertising exception seem to rest their position on what they perceive as crass, profit-motivated advertising of prescription drugs. Once pharmaceutical manufacturers stoop to direct consumer advertising, the argument goes, they no longer deserve the special treatment that they have enjoyed under tort law.”); Twerski, *supra* note 20, at 1149 (“The basis for the rule is seriously undercut when drugs such as Lipitor, Rogaine, Viagra, and Celebrex are huckstered to the public as if they were M&M candies.”); *id.* at 1152 (“If one believes that media advertisement of prescription drugs is a bad idea, one will have little sympathy for providing drug companies with an immunity from liability . . . .”); *id.* at 1154 (“Ultimately, the learned intermediary defense will stand or fall based on whether we view drug advertisements as an important public good or as an avaricious over-reaching by the pharmaceutical manufacturers to force unwanted and unnecessary drugs on the American public.”). This represents precisely the sort of content- and speaker-based restrictions that the U.S. Supreme Court found objectionable even in the context of commercial speech. See *Sorrell v. IMS Health Inc.*, 564 U.S. 552, 564–65 (2011) (“The [prescription data mining] law on its face burdens disfavored speech by disfavored speakers. . . . [T]he law’s express purpose and practical effect are to diminish the effectiveness of marketing by manufacturers of brand-name drugs.”); see also *supra* note 31 (elaborating).

One other feature makes the DTCA exception perhaps more striking than other cases where constitutional objections have worked to limit the scope of tort law. In defamation and related claims, state common law has not singled out speech targeting public figures for enhanced exposure to liability.<sup>126</sup> Instead, the U.S. Supreme Court has worried that generally applicable doctrine may allow jurors and judges to act on their prejudices,<sup>127</sup> which would chill persons wishing to engage in core speech—in short, the First and Fourteenth Amendments necessitate an exemption from the operation of tort rules having general application.<sup>128</sup>

Insofar as commercial speech enjoys somewhat less constitutional protection than political speech, companies would have no basis for demanding special exemption from the threat of liability imposed by jurors harboring a prejudice against advertisers. Nonetheless, companies seemingly do have a basis for demanding that judges expressing such prejudices not shape doctrine in a manner that visits *greater* burdens on those exercising their rights to engage in commercial speech. Although some commentators have questioned the Supreme Court's tendency to treat jury verdicts as having a

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126. *Cf.* Anderson, *supra* note 106, at 95 (“Nothing in the common law of privacy distinguishes between media publicity and nonmedia disclosures; if it did it almost certainly would be unconstitutional for discriminating against the press.”). The defamation torts do, however, broadly target speech, and the First Amendment has limited the common law’s reach even in claims brought by nonpublic figures. In contrast, intentional infliction of emotional distress and other types of tort claims do not spring solely from speech, but the Court has carved out protection in those contexts as well.

127. *See, e.g.*, Snyder v. Phelps, 562 U.S. 443, 458 (2011); *see also* Tilley, *supra* note 114, at 1120 (“[T]he Court identified as state action not just the specific verdict against the Times but the entirety of Alabama libel law as it was applied to litigants generally.”); *id.* at 1139–43 (elaborating); *id.* at 1152 (“[B]y ignoring the prudential practice of defining state action modestly, the Court reached horizontally into the legislative prerogative to devise rules that balance public welfare and speech rights, and reached vertically into the states’ prerogative to develop tort law in accord with their unique cultures.”); *cf. id.* at 1124 (“[T]he Court has followed what appears to be a prudential rule that the relevant state action should be defined at the most granular level possible. As a result, the Court generally considers the actual verdict in the case as the state action, and does not examine the abstract private law rules that produced the verdict.”).

128. *Cf.* Cohen v. Cowles Media Co., 501 U.S. 663, 668–69 (1991) (conceding that state action existed but allowing a promissory estoppel claim against a newspaper for revealing a confidential source, explaining that “generally applicable laws do not offend the First Amendment simply because their enforcement against the press has incidental effects on its ability to gather and report the news”). This test for whether or not recognition of liability might run afoul of the First Amendment has attracted a good deal of criticism. *See, e.g.*, Daniel J. Solove & Neil M. Richards, *Rethinking Free Speech and Civil Liability*, 109 COLUM. L. REV. 1650, 1673–75 (2009); *id.* at 1675 (“Since the level of generality drives the outcomes under the generally applicable law approach, and there is no coherent explanation for how to define the level of generality, the generally applicable law approach ultimately tells us nothing.”).

regulatory effect,<sup>129</sup> particularly in the course of limiting speech torts,<sup>130</sup> doctrinal modifications announced by a state's high court and designed to punish those exercising their First Amendment (or other) rights should make the constitutional analysis fairly straightforward.

For a parallel, consider an old Louisiana statute that deprived abortion providers of the normal limitations on liability enjoyed by physicians when they perform other medical procedures—namely, a forgiving standard of care, an assumption of risk defense, caps on available damages, a shorter statute of limitations, and other procedural advantages.<sup>131</sup> This legislation threatened to impose strict (even absolute) liability for any abortion-related injuries, which would deter health care providers from offering such procedures.<sup>132</sup> The Louisiana statute struck some commentators as especially pernicious

129. This distinction between judges and juries (or doctrinal commands and individual verdicts) occasionally has arisen in federal preemption cases. *See, e.g.,* *Bates v. Dow AgroSciences LLC*, 544 U.S. 431, 443 (2005); *id.* at 445 (“A requirement is a rule of law that must be obeyed; an event, such as a jury verdict, that merely motivates an optional decision is not a requirement.”); *see also* *Wyeth v. Levine*, 555 U.S. 555, 565 (2009) (“[T]he jury verdict established only that Phenergan’s warning was insufficient. It did not mandate a particular replacement warning . . . .”); Christina E. Wells et al., *Preemption of Tort Lawsuits: The Regulatory Paradigm in the Roberts Court*, 40 *STETSON L. REV.* 793, 794–95, 802–03 (2011). Whatever the impact of individual jury verdicts applying obligations and standards framed in broad (or vague) terms, when judges announce in their opinions particular duties owed under a state’s common law in ways that conflict with federal law, little doubt should remain about the proper operation of the Supremacy Clause.

130. *See* Anderson, *supra* note 6, at 768 n.67 (“Sometimes [in applying the First Amendment to speech torts] the Court doesn’t seem to distinguish between the state rule of law and its application by the courts to the case at hand.”); Nathan B. Oman & Jason M. Solomon, *The Supreme Court’s Theory of Private Law*, 62 *DUKE L.J.* 1109, 1165 (2013) (noting “the twice-removed-from-the-sovereign (plaintiff brings action, jury enforces) posture of *Snyder*” v. *Phelps*, 562 U.S. 443 (2011)); *id.* at 1141 (“The state of Maryland, not just a particular jury deputized by it, wants to protect its citizens from emotional harm, the argument goes, by suppressing speech. Attributing this goal to the state, however, is problematic in many respects.”); *id.* at 1143 (questioning the widespread “assumption that the primary goal of state tort law is regulatory”); *id.* at 1161 (“[T]he evolution of First Amendment doctrine, the unitary nature of the state-action doctrine, and the influence of instrumentalist thinking have combined to shape the Court’s view of the role of private law.”); Solove & Richards, *supra* note 128, at 1686–90 (advocating a test that asked instead whether the government had defined a duty rather than simply acted to enforce private ordering undertaken by the parties); *id.* at 1695–97 (explaining that this represented a narrower inquiry than whether state action existed).

131. *See* Liability for Termination of a Pregnancy, 1997 La. Acts, No. 825, § 1 (codified at LA. STAT. ANN. § 9:2800.12(C)(2) (West 2018)); *see also* *Okpalobi v. Foster*, 244 F.3d 405, 424–29, 429 n.40 (5th Cir. 2001) (en banc) (declining to review constitutional challenges to this statute); *Women’s Health Clinic v. State*, 825 So. 2d 1208, 1210–13 (La. Ct. App. 2002) (same). Insofar as the regulation of comparable medical procedures should serve as the baseline for assessing the constitutionality of state-enforced restrictions, *see* Kate L. Fetrow, Note, *Taking Abortion Rights Seriously: Toward a Holistic Undue Burden Jurisprudence*, 70 *STAN. L. REV.* 319, 338, 343–44, 352–53, 356–59, 362 (2018), singling out abortion providers for such disfavored treatment strikes me as particularly objectionable.

