ESSAY

BANNING OFF-LABEL DRUG PROMOTION OFFENDS THE U.S. CONSTITUTION: MAKING THE STRONGEST CASE

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Commentators continue to debate whether the restrictions that the U.S. Food and Drug Administration (FDA) imposes on the dissemination of information about “off-label” uses of approved therapeutic products violate the First Amendment. In previous work I have sided with those who question the constitutionality of these rules, and lower federal courts have become increasingly receptive to the argument that commercial free speech principles enunciated by the U.S. Supreme Court may limit the government’s ability to prevent pharmaceutical and medical device manufacturers

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from engaging in such communications. Even so, one of the clearest illustrations of the unconstitutional operation of these restrictions has gone entirely unnoticed. This Essay explains why the application of restrictions on promoting off-label uses to bar generic drug manufacturers from touting uses newly approved by the FDA but only for their brand-name competitors cannot possibly pass muster under the First Amendment.

Since the mid-1970s, the U.S. Supreme Court has recognized that advertising enjoys some of the First Amendment’s guarantees for freedom of expression, with its earliest decisions in this line all arising in the health care context. Its newer decisions striking down laws for abridging commercial speech arose in that setting as well. Although the Court has regularly applied a form of heightened scrutiny in such cases, the requirement that the government demonstrate it has narrowly tailored laws to serve a substantial interest has become more demanding over time. Whenever officials seek to pursue collateral purposes such as dampening consumer demand, non-speech-restrictive alternatives (for example, barring the underlying conduct) invariably exist for accomplishing such goals. As a consequence, this much has become abundantly clear: although it may protect consumers from false or misleading

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3 See, e.g., United States v. Caronia, 703 F.3d 149, 162–69 (2d Cir. 2012) (reversing the conviction of a sales representative for conspiring to misbrand a narcolepsy drug by urging off-label uses, concluding that the First Amendment required narrowly construing a provision of the statute); Amarin Pharma, Inc. v. FDA, 119 F. Supp. 3d 196, 209–12, 226–29, 237 (S.D.N.Y. 2015) (issuing a preliminary injunction allowing the manufacturer of a prescription omega-3 fatty acid product to make qualified statements concerning—and distribute reprints of—a study suggesting effectiveness in a broader group of patients with high triglycerides even though the FDA concluded that this clinical trial could not support supplemental approval).


6 See Lars Noah, When Constitutional Tailoring Demands the Impossible: Unrealistic Scrutiny of Agencies?, 85 GEO. WASH. L. REV. 1462, 1465 (2017); see also Adam Liptak, How Free Speech Was Weaponized by Conservatives, N.Y. TIMES, July 1, 2018, at A1 (discussing the Supreme Court’s increasing use of the First Amendment to strike down laws or regulations restricting speech).

information, the government generally may not prohibit truthful and nondeceptive claims in pursuit of some other valuable ends.8

The FDA strictly controls what information may appear in the labeling of pharmaceutical products.9 When it approves a new drug application (NDA), the agency specifies the allowable indications for use.10 For some products, these statements are broad and general (for example, “temporary pain relief”); for others, the approved uses may be incredibly narrow and specific (for example, for particular types of cancer with certain genetic mutations in patients who have failed to respond to other available chemotherapy agents).11 Physicians generally need not, however, restrict their administration or prescribing of drugs based on FDA-approved labeling—they enjoy the freedom to engage in “off-label” use.12 Knowing this, sponsors of new drugs may seek FDA approval for only a subset of possible indications, typically those that companies can most easily establish as safe and effective to the agency’s satisfaction.13 Once in the marketplace for one use, pharmaceutical manufacturers can often bank on widespread off-label use.

The brand-name manufacturer enjoys at least a five-year period of market exclusivity against generic competition.14 After that time has elapsed (and any relevant patents expired), the FDA may approve an abbreviated new drug application (ANDA) so long as the sponsor of the generic version can establish its bioequivalence to the originally

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8 See id. at 67–68 (“[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. . . . [T]he First Amendment allows the government to guard against the dissemination of false or deceptive commercial speech but not much else.”). Recently, the Centers for Medicare and Medicaid Services (CMS) issued a proposed rule requiring the disclosure of list prices in prescription drug advertisements broadcast on television, which the industry immediately assailed on First Amendment grounds. See Robert Pear, Rule Would Compel Drug Makers to Disclose Prices in Commercials, N.Y. TIMES, Oct. 16, 2018, at B6. A federal court invalidated the final rule without, however, having to reach the constitutional question. See Merck & Co. v. HHS, 385 F. Supp. 3d 81, 89–98 (D.D.C. 2019) (holding that CMS lacked the statutory authority to promulgate this rule).
9 See, e.g., Noah, supra note 7, at 68–71.
10 See id. at 68.
12 See Noah, supra note 7, at 68–69.
approved brand-name product. The labeling for the generic must mimic the brand-name in almost all respects, though additional uses subsequently approved for the brand-name drug initially may get carved out in the labeling for the generic. Nowadays, generic drugs account for roughly ninety percent of all filled prescriptions.