132. *See* Jennifer L. Achilles, Comment, *Using Tort Law to Circumvent Roe v. Wade and Other Pesky Due Process Decisions: An Examination of Louisiana’s Act 825*, 78 *TUL. L. REV.* 853, 854–55, 857–60, 880–81 (2004) (discussing the operation and impact of this statute, though incorrectly suggesting on several occasions that it also made abortion providers personally liable for adverse judgments by excluding such claims from coverage under professional liability insurance policies); *see also* Michael Auslen, *Proposal Opens Doctors to Abortion Suits for 10 Years*, *TAMPA BAY TIMES*, Feb. 10, 2017, at A1 (reporting that Florida and Iowa recently considered bills similar to the Louisiana law). Such subtlety seems quaint nowadays. *See* Alan Blinder, *Louisiana Moves to Ban Abortions Once Heartbeat of Fetus Can Be Detected*, *N.Y. TIMES*, May 30, 2019, at



because it largely escaped judicial review,<sup>133</sup> and they warned that the practice could spread beyond abortion.<sup>134</sup> In fact, a few state legislatures have granted rights of action against public interest groups and the media when they dare to criticize perishable agricultural products,<sup>135</sup> which threaten to chill expressive activity without any opportunity for pre-enforcement review.<sup>136</sup>

One critic of the Louisiana statute hypothesized private rights of action allowing claims for emotional distress against persons who burn the American flag or protest in front of abortion clinics.<sup>137</sup> Unlike statutes targeting health care professionals,<sup>138</sup> however, such laws likely would fail to accomplish their goals because the expressive

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A11 (reporting passage of a law prohibiting essentially all abortions, adding that the state's "Department of Health said there were 8,084 abortions performed in Louisiana last year").

133. See Caitlin E. Borgmann, *Legislative Arrogance and Constitutional Accountability*, 79 S. CAL. L. REV. 753, 764–65 (2006); *id.* at 755 ("[A] potent and more insidious form of legislative defiance has emerged—one that is specifically designed to escape judicial review. In this new iteration, state legislatures have burdened or suppressed constitutionally protected conduct, not by banning the targeted conduct outright, but by creating the risk of massive civil liability for engaging in it."); Maya Manian, *Privatizing Bans on Abortion: Eviscerating Constitutional Rights Through Tort Remedies*, 80 TEMP. L. REV. 123, 125–27, 130–33, 142–51 (2007) (explaining that, by exposing physicians to potentially ruinous liability, the Louisiana statute imposed an undue burden on patients wishing to exercise their right to choose but largely escaped judicial review unless an undaunted physician ever faced a private lawsuit and then challenged its constitutionality). In the only reported lawsuit filed under this provision (brought against one of the plaintiff-intervenors in the unsuccessful pre-enforcement challenges), the state courts dismissed the claim as untimely without making any reference to possible constitutional infirmities. See *Doe v. Delta Women's Clinic of Baton Rouge*, 37 So. 3d 1076, 1079–81 (La. Ct. App. 2010); *cf. Filogene v. Brown*, 871 So. 2d 1206, 1207–08 (La. Ct. App. 2004) (declining to apply the law retroactively where the defendant allegedly failed to obtain informed consent in performing an abortion more than four months before the statute's effective date, which meant that the plaintiff first had to submit her claim to a medical review panel).

134. See Borgmann, *supra* note 133, at 756 ("So far, the tactic has been largely confined to the abortion context; however, its potential reach is far broader."); *id.* at 759–61 (imagining extensions); Manian, *supra* note 133, at 148 ("[A] state may deny the fundamental right to choose abortion (or other fundamental rights) by empowering individual citizens to claim enormous damages when those rights are exercised. . . . This possibility poses a grave and growing threat to constitutional rights across the board."); *id.* at 153 ("One could imagine any number of state tort statutes written to directly challenge [U.S.] Supreme Court decisions on fundamental rights yet evade judicial review."); *id.* at 161–63 (elaborating); *id.* at 198–99 ("If tort statutes are categorically immune from pre-enforcement review, there is no logical limit to state officials' ability to violate constitutional rights through the use of ostensibly 'private' tort remedies.").

135. See Lars Noah, *Giving Personal Injury Attorneys Who Run Misleading Drug Ads a Dose of Their Own Medicine*, 2019 U. ILL. L. REV. 701, 725 & n.127 (noting that "several states have enacted legislation to create a private right of action against anyone who improperly questions the safety of certain agricultural goods").

136. See *Action for Clean Env't v. State*, 457 S.E.2d 273, 274 (Ga. Ct. App. 1995) (declining to review constitutional objections to such a statute); David J. Bederman et al., *Of Banana Bills and Veggie Hate Crimes: The Constitutionality of Agricultural Disparagement Statutes*, 34 HARV. J. ON LEGIS. 135, 150–68 (1997); see also Eileen Gay Jones, *Forbidden Fruit: Talking About Pesticides and Food Safety in the Era of Agricultural Product Disparagement Laws*, 66 BROOK. L. REV. 823, 856 (2000) ("Silencing critics of agricultural products is the primary goal."). *But see* Lisa Dobson Gould, Note, *Mad Cows, Offended Emus, and Old Eggs: Perishable Product Disparagement Laws and Free Speech*, 73 WASH. L. REV. 1019, 1037–48 (1998) (defending the constitutionality of these statutes).

137. See Manian, *supra* note 133, at 153, 161–62.

138. See Achilles, *supra* note 132, at 882 ("[I]magine a law making a doctor civilly liable for prescribing birth control. Pharmacists might also be liable for distributing the birth control.").

conduct of judgment-proof defendants will hardly get chilled by the empty threat of civil liability.<sup>139</sup> Nonetheless, these hypothetical enactments would threaten to directly penalize persons exercising their constitutional rights, while the Louisiana statute only indirectly (though still unconstitutionally) burdens those wishing to procure an abortion by making it harder to locate willing providers.

Manufacturers of a product targeted by comparable legislation would find it easier than an individual health care professional to take their chances and invoke the constitutional rights of their customers to fend off the application of this kind of state law when later subject to a tort claim.<sup>140</sup> Moreover, this Article focuses on tort doctrines announced by judges, which should provide a ready opportunity to question the constitutionality of novel rules in the course of the litigation that initially leads to their announcement, though in practice products liability defendants typically fail to bother doing so.<sup>141</sup> In any case, if courts have the occasion to consider such a challenge, then they should recognize that doctrinal modifications cannot single out certain defendants for unfavorable treatment simply because they choose to exercise their federal constitutional rights in ways not to the liking of, for instance, liberal judges in New Jersey any more so than conservative legislators in Louisiana.

## II. THE NEXT STEP: SPECIAL IMMUNITIES FOR CONSTITUTIONALLY SACROSANCT PRODUCTS?

As noted at the outset, one commentator recently argued that the Second Amendment would serve to limit the liability of gun manufacturers.<sup>142</sup> If that position has merit, then it would seem that other types of products should enjoy special protections from the threat of tort liability as well. Perhaps the fact that no one has ever

139. See generally Stephen G. Gilles, *The Judgment-Proof Society*, 63 WASH. & LEE L. REV. 603 (2006).

140. For instance, one commentator imagined that state “legislatures could inhibit the sale of guns by imposing huge damage awards against gun manufacturers, distributors, and retailers for any harm caused by a gun.” Borgmann, *supra* note 133, at 761; cf. Blocher & Miller, *supra* note 16, at 346 (“[P]ermitt[ing] punitive damages only for reckless use of a firearm, but not for reckless use of a vehicle, could justify the application of constitutional scrutiny.”). Wholly apart from my suggestion in the main text that this class of defendants could better afford to test the constitutionality of such an existential threat to their core business, Ms. Borgmann neglected to recognize that one year earlier Congress had expressly preempted the bulk of such claims. See Protection of Lawful Commerce in Arms Act, Pub. L. No. 109-92, §§ 2–4, 119 Stat. 2095, 2095–99 (2005) (codified at 15 U.S.C. §§ 7901–7903 (2018)); see also *City of New York v. Beretta U.S.A. Corp.*, 524 F.3d 384, 392–98 (2d Cir. 2008) (rejecting various constitutional objections to this statute). Then again, absent the opportunity to pursue a pre-enforcement challenge in this hypothetical, such defendants would not be certain of ultimate success in using the Supremacy Clause (like any other constitutional defense) to invalidate the state-created private right of action lodged against them.

141. See Phillips, *supra* note 123, at 396 (“What, if any, effect does the first amendment have on the rules pertaining to strict liability and punitive damages in products liability? There has been remarkably little litigation on these issues . . . .”); *id.* at 400 (“Since it cannot be expected that a highly capable defense bar would consistently overlook a major basis for significantly restricting strict liability in products litigation, it must be assumed that a first amendment defense is for some reason thought inappropriate in products litigation involving failure to warn . . . [or] misrepresentation.”).

142. See Jacobs, *supra* note 1, at 986–89; see also Tilley, *supra* note 114, at 1136 n.81 (noting other possible uses of this right in private litigation); cf. Phillips, *supra* note 1, at 1339 (“Curiously, the Second Amendment to the U.S. Constitution and similar state constitutional provisions have not usually been raised as defenses in these cases.”).

before suggested as much provokes justified skepticism about the argument of those preoccupied with guns; otherwise, courts will have to retool their products liability doctrine to carve out any number of other constitutionally valued consumer goods.

In fact, sellers of books that contain potentially hazardous misinformation often enjoy special protection from the prospect of tort liability thanks in part to concerns derived from constitutional safeguards for free speech.<sup>143</sup> In particular, several courts have explained that books do not qualify as products because the prospect of visiting strict liability on sellers would run afoul of the Supreme Court's standards for recovery in cases of defamation.<sup>144</sup> Although this view would leave open the possibility of negligent misrepresentation or similar claims predicated upon some showing of fault, in practice even these theories offer little prospect of recovery for injured readers.<sup>145</sup>

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143. See, e.g., *Winter v. G.P. Putnam's Sons*, 938 F.2d 1033, 1037 (9th Cir. 1991) (rejecting negligence claims against a book publisher after noting "the gentle tug of the First Amendment and the values embodied therein"); *Alm v. Van Nostrand Reinhold Co.*, 480 N.E.2d 1263, 1267 (Ill. App. Ct. 1985) ("Even if liability could be imposed consistently with the Constitution, we believe that the adverse effect of such liability upon the public's free access to ideas would be too high a price to pay."); see also Richard C. Ausness, "The Disorderly Conduct of Words": *Civil Liability for Injuries Caused by the Dissemination of False or Inaccurate Information*, 65 S.C. L. REV. 131, 157–89 (2013) (providing an exhaustive description of the available case law); *id.* at 187–88 (summarizing judicial references to constitutional concerns); *id.* at 210 ("Time and time again, courts have expressed concern that holding book publishers and others liable would create a chilling effect . . ."); Lars Noah, *Authors, Publishers, and Products Liability: Remedies for Defective Information in Books*, 77 OR. L. REV. 1195, 1197 (1998) ("[C]ourts have treated books unlike other mass-produced commercial products, often citing policies derived from the First Amendment's protections against governmental interference with free speech for their special treatment."); *id.* at 1218 ("In rejecting tort claims against authors and publishers, courts routinely invoke the First Amendment or its underlying values as expressing a public policy against chilling speech."); *cf. id.* at 1219 ("To the extent that courts simply invoke a policy argument informed by constitutional values, they provide scant support for their fears of chilling authors and publishers.")

144. See, e.g., *Winter*, 938 F.2d at 1035 ("We place a high priority on the unfettered exchange of ideas. . . . The threat of liability without fault . . . could seriously inhibit those who wish to share thoughts and theories."); *Cardozo v. True*, 342 So. 2d 1053, 1056–57 (Fla. Dist. Ct. App. 1977); see also RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 19 cmt. d (AM. LAW INST. 1998) ("Most courts, expressing concern that imposing strict liability for the dissemination of false and defective information would significantly impinge on free speech have, appropriately, refused to impose strict products liability in these cases."); *cf. id.* (suggesting that "the better view is that false information in such documents [i.e., maps and navigational charts] constitutes a misrepresentation that the user may properly rely upon").

145. See, e.g., *Gorran v. Atkins Nutritionals, Inc.*, 464 F. Supp. 2d 315, 325–28 (S.D.N.Y. 2006) (dismissing negligent misrepresentation and other claims against the source of diet books, products, and a website that recommended consumption primarily of high-fat and high-protein foods, concluding that the information qualified as fully protected noncommercial speech), *aff'd*, 279 F. App'x 40, 41–42 (2d Cir. 2008); *Smith v. Linn*, 563 A.2d 123, 124–27 (Pa. Super. Ct. 1989) (rejecting negligent misrepresentation and strict products liability claims brought on behalf of the reader of a diet book who died of complications associated with the diet), *aff'd*, 587 A.2d 309 (Pa. 1991); see also Ausness, *supra* note 143, at 185 ("For the most part, courts have also rejected negligence and negligent misrepresentation claims . . ."); *id.* at 210–11 (same); Noah, *supra* note 143, at 1209–10 & n.43; *id.* at 1196 ("[A]part from libel claims, [books] are rarely the subject of tort litigation."); *id.* at 1210 ("[C]ourts often conclude that publishers have no duty of care running to readers unless they were involved in the process of authorship. This distinguishes negligence from strict products liability, which generally applies to all persons in the chain of distribution." (footnote omitted)); *id.* at 1216 ("[S]ome courts have expressed concerns about imposing potentially ruinous liability and excessive fact-checking or verification obligations on editors and publishers."); *cf. Lars Noah, Medicine's Epistemology: Mapping the Haphazard Diffusion of Knowledge in the Biomedical Community*, 44 ARIZ. L. REV. 373, 464–65 (2002) (discussing the potential liability of third parties that supply inaccurate information about therapeutic products).

In contrast to books, contraceptives enjoy no immunity from the normal operation of products liability doctrine.<sup>146</sup> As discussed previously, the handful of jurisdictions that recognize an exception to the learned intermediary rule for contraceptive products thereby have imposed a special burden on their sale.<sup>147</sup> Here, instead, the question asks whether courts must free the sellers of contraceptive drugs and devices from the operation of generally applicable rules governing claims of, for instance, defective design. Under longstanding constitutional doctrine, contraceptives enjoy heightened protection against state restrictions.<sup>148</sup> The lengthy history of tort litigation against sellers of these products reveals, however, absolutely no suggestion that the Fourteenth Amendment might place some outer boundary on these lawsuits.

The constitutional decisions focused on an individual's right of contraceptive access and use rather than a seller's right of production and distribution,<sup>149</sup> but the Court has recognized that these represent two sides of the same coin.<sup>150</sup> Nonetheless, in the

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146. See Jay M. Zitter, Annotation, *Liability of Manufacturer or Seller for Injury or Death Allegedly Caused by Use of Contraceptive*, 54 A.L.R.5th 1, § 2(a) (1997 & 2018 Supp.) (“The reported cases in which the courts have considered the liability of manufacturers or sellers of contraceptive products have primarily relied on the same general rules or principles generally applied in actions dealing with products liability for pharmaceuticals.”).

147. See *supra* notes 69, 124 and accompanying text; cf. *Bolger v. Youngs Drug Prods. Corp.*, 463 U.S. 60, 68–75 (1983) (holding unconstitutional a federal law with origins in the Comstock Act enacted in 1873, which prohibited mailings of unsolicited contraceptive advertisements, when applied to a condom manufacturer wishing to distribute flyers and informational pamphlets); *id.* at 69 (“[A]dvertising for contraceptives not only implicates . . . the free flow of commercial information, but also relates to activity which is protected from unwarranted state interference.”). In fact, such an exception might have consequences beyond failure-to-warn claims, potentially exposing sellers to greater liability for defective designs as well. See Noah, *supra* note 60, at 895–96 (“If an exception to the learned intermediary rule covers a particular case, such as [contraceptives] . . . , would that also render inapplicable the [Restatement’s] protective design defect standard . . . ?”); see also *Shanks v. Upjohn Co.*, 835 P.2d 1189, 1195 n.7 (Alaska 1992) (“In strict liability design defect cases involving such products [e.g., contraceptives], it may be appropriate to apply the ‘ordinary consumer expectation’ test rather than the ‘ordinary doctor expectation test.’”).