Under FDA regulations that go back more than half a century, manufacturers cannot share any information about off-label uses with doctors. I happen to think that this blanket restriction runs afoul of the First Amendment, but that view has made only limited inroads on the prevailing wisdom among commentators.

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16 See 21 C.F.R. § 314.94(a)(8)(iv); Mut. Pharm. Co. v. Bartlett, 570 U.S. 472, 477, 486 (2013); see also AstraZeneca Pharm., LP v. FDA, 713 F.3d 1134, 1139–40 (D.C. Cir. 2013) (agreeing that revisions of labeling to summarize studies about metabolic side effects when using the atypical antipsychotic Seroquel (quetiapine) did not entitle the sponsor to extended exclusivity against generic competitors who would have to supply the same risk information in their labeling); Supplemental Applications Proposing Labeling Changes for Approved Drugs and Biological Products, 78 Fed. Reg. 67,985, 67,988–89 (proposed Nov. 13, 2013) (proposing to loosen this requirement by allowing ANDA holders to strengthen risk information unilaterally), withdrawn, 83 Fed. Reg. 64,299 (Dec. 14, 2018).

17 See Spectrum Pharm., Inc. v. Burwell, 824 F.3d 1062, 1066 (D.C. Cir. 2016) (“FDA permits what is called a labeling ‘carve-out’ that allows producers to sell a generic if they exclude from its label any indication that is still protected by exclusive marketing rights.”); id. at 1069 (noting that the generic manufacturer would risk sanctions if it promoted its drug for the carved-out use (citing Wash. Legal Found. v. Henney, 202 F.3d 331, 333 (D.C. Cir. 2000))); Julie Dohm, Comment, Expanding the Scope of the Hatch-Waxman Act’s Patent Carve-Out Exception to the Identical Drug Labeling Requirement: Closing the Patent Litigation Loophole, 156 U. Pa. L. Rev. 151, 157–59 (2007) (explaining that the FDA does not expect the labeling for generic drugs to include uses still covered by the pioneer’s method patents).

18 Christopher Rowland, Alleged Price-Fixing Was Big Win for Wholesalers, WASH. POST, Feb. 3, 2019, at A14 (“[G]enerics mak[e] up about 90 percent of all prescriptions filled in the United States . . . .”)

19 See 21 C.F.R. § 202.1(e)(4)(i)(a) (“[Advertising] shall not recommend or suggest any use that is not in the labeling accepted in such approved new-drug application or supplement . . . .”); id. § 202.1(e)(6)(ii); see also 21 U.S.C. § 352(n) (2012) (providing that a prescription drug shall be deemed to be misbranded unless its seller includes in all advertisements a true statement of “such other information . . . as shall be required in regulations”). But see United States v. Caronia, 703 F.3d 149, 160 (2d Cir. 2012) (concluding inaccurately that the “regulations do not expressly prohibit or criminalize off-label promotion”).

20 See Noah, supra note 7, at 72–84; see also Greene & Noah, supra note 2, at 251–54; Noah, supra note 2, at 145–46 (“Although case-by-case, after the fact enforcement—as done, for instance, by the Federal Trade Commission—typically is less efficient than broad-based, prospective rulemaking, the First Amendment may demand such a more particularized regulatory approach . . . .”).

21 See sources cited supra note 1 and accompanying text. Lower federal courts have become more receptive to the argument. See United States v. Caronia, 703 F.3d 149, 162–69 (2d Cir. 2012); Amarin Pharma, Inc. v. FDA, 119 F. Supp. 3d 196, 208–29, 237 (S.D.N.Y. 2015); text accompanying supra note 3. In any event, the particulars of this debate need not detain us here.
the prohibition on off-label promotion treats indications not approved for labeling as unreliable unless and until the agency has had an opportunity to assess their validity. A company first would have to file a supplemental new drug application (SNDA) and await approval from the FDA. Although such “efficacy supplements” require far less effort than the original NDA, they are neither cheap nor fast (nor invariably successful).

If approved, the SNDA would authorize the company to add a line or two to the list of indications in the package insert, which in turn would allow the company to advertise this new on-label use, but in all other respects the product would remain identical to the one originally introduced. In an effort to encourage the filing of SNDAs, Congress decided to grant the SNDA sponsor (typically the brand-name manufacturer) three years of additional though partial exclusivity, which means that competitors could not include any information about newly approved uses in the labeling or advertising for their otherwise identical products. As a result, the seller of a generic drug cannot add the new indication to its labeling and also cannot advertise it as safe and effective for that use even though the