148. See *Carey v. Population Servs. Int’l*, 431 U.S. 678, 686–91 (1977) (invalidating New York law that allowed only pharmacists to dispense OTC contraceptives); *id.* at 691–99 (plurality opinion) (invalidating provision that barred almost all contraceptive access for individuals under 16-years-of-age); *Eisenstadt v. Baird*, 405 U.S. 438, 447–55 (1972) (invalidating Massachusetts law that prohibited their distribution to unmarried individuals as irrational under the Equal Protection Clause); *Griswold v. Connecticut*, 381 U.S. 479, 485–86 (1965) (invalidating Connecticut prohibition as infringing marital right of privacy); see also Justin Driver, *Constitutional Outliers*, 81 U. CHI. L. REV. 929, 971 (2014) (“While Connecticut and Massachusetts were alone in prohibiting all sale and distribution of contraceptives, more than half of the states in the nation joined them with statutes forbidding advertisements for contraceptives. Nearly one-third of the states, moreover, had laws permitting only certain authorized medical professionals to distribute contraceptives.” (footnote omitted)). See generally Ryan C. Williams, *The Paths to Griswold*, 89 NOTRE DAME L. REV. 2155 (2014).

149. See *Burwell v. Hobby Lobby Stores, Inc.*, 573 U.S. 682, 727 (2014) (citing *Griswold* for the proposition that “[u]nder our cases, women (and men) have a constitutional right to obtain contraceptives”); *Planned Parenthood of Se. Pa. v. Casey*, 505 U.S. 833, 852 (1992) (plurality opinion) (reading *Griswold* and its progeny as protecting “the decision to use contraception”); see also Lars Noah, *State Affronts to Federal Primacy in the Licensure of Pharmaceutical Products*, 2016 MICH. ST. L. REV. 1, 46 (“The Supreme Court has treated choices about procreation as central aspects of a person’s liberty and associated rights to privacy.”).

150. See *Carey*, 431 U.S. at 687–88 (“A total prohibition against sale of contraceptives, for example, would intrude upon individual decisions in matters of procreation and contraception as harshly as a direct ban on their use. Indeed, . . . since more easily and less offensively enforced, [it] might have an even more devastating effect . . . .”); cf. *Jacobs*, *supra* note 1, at 987 (“[T]he right to sell and manufacture firearms must be part of the

event of tort litigation, the plaintiff (a member of the class of right holders) presumably will resist the vicarious invocation of those rights by the defendant, which represents an alignment that differs from that found in defamation claims.<sup>151</sup> Furthermore, special constitutional status does not inevitably mean immunity from suit, though states might well struggle to justify the undue burden created by expansive exposure to liability.<sup>152</sup>

Contraceptive drugs and devices have encountered a good deal of design defect litigation. In the early 1970s, for instance, scientists found that oral contraceptives containing high doses of estrogen posed a greater risk of cerebral thrombosis, and, even though it now appears that lower-dose versions did not work quite as well,<sup>153</sup> at the time it seemed that the high-dose products offered no advantage in preventing pregnancy. Physicians sometimes prescribed the higher-dose versions to patients who suffered breakthrough bleeding when using the lower-dose products, a bothersome side effect that may reduce patient compliance with daily dosing directions and, thereby, reduce effectiveness in practice, but courts typically left an analysis of this trade-off to juries.<sup>154</sup>

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core of the Second Amendment right, since it would be impossible for citizens to keep arms for self-defense in the home without the ability to purchase firearms.”); *id.* at 987–88 (conceding, however, that “‘laws imposing conditions and qualifications on the commercial sale of arms’ were presumptively lawful” (quoting *District of Columbia v. Heller*, 554 U.S. 570, 626–27 (2008))). Similarly, while the abortion right resides with pregnant women, physicians have long enjoyed standing to assert that right in challenging restrictions on behalf of their patients. *See Singleton v. Wulff*, 428 U.S. 106, 117–18 (1976) (plurality opinion); *see also Whole Woman’s Health v. Hellerstedt*, 136 S. Ct. 2292, 2321–23 (2016) (Thomas, J., dissenting) (criticizing the loosening of third-party standing doctrine, though conceding that “since *Singleton*, the Court has unquestioningly accepted doctors’ and clinics’ vicarious assertion of the constitutional rights of hypothetical patients”).

151. *See infra* note 172 and accompanying text. In the context of speech torts, defendants represent the directly affected rights holders, while private plaintiffs must attempt to defend the constitutionality of the state’s liability regime. *See Anderson, supra* note 106, at 94–96 (explaining that victims would have to invoke the state’s interest); *cf. Anderson, supra* note 6, at 805 (“Nor is it necessary for the speaker to claim that its own future speech will be deterred, and typically they do not. The claim is that the tort law chills the speech of others.”).

152. *Cf. Noah, supra* note 149, at 52 (“The act of federal licensure, even if not enough to trigger implied preemption under the Supremacy Clause, seems to make the state’s burden of justification nearly impossible in the event that some form of heightened scrutiny applies.”).

153. *See Anna Wilde Mathews, FDA Mulls Birth-Control Standards*, WALL ST. J., Jan. 19, 2007, at B5; *see also Michael Mason, Pressing to Look Closer at Blood Clots and the Pill*, N.Y. TIMES, Feb. 13, 2007, at F5 (reporting that “third-generation” low-dose contraceptives also may pose heightened risks); *U.S. Orders Review of Risks of Some Birth Control Pills*, N.Y. TIMES, June 1, 2011, at B5 (reporting that a pair of recent studies found up to a threefold greater risk of blood clots in women taking drospirenone (e.g., Yaz®) than other oral contraceptives). In the event of a contraceptive failure, a woman might have a “wrongful pregnancy” claim against the manufacturer. *See Willis v. Wu*, 607 S.E.2d 63, 66 (S.C. 2004) (distinguishing this from a wrongful life claim); *see also Gersh Kuntzman, 117 Sue over Pill Babies*, N.Y. DAILY NEWS, Nov. 14, 2015, at 12 (discussing litigation that arose after a packaging error led to out-of-sequence oral contraceptive pills and several accidental pregnancies); *cf. Doherty v. Merck & Co.*, 154 A.3d 1202, 1206–07 (Me. 2017) (holding that a state statute barring wrongful birth claims protected the manufacturer of a long-acting contraceptive).

154. *See, e.g., Brochu v. Ortho Pharm. Corp.*, 642 F.2d 652, 654–55, 655 n.4 (1st Cir. 1981); *Ortho Pharm. Corp. v. Heath*, 722 P.2d 410, 414–16 (Colo. 1986); *Glassman v. Wyeth Lab.*, 606 N.E.2d 338, 340–41, 343 (Ill. App. Ct. 1992). Transdermal patches might reduce concerns about patient noncompliance, but these contraceptive products carry their own set of problems. *See Anne Marie Chaker, Doctors Back off Birth-Control Patch*, WALL ST. J., Nov. 22, 2005, at D1 (reporting that the FDA has added a warning about elevated estrogen levels associated with a once-a-week transdermal product); Dawn Fallik, *Experts: Patches + Heat = Danger*, PHILA. INQUIRER, Mar. 5, 2006, at A1 (describing some of the resulting litigation); Gardiner Harris & Alex Berenson, *Drug Makers Near Old Goal: A Legal Shield*, N.Y. TIMES, Apr. 6, 2008, at A1 (“More than 3,000

Intrauterine devices (IUDs) also have triggered significant products liability litigation, including claims that certain types of these contraceptives suffered from design defects. Many of the earliest cases involved unmistakable negligence by the manufacturer and even justified the imposition of punitive damages.<sup>155</sup> More recent targets of such lawsuits have posed far closer questions about the risks and utility of a chosen design.<sup>156</sup> The threat of such seemingly open-ended tort liability reportedly has caused companies to shy away from developing new birth control products.<sup>157</sup>

Although they may offer the clearest example, contraceptives hardly exhaust the range of products that may deserve constitutional protection from the prospect of strict liability.<sup>158</sup> The U.S. Supreme Court has treated most choices related to procreation as central aspects of a person's liberty and associated rights to privacy.<sup>159</sup> A variety of

women and their families have sued Johnson & Johnson, asserting that users of the Ortho Evra patch suffered heart attacks, strokes and, in 40 cases, death.”).

155. The most notorious involved the Dalkon Shield, which used a multifilament tail string that transferred bacteria into the uterus at a far higher rate than other IUDs, causing pelvic inflammatory disease and occasional septic abortions. *See, e.g.,* Tetuan v. A.H. Robins Co., 738 P.2d 1210, 1216–24, 1241 (Kan. 1987) (summarizing the history of this product disaster, and affirming a sizeable judgment for one plaintiff asserting primarily fraud claims). In the end, the Dalkon Shield caused more than two hundred thousand injuries and almost twenty deaths in the United States. *See generally* RONALD J. BACIGAL, *THE LIMITS OF LITIGATION: THE DALKON SHIELD CONTROVERSY* (1990); Georgene M. Vairo, *The Dalkon Shield Claimants Trust: Paradigm Lost (or Found)?*, 61 *FORDHAM L. REV.* 617 (1992).

156. For instance, some lawsuits alleged design defects against the maker of the Cu-7, an IUD containing copper, based on allegations that the use of a polypropylene withdrawal string was more likely than a polyethylene string to retract into the uterus where it might cause a perforation or pelvic inflammatory disease. *See, e.g.,* Amore v. G.D. Searle & Co., 748 F. Supp. 845, 847, 854 (S.D. Fla. 1990); Adams v. G.D. Searle & Co., 576 So. 2d 728, 732–34 (Fla. Dist. Ct. App. 1991) (reversing summary judgment for defendant on design defect claim); *see also In re Mirena IUD Prods. Liab. Litig.*, 713 F. App'x 11, 15–16 (2d Cir. 2017) (affirming summary judgment granted to the manufacturer because the plaintiffs lacked admissible evidence that their IUDs could perforate the uterus and migrate after successful insertion).

157. *See* INST. OF MED., *CONTRACEPTIVE RESEARCH AND DEVELOPMENT: LOOKING TO THE FUTURE* 21–23 (Polly F. Harrison & Allan Rosenfield eds., 1996); William M. Brown, *Déjà Vu All over Again: The Exodus from Contraceptive Research and How to Reverse It*, 40 *BRANDEIS L.J.* 1, 1–2, 29–34 (2001); Tamar Lewin, *Searle, Assailing Lawsuits, Halts U.S. Sales of Intrauterine Devices*, *N.Y. TIMES*, Feb. 1, 1986, § 1, at 1 (“With the company’s withdrawal, this type of birth control device [i.e., the IUD] will no longer be available in this country.”); *see also* Laurie McGinley, *After Lawsuits over Safety, Bayer to Stop Sales of Essure Birth-Control Device*, *WASH. POST*, July 21, 2018, at A4 (reporting that the manufacturer of an FDA-approved device, which offered a nonsurgical alternative to tubal ligation for sterilization, ceased marketing after it had “been served with lawsuits representing more than 16,000 patients”); *supra* note 76 (explaining that litigation helped to drive Norplant off of the market); *cf.* Sabrina Tavernise, *Women’s Use of Long-Acting Birth Control Methods Is Surging*, *U.S. Agency Reports*, *N.Y. TIMES*, Nov. 10, 2015, at A13 (noting that IUDs have become more popular). *See generally* Lars Noah, *Triage in the Nation’s Medicine Cabinet: The Puzzling Scarcity of Vaccines and Other Drugs*, 54 *S.C. L. REV.* 741, 743, 759–64 (2003) (discussing exposure to tort liability as one cause for supply shortages).

158. Indeed, one might argue that all therapeutic products deserve special protection under substantive due process, *see* Noah, *supra* note 149, at 42–53, but cobbling together a fundamental right of noninterference in accessing FDA-approved drugs and devices takes a good deal more work than necessary to make my point here about the possible undue burdens of products liability doctrine for an unmistakably protected subset of therapeutic items.

159. *See, e.g.,* Lawrence v. Texas, 539 U.S. 558, 564–66, 573–74 (2003); Hodgson v. Minnesota, 497 U.S. 417, 434 (1990) (plurality opinion) (“A woman’s decision to conceive or to bear a child is a component of her liberty that is protected by the Due Process Clause . . . .”); Carey v. Population Servs. Int’l, 431 U.S. 678,

pharmaceuticals enjoy recognized uses in either terminating or sustaining a pregnancy, and the manufacturers of several of these products have faced tort litigation that could well discourage them from continuing to serve the constitutionally protected choices of these patients.

For instance, the abortifacient drug mifepristone, which only works during the first trimester of pregnancy (long before viability), might pose the issues rather starkly.<sup>160</sup> Although not yet the subject of much tort litigation,<sup>161</sup> abortifacients could become less readily available unless granted some protection from the full brunt of products liability doctrine.<sup>162</sup> Moreover, if drugs useful in avoiding or terminating a pregnancy enjoy constitutional safeguards against demanding scrutiny under tort law, then the same rationales seemingly would extend to drugs used to treat infertility,<sup>163</sup> to guard against

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685 (1977) (“The decision whether or not to beget or bear a child . . . holds a particularly important place in the history of the right of privacy . . . [D]ecisions whether to accomplish or to prevent conception are among the most private and sensitive.”); *see also* Lars Noah, *Too High a Price for Some Drugs?: The FDA Burdens Reproductive Choice*, 44 SAN DIEGO L. REV. 231, 248–50 (2007).

160. *See* Lars Noah, *A Miscarriage in the Drug Approval Process?: Mifepristone Embroils the FDA in Abortion Politics*, 36 WAKE FOREST L. REV. 571, 599–603 (2001) (explaining that state restrictions would violate the Constitution); Noah, *supra* note 149, at 18–19 (discussing more recent state laws mandating strict adherence to the FDA-approved instructions for use and the split among federal appellate courts assessing constitutional challenges); *see also* Erik Eckholm, *Arizona Governor Signs Abortion Bill That Skirts F.D.A. Decision*, N.Y. TIMES, Apr. 2, 2016, at A8 (reporting that, immediately after the FDA approved directions for the expanded use of mifepristone, one state reacted by mandating continued adherence to the now obsolete older protocol). In the course of recently invalidating restrictions in a Texas statute, which required that abortion providers work in a facility on par with an ambulatory surgical center and have admitting privileges at a nearby hospital, the U.S. Supreme Court noted that “the surgical-center requirement provides no benefit when complications arise in the context of an abortion produced through medication.” *Whole Woman’s Health v. Hellerstedt*, 136 S. Ct. 2292, 2315 (2016). *But cf.* *Planned Parenthood Ark. & E. Okla. v. Jegley*, 864 F.3d 953, 959–61 (8th Cir. 2017) (vacating, because of insufficient findings of an undue burden, a preliminary injunction of an Arkansas statute that required physicians wishing to provide access to abortifacient drugs to enter into a contract with another physician with hospital privileges in order to handle any complications), *cert. denied*, 138 S. Ct. 2573 (2018). The Court may, however, revisit that decision. *See* *June Med. Servs., L.L.C. v. Gee*, 905 F.3d 787, 805–15 (5th Cir. 2018) (rejecting a facial challenge to Louisiana’s admitting privileges requirement applicable to both surgical and medication abortions), *cert. granted*, No. 18-1323, 2019 WL 4889929 (U.S. Oct. 4, 2019).

161. *See, e.g.*, *Sheppard-Mobley v. King*, 830 N.E.2d 301, 303 (N.Y. 2005) (summarizing tort claims brought on behalf of an infant whose mother declined to undergo a surgical abortion after a nonsurgical attempt using methotrexate failed and caused serious birth defects). The lack of reported tort litigation involving mifepristone may come as a surprise—after all, it remains a lightning rod for controversy. *See* David Crary, *Abortion Pill Remains Controversial*, WASH. POST, Oct. 3, 2010, at A3; *see also* Pam Belluck & Jan Hoffman, *Medical Gains Are Reshaping Abortion Fight*, N.Y. TIMES, July 2, 2018, at A1 (“In 2013, nearly a quarter of abortions were accomplished with medication . . .”).

162. *See* Leslie A. Rubin, Note, *Confronting a New Obstacle to Reproductive Choice: Encouraging the Development of RU-486 Through Reform of Products Liability Law*, 18 N.Y.U. REV. L. & SOC. CHANGE 131, 144–48 (1991); *see also id.* at 145 (“[A]s long as some abortions remain constitutionally protected, it should be difficult for a state court to determine that a highly safe and efficient means of securing an abortion is not desirable and thus not worthy of protection [from strict liability].”); *id.* at 133 (“[P]rotecting manufacturers from excessive liability . . . does not stem from concern for the plight of manufacturers, but from concern for the plight of women who are denied access to this important drug.”).

163. *See, e.g.*, *Lust v. Merrell Dow Pharm., Inc.*, 89 F.3d 594, 596–98 (9th Cir. 1996) (affirming the exclusion of unreliable testimony from the plaintiff’s expert seeking to link the fertility drug Clomid® (clomiphene) to a particular birth defect); *see also* Lars Noah, *Assisted Reproductive Technologies and*

miscarriage or preterm labor,<sup>164</sup> or to otherwise serve a therapeutic purpose in sustaining a pregnancy.<sup>165</sup>

Even the checkered history of diethylstilbestrol (DES) begins to look different when using a constitutional lens. Although the discovery of serious risks from *in utero* exposure rendered its continued use in the prevention of miscarriages unjustified, especially in light of doubts that it ever worked for that purpose,<sup>166</sup> the drug had other legitimate uses, including as a contraceptive.<sup>167</sup> The wave of DES lawsuits prompted several courts to adopt innovative rules to help plaintiffs overcome problems that they would otherwise encounter in identifying the source of the product ingested by their mothers while pregnant.<sup>168</sup> For the most part, courts have declined to extend “market

*the Pitfalls of Unregulated Biomedical Innovation*, 55 FLA. L. REV. 603, 635 & n.133 (2003) (noting the relative infrequency of claims asserted against manufacturers); *id.* at 648 (suggesting that a “plaintiff might argue that—in light of the current state of the art—the older fertility drugs are defectively designed insofar as the risk of multifetal pregnancy now outweighs their limited benefits when compared with alternative, safer” assisted reproductive technologies, including procedures such as *in vitro* fertilization); *id.* at 659–65 (offering a constitutional defense of a hypothetical ban on fertility drugs).

164. *See, e.g.*, *Tobin v. Astra Pharm. Prods., Inc.*, 993 F.2d 528, 540 (6th Cir. 1993) (affirming a judgment for the plaintiff against the seller of the tocolytic agent Yutopar® (ritodrine)); *see also* Noah, *supra* note 60, at 869–71 (criticizing the *Tobin* decision).

165. *See, e.g.*, *Richardson v. Richardson-Merrell, Inc.*, 857 F.2d 823, 824 (D.C. Cir. 1988); *Brown v. Superior Ct.*, 751 P.2d 470, 479 (Cal. 1988) (“Ben[de]ctin, the only antinauseant drug available for pregnant women, was withdrawn from sale in 1983 because the cost of insurance almost equalled the entire income from sale of the drug. Before it was withdrawn, the price of Ben[de]ctin increased by over 300 percent.”); *see also* Lars Noah, *Civil Jury Nullification*, 86 IOWA L. REV. 1601, 1656–57 (2001) (recounting birth defect litigation involving the morning sickness drug Bendectin® (doxylamine with pyridoxine)).

166. *See, e.g.*, *Gray v. United States*, 445 F. Supp. 337, 339–42 (S.D. Tex. 1978) (rejecting a claim under the Federal Tort Claims Act against the FDA for originally having approved DES for use during pregnancy without warning of its risks); *Payton v. Abbott Labs.*, 437 N.E.2d 171, 182 (Mass. 1982) (“[W]e hold that if the trier of fact finds that a preponderance of the credible evidence supports the conclusion that a particular plaintiff would not have been born except for her mother’s ingestion of DES, the plaintiff is barred from recovery.”); *Bichler v. Eli Lilly & Co.*, 436 N.E.2d 182, 188–90 (N.Y. 1982) (allowing plaintiff’s claim that a DES manufacturer could have discovered reproductive toxicity if it had undertaken rodent testing); *see also* Notice, *Certain Estrogens for Oral or Parenteral Use*, 36 Fed. Reg. 21,537, 21,538 (Nov. 10, 1971) (ordering that DES manufacturers label the drug as contraindicated for further use in pregnancy); Robert N. Hoover et al., *Adverse Health Outcomes in Women Exposed In Utero to Diethylstilbestrol*, 365 NEW ENG. J. MED. 1304 (2011); Leef Smith, *The DES Legacy*, WASH. POST, Sept. 23, 2003, at F1.

167. *See* *Diethylstilbestrol as Postcoital Oral Contraceptive; Patient Labeling*, 40 Fed. Reg. 5351, 5354–55 (Feb. 5, 1975) (codified at 21 C.F.R. § 310.501(b) (1988)), *revoked*, 54 Fed. Reg. 22,585, 22,586 (May 25, 1989); *cf.* *Smith v. Eli Lilly & Co.*, 560 N.E.2d 324, 328 (Ill. 1990) (“Although DES is no longer used during pregnancy, it is . . . a major ingredient in the ‘morning after’ pill, a post-coital contraceptive.”).

168. *See, e.g.*, *Sindell v. Abbott Labs.*, 607 P.2d 924, 936–38 (Cal. 1980), *modified*, *Brown*, 751 P.2d at 485–87; *Conley v. Boyle Drug Co.*, 570 So. 2d 275, 282–87 (Fla. 1990); *Collins v. Eli Lilly Co.*, 342 N.W.2d 37, 49–53 (Wis. 1984). *But see, e.g.*, *Galvin v. Eli Lilly & Co.*, 488 F.3d 1026, 1031 (D.C. Cir. 2007) (applying Kansas law to reject DES market share liability claim); *Wood v. Eli Lilly & Co.*, 38 F.3d 510, 513–14 (10th Cir. 1994) (same, applying Oklahoma law); *Sutowski v. Eli Lilly & Co.*, 696 N.E.2d 187, 193 (Ohio 1998). *See generally* RESTATEMENT (THIRD) OF TORTS: LIAB. FOR PHYSICAL AND EMOTIONAL HARM § 28 cmt. p (AM. LAW INST. 2010) (“[We previously] left the matter to the developing law. Since publication of the Products Liability Restatement [in 1998], there have been no developments that would justify the Institute changing course. The lack of activity in this area may reflect the declining significance of the issue . . .”).



share” principles beyond DES,<sup>169</sup> which again offers an illustration of sellers of a drug that might deserve some added constitutional protection getting singled out for unfavorable treatment under state tort law. Indeed, under the strictest version of market share liability, defendants able to demonstrate that they could not possibly have supplied the dose that injured a particular plaintiff cannot escape partial responsibility,<sup>170</sup> though sellers of DES labeled for non-pregnancy uses get off the hook.<sup>171</sup>

In contrast to the typical alignment in speech tort cases, the plaintiffs in these lawsuits do not mind declining to invoke their constitutional rights to unimpeded access,<sup>172</sup> and it may seem strange to argue against recognizing a right to recover for

169. See, e.g., *Sanderson v. Int'l Flavors & Fragrances, Inc.*, 950 F. Supp. 981, 991–93 (C.D. Cal. 1996) (perfumes containing aldehydes); *George v. Housing Auth. of New Orleans*, 906 So. 2d 1282, 1287 (La. Ct. App. 2005) (smoke detectors); *Hamilton v. Beretta U.S.A. Corp.*, 750 N.E.2d 1055, 1066–68 (N.Y. 2001) (handguns); *In re N.Y. State Silicone Breast Implant Litig.*, 631 N.Y.S.2d 491, 494 (Sup. Ct. 1995), *aff'd mem.*, 650 N.Y.S.2d 558 (App. Div. 1996); *Black v. Abex Corp.*, 603 N.W.2d 182, 189–91 (N.D. 1999) (asbestos friction products); *Skipworth ex rel. Williams v. Lead Indus. Ass'n*, 690 A.2d 169, 172–73 (Pa. 1997) (lead paint). *But see, e.g., State v. Exxon Mobil Corp.*, 126 A.3d 266, 294–99 (N.H. 2015) (gasoline additive linked to groundwater contamination). See generally Allen Rostron, *Beyond Market Share Liability: A Theory of Proportional Share Liability for Nonfungible Products*, 52 UCLA L. REV. 151, 153, 167 (2004) (noting only rare use in non-DES cases); *id.* at 215 (cautioning that judicial insistence on product fungibility “effectively turns market share liability into a special rule for DES cases only”).

170. This position poses constitutional questions, though normally framed in procedural due process terms. See, e.g., *In re N.Y. Cty. DES Litig.*, 615 N.Y.S.2d 882, 885 (App. Div. 1994) (rejecting an objection to the exercise of personal jurisdiction over a California company that had never sold DES in New York or any adjacent states); see also *In re DES Mkt. Share Litig.*, 591 N.E.2d 226, 229–31 (N.Y. 1992) (rejecting the argument that the market share theory represented an equitable claim for which the plaintiff would have no right to a jury trial); Colby, *supra* note 9, at 377–78 (“[A] state could be found in violation of due process if it altered the traditional defenses of substantive tort law in a way that effectively eliminated the defendant’s ability to establish that it did not cause the injury.”); *id.* at 378 & nn.130–31 (noting an unsuccessful petition for certiorari making this argument in a market share case against lead paint manufacturers). Other jurisdictions would allow exculpation in such circumstances. See, e.g., *Martin v. Abbott Labs.*, 689 P.2d 368, 382–84 (Wash. 1984); *Collins*, 342 N.W.2d at 52.

171. See *Hymowitz v. Eli Lilly & Co.*, 539 N.E.2d 1069, 1078 (N.Y. 1989); *cf. Miles Labs., Inc. v. Superior Ct.*, 184 Cal. Rptr. 98, 101–03 (Ct. App. 1982) (allowing a claim for failure to warn of risks of use during pregnancy against the manufacturer of a DES product labeled solely for use in male prostate cancer patients because it might have been dispensed in place of other DES products labeled for the prevention of miscarriages). Although this peculiar feature of New York law has a perfectly good explanation (i.e., selling for non-pregnancy uses was not tortious to begin with even if a particular plaintiff’s injury might get traced back to that supplier) as may the distinctive treatment of DES cases more generally, it reinforces the sense that the sellers of a product used in connection with pregnancy have gotten a raw deal. *Cf. Shackil v. Lederle Labs.*, 561 A.2d 511, 522–24 (N.J. 1989) (worrying about the potential public health consequences of extending market share liability to vaccine manufacturers); Andrew R. Klein, *Beyond DES: Rejecting the Application of Market Share Liability in Blood Products Litigation*, 68 TUL. L. REV. 883, 919 (1994) (“Imposing liability without proof of causation is every bit as expansive as imposing liability without proof of fault; indeed, the former is likely more expansive, because it forces a manufacturer to assume liability for injuries caused by products over which it has no control.”).

172. See *Rubin*, *supra* note 162, at 150 (noting that “some feminist groups are pushing for the exclusion of all manufacturers of contraceptives and other reproductive drugs from the [federal products liability reform] bill’s protections”); see also *supra* note 151 and accompanying text. Indeed, feminist treatments of tort law routinely object to limitations on the scope of liability that arguably disadvantage (primarily) women as plaintiffs. See, e.g., Dolly M. Trompeter, Comment, *Sex, Drugs, and the Restatement (Third) of Torts, Section 6(c): Why Comment e Is the Answer to the Woman Question*, 48 AM. U. L. REV. 1139, 1161–63 (1999) (surveying this literature); *id.* at 1164–65 (applauding a sizeable punitive damage award for driving an FDA-approved IUD

flawed products that cause physical injuries.<sup>173</sup> Nonetheless, exposure to tort liability—including the prospect of claims that have little or no merit—may send signals to manufacturers about the wisdom of continuing to serve a market associated with frequent claims,<sup>174</sup> and the strict liability aspects of product defect litigation may invite lawsuits based on little more than consumer disappointment, regret, or surprise after experiencing a poor outcome.<sup>175</sup> If the First Amendment requires tolerating some defamatory falsehoods in order to avoid chilling valuable speech,<sup>176</sup> then other fundamental rights might mean having to tolerate the sale of certain arguably defective products lest suppliers become spooked about distributing even nondefective versions that individuals have a right to use.

Constitutional regard for ensuring the availability of certain products would not entirely insulate sellers, just as authors and publishers remain subject to defamation lawsuits, but it would necessitate imposing a higher pleading standard on plaintiffs. Although many jurisdictions grant limited protection from liability to sellers of prescription drugs and devices as compared with other consumer goods,<sup>177</sup>

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off of the market). This Article argues instead that the lack of limitations on products liability may disadvantage (primarily) women as consumers in ways that run afoul of the Constitution, even if manufacturers will have to (vicariously) assert the rights of individuals not party to the litigation.

173. The special treatment of speech tort claims may, in fact, represent a judgment that harms to reputation and other dignitary interests do not really count for much. See Michael Passaportis, Note, *A Law and Norms Critique of the Constitutional Law of Defamation*, 90 VA. L. REV. 1985, 2019–22, 2031, 2038 (2004) (critiquing the undervaluation of reputational harms). As explained previously, however, nonfiction books that foreseeably may cause serious physical harms also largely escape tort liability. See *supra* notes 143–145 and accompanying text.

174. For instance, the threat of often spurious litigation plainly has discouraged the introduction of drug products indicated for use during pregnancy. See Noah, *supra* note 165, at 1657 (“[P]harmaceutical companies have gotten the clear message that marketing any drugs for the treatment of conditions during pregnancy will attract tort litigation because some juries will not overly concern themselves with questions of causation.”); Elyse Tanouye, *Medicine: Suits Involving Defunct Bendectin Chill Development of Pregnancy Medications*, WALL ST. J., June 22, 1993, at B1.

175. See, e.g., *Fraser v. Wyeth, Inc.*, 992 F. Supp. 2d 68, 83–84, 90 (D. Conn. 2014) (applying a “modified” consumer expectations test to assess the design of a hormone replacement therapy); *Green v. Smith & Nephew AHP, Inc.*, 629 N.W.2d 727, 741–52, 759 (Wis. 2001) (rejecting a risk-utility standard on a design defect claim against the seller of latex gloves used by health care workers, and holding that the defendant faced liability even if it could not have known of the risk of allergic reactions at the time of sale); see also *Wells v. Ortho Pharm. Corp.*, 788 F.2d 741, 745–46 (11th Cir. 1986) (holding that a spermicide manufacturer had a duty to warn of possible teratogenicity notwithstanding the FDA’s conclusion that these drugs did not cause birth defects); Noah, *supra* note 149, at 26 (“The prospect that such a [design defect] claim might succeed, and that it could lead to the imposition of a hefty fine (i.e., an award of damages), would make manufacturers think twice before marketing an FDA-approved drug—in fact, that is precisely the stated goal of those who favor allowing jury scrutiny in such circumstances.” (footnote omitted)).

176. See *Gertz v. Robert Welch, Inc.*, 418 U.S. 323, 341 (1974) (“The First Amendment requires that we protect some falsehood in order to protect speech that matters.”).

177. See, e.g., *Lance v. Wyeth*, 85 A.3d 434, 450–53, 458–61 (Pa. 2014) (exempting all prescription products from strict liability though not negligence-based claims of design defect); see also Noah, *supra* note 60, at 842–88, 912–15. In addition, preemption has become increasingly protective in this context. See *Mut. Pharm. Co. v. Bartlett*, 570 U.S. 472, 482–93 (2013); *Yates v. Ortho-McNeil-Janssen Pharm., Inc.*, 808 F.3d 281, 298–300 (6th Cir. 2015) (affirming summary judgment granted to the manufacturer of a contraceptive patch because design defect claims were impliedly preempted); Noah, *supra* note 149, at 34 (discussing *Bartlett*’s application to brand-name drug manufacturers); *id.* at 54 (wondering, however, whether to “take[] seriously the Supreme Court’s expansive approach to implied preemption in its latest tort decision”); see also *Riegel v.*

contraceptives actually may do less well than therapeutic products lacking any constitutional pedigree.<sup>178</sup> If the Bill of Rights does constrain products liability claims, then courts should take precisely the opposite approach and offer greater—not just comparable, and certainly not reduced—protection to the sellers of contraceptives and the like.<sup>179</sup> At the very least, courts need to limit the prospect of punitive damages,<sup>180</sup> just as the U.S. Supreme Court has insisted that they do in the context of speech torts.<sup>181</sup>

In order to really safeguard constitutionally valuable products, even allegations of negligence would not suffice; instead, courts should have to recognize a regulatory compliance defense. The record of litigation against sellers of contraceptives plainly

Medtronic, Inc., 552 U.S. 312, 321–25, 330 (2008) (finding express preemption of tort claims against manufacturers of FDA-approved medical devices except for “parallel claims” that allege noncompliance with federal requirements); Noah, *supra* note 60, at 913 (“[E]xpress federal preemption as a defense to tort claims against medical device manufacturers, which has evolved fitfully and attracted its share of criticism, may better define those contexts where courts should decline to engage in duplicative design defect review—namely, those devices that have undergone full premarket review and approval . . . .” (footnote omitted)).

178. See, e.g., Hill v. Searle Labs., 884 F.2d 1064, 1069–70, 1070 n.9 (8th Cir. 1989) (finding that IUDs do not serve an “exceptional social need” in part because many alternative forms of contraception exist, including abstinence); see also Odgers v. Ortho Pharm. Corp., 609 F. Supp. 867, 878 (E.D. Mich. 1985) (expressing confidence that patient noncompliance with a prescription for an oral contraceptive “is not life threatening”); MacDonald v. Ortho Pharm. Corp., 475 N.E.2d 65, 69–70 (Mass. 1985) (emphasizing the elective nature of contraceptives); cf. Doe v. Solvay Pharm., Inc., 350 F. Supp. 2d 257, 272 (D. Me. 2004) (declining to extend the rationales underlying the contraceptive exception to an antidepressant prescribed for the treatment of obsessive-compulsive disorder); Noah, *supra* note 3, at 383 (“[A]re powerful analgesics ‘lifestyle’ drugs? Contraceptive products sometimes get trivialized in precisely this fashion.”). Nonprescription contraceptive products do not enjoy even the possibility of some protection from strict products liability. See Mitchell v. VLI Corp., 786 F. Supp. 966, 970 (M.D. Fla. 1992) (declining to apply the learned intermediary rule to an OTC contraceptive sponge that a physician had supplied to his patient).

179. Contrast the judicial response to wrongful conception (or pregnancy) claims based on the negligent performance of a sterilization procedure by a physician, at least as distinguished from wrongful birth (or life) claims typically based on negligent failures by physicians to diagnose or disclose a fetal abnormality in time to allow for an abortion. See *supra* note 153 (noting the distinction). Although this particular concern rarely gets articulated (vague references to visiting “disproportionate” liability on physicians notwithstanding, see, e.g., Chaffee v. Seslar, 786 N.E.2d 705, 708 (Ind. 2003)), courts may limit the types of damages that a jury can award in order to guard against the possibility that otherwise this form of (permanent) contraception will become prohibitively expensive or entirely unavailable. See Anthony Jackson, *Action for Wrongful Life, Wrongful Pregnancy, and Wrongful Birth in the United States and England*, 17 LOY. L.A. INT’L & COMP. L.J. 535, 600 (1995) (“Medical professionals should not be required to pay damages that impose an unreasonable burden upon them, completely disproportionate to their culpability. This is particularly true when these disproportionate awards could necessarily deprive future patients of essential health treatment.”); Shelley A. Ryan, *Wrongful Birth: False Representations of Women’s Reproductive Lives*, 78 MINN. L. REV. 857, 887 n.173 (1994) (“suspect[ing]” such an explanation); cf. Bowman v. Davis, 356 N.E.2d 496, 499 (Ohio 1976) (“For this court to endorse a policy that makes physicians liable for the foreseeable consequences of all negligently performed operations *except* those involving sterilization would constitute an impermissible infringement of a fundamental right [not to procreate].”).

180. A few states have done so through tort reform legislation. See Elissa Levy, Note, *The HEALTH Act’s FDA Defense to Punitive Damages: A Gift to Drug Makers or to the Public?*, 74 FORDHAM L. REV. 2425, 2438–39, 2439 n.93 (2006) (counting a half-dozen states).

181. See *supra* note 113; cf. Lundman v. McKown, 530 N.W.2d 807, 816–17, 825–26 (Minn. Ct. App. 1995) (reversing, in part on free exercise grounds, a \$9 million punitive damage award against the headquarters of the Christian Science religion in a wrongful death claim where its adherents had treated a case of juvenile diabetes with faith healing).

demonstrates judicial indifference to the judgments of the FDA.<sup>182</sup> If, instead, compliance served as a defense, then plaintiffs would have to demonstrate either fraud in securing agency approval or a manufacturer's noncompliance with the terms of the license.<sup>183</sup> In effect, like the actual malice standard imported to limit the availability of most defamation claims, marketing a product that complies with federal safety requirements would defeat allegations of defectiveness or negligent behavior unless a plaintiff could prove some more serious form of misconduct.

#### CONCLUSION

The time may have come to extend the U.S. Supreme Court's drive to constitutionalize the domain of speech torts into the field of products liability. This Article first considered a pointed way of testing this proposition: decisions recognizing an exception to the learned intermediary doctrine whenever manufacturers of prescription drugs or medical devices advertise directly to consumers, which seems to represent a fairly blatant violation of federal constitutional protections for commercial speech. Venturing into far more debatable territory, this Article then suggested that certain consumer goods closely connected to the exercise of fundamental rights—including but not limited to contraceptives—might deserve additional protection from the operation of well-established principles of strict products liability. If, however, that comes across as too radical an idea, then perhaps the longstanding constitutionalization of speech torts must remain distinctive,<sup>184</sup> which also means that developments in the law of defamation can offer little assistance to those commentators who promote the notion that the Second Amendment should infiltrate the law of torts.

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182. See, e.g., *Wells v. Ortho Pharm. Corp.*, 788 F.2d 741, 746 (11th Cir. 1986) (“An FDA determination that a warning is not necessary may be sufficient for federal regulatory purposes but still not be sufficient for state tort law purposes.”); *Gurski v. Wyeth-Ayerst*, 953 F. Supp. 412, 416–18 (D. Mass. 1997) (holding that compliance with FDA labeling requirements would not preclude tort liability); *Kociemba v. G.D. Searle & Co.*, 707 F. Supp. 1517, 1524–27, 1537 (D. Minn. 1989) (rejecting objections to a verdict, which included an award of \$7 million in punitive damages, based in part on an intentional misrepresentation claim premised on the manufacturer's statement that an FDA-approved IUD was “safe and effective”); *Wooderson v. Ortho Pharm. Corp.*, 681 P.2d 1038, 1057 (Kan. 1984) (ignoring an agency letter to a contraceptive manufacturer rejecting the addition of a requested warning about an unfounded risk in the course of affirming an almost \$3 million punitive damage award on top of \$2 million in compensatory damages); *McEwen v. Ortho Pharm. Corp.*, 528 P.2d 522, 534 (Or. 1974).

183. See Lars Noah, *Rewarding Regulatory Compliance: The Pursuit of Symmetry in Products Liability*, 88 GEO. L.J. 2147, 2162 & n.62, 2165 (2000); cf. *id.* at 2158 (“Preemption offers a blunter tool for securing judicial respect for federal standards.”). As with so many other sensible positions that I have staked out over the years, urging an FDA compliance defense seemed like an exercise in tilting at windmills. The Supremacy Clause aside, it had not previously occurred to me to use the U.S. Constitution to force it down the throats of unenlightened or unwilling judges, even if only a small subset of products would benefit from such a maneuver.

184. See Adam Liptak, *Justice Thomas Calls for Reconsideration of a Landmark 1964 Libel Ruling*, N.Y. TIMES, Feb. 20, 2019, at A16 (explaining the peculiar facts that prompted the original decision and the apparent lack of interest among most members of the current Court to revisit the question). Unless something about the freedom of speech explains why it should interact with tort law differently than other constitutional rights, this may just represent another illustration of “path dependence” in the law. See Lars Noah, *An Inventory of Mathematical Blunders in Applying the Loss-of-a-Chance Doctrine*, 24 REV. LITIG. 369, 383 & n.50 (2005) (offering a couple of examples from tort law). See generally John Bell, *Path Dependence and Legal Development*, 87 TUL. L. REV. 787 (2013); Oona A. Hathaway, *Path Dependence in the Law: The Course and Pattern of Legal Change in a Common Law System*, 86 IOWA L. REV. 601 (2001).