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22 See Noah, supra note 13, at 144.
23 See id.
24 See id. at 145 & n.26; see also Bo Wang & Aaron S. Kesselheim, Characteristics of Efficacy Evidence Supporting Approval of Supplemental Indications for Prescription Drugs in United States, 2005-14: Systematic Review, 351 BMJ, no. 8026, h4679, Sept. 26, 2015, at 1–2, https://www.bmj.com/content/bmj/351/bmj.h4679.full.pdf [https://perma.cc/BDV6-RSDR] (“In 2014 the FDA approved 40 new supplemental indications for already marketed drugs, compared with original approvals of 44 novel small molecule and biologic agents during the same period.”). At a minimum, the application fee costs nearly $3 million. See Prescription Drug User Fee Rates for Fiscal Year 2020 Notice, 84 Fed. Reg. 37,882, 37,883 (Aug. 2, 2019) (setting the fee for applications such as efficacy supplements “requiring clinical data”).
25 See, e.g., Justin Gillis, Cancer Drug Gets New-Use Approval: Rituxan Can Treat Rheumatoid Arthritis, WASH. POST, Mar. 1, 2006, at D1; Scott Hensley, Pfizer’s Lipitor Gets Marketing Tool: Expanded FDA Instructions Allow Company to Claim Drug Prevents Heart Attacks, WALL STREET J., Aug. 2, 2004, at B5; see also Noah, supra note 13, at 145 (“[C]ompanies will sometimes invest in clinical studies to obtain approval of new uses so that they can promote such uses and thereby bring them to the attention of a wider audience of prescribing physicians.”).
27 See 21 C.F.R. § 314.150(b)(10)(i)–(ii) (2019); Nat’l Ass’n of Pharm. Mfrs. v. Ayerst Labs., 850 F.2d 904, 913 (2d Cir. 1988); sources cited supra note 17 (discussing carve-outs in labeling); cf. Sigma-Tau Pharm., Inc. v. Schuetz, 288 F.3d 141, 145 (4th Cir. 2002) (holding that the approval of a second indication (protected by a separate exclusivity period) did not prevent FDA from approving generic versions for only the original (and no longer protected) indication notwithstanding the likelihood of off-label prescribing of the generic drugs for the new indication); Bristol-Myers Squibb Co. v. Shalala, 91 F.3d 1493, 1500 (D.C. Cir. 1996) (sustaining the FDA’s authority to approve a generic drug for only a subset of the innovator drug’s labeled indications).
FDA has approved precisely such a statement for brand-name product. See Lars Noah, Product Hopping 2.0: Getting the FDA to Yank Your Original License Beats Stacking Patents, 19 MARQ. INT’L PROF. L. REV. 161, 168–69 (2015). Indeed, the agency may approve a generic in the hopes that physicians will use it off-label when they may find it difficult to prescribe the brand-name drug labeled with the additional indication for use. See Spectrum Pharm., Inc. v. Burwell, 107 F. Supp. 3d 23, 29 (D.D.C. 2015) (“That the FDA may have known or even intended that Sandoz’s generic would be commonly used by healthcare providers for the carved-out, orphan-protected, and off-label colorectal indication [given concerns about potential shortages of the innovator drug] does not rise to the level of violating Spectrum’s exclusivity right . . . .”), aff’d, 824 F.3d 1062 (D.C. Cir. 2016); Rob Stein, Price Tag Soars on Preterm Birth Drug, WASH. POST, Mar. 29, 2011, at A1 (reporting that an FDA official suggested that it might approve a generic version of the exorbitantly priced preterm labor drug Makena® (hydroxyprogesterone caproate) for a different indication, which would then allow physicians to use it off-label).

29 For this reason, some brand-name companies evidently tried to withdraw their originally approved indication(s) upon getting approval of a new use in an effort to prevent FDA approval of any generics labeled only for those original use(s), prompting the agency to explain that it would not get duped by such anticompetitive behavior. See Noah, supra note 28, at 168.

30 See, e.g., Allergan, Inc. v. Alcon Labs., Inc., 324 F.3d 1322, 1328, 1333–34 (Fed. Cir. 2003) (emphasizing that the ANDA had not requested labeling for patented off-label uses of the glaucoma drug Alphagan® (brimonidine)); see also Takeda Pharm. U.S.A., Inc. v. West-Ward Pharm. Corp., 785 F.3d 625, 630–35 (Fed. Cir. 2015) (affirming the denial of a preliminary injunction requested by the manufacturer of Colcrys® (colchicine), which alleged that the labeling for Mitigare® would induce infringement of its method patents covering treatment of acute gout flares, because the NDA approved by the FDA for the latter drug had carved out those patented indications and only specified its prophylactic use). This caveat may pose its own constitutional difficulties. See infra notes 40–50 and accompanying text.

not, however, stand much of a chance under the demanding scrutiny currently used to assess restrictions on commercial speech. Indeed, it represents the flip-side of the problem confronted in Sorrell v. IMS Health Inc., \(^{33}\) where the Supreme Court invalidated a state law designed to make it harder for brand-name drug companies to get the word out: the majority emphasized that the state had imposed a restriction on the creation and dissemination of information based on its content and speaker without adequate justification.\(^{34}\)

Instead of granting three years of partial exclusivity, Congress could amend the statute to grant the NDA-holder two more years of full exclusivity with the first added use (and perhaps another year with a second added use). This would have the dual benefit of improving the incentive for filing ANDAs—without having to bar off-label promotion by the brand-name manufacturer—and ensuring that generic drug manufacturers do not encounter the prohibition on making off-label claims once the FDA approves their ANDAs. Congress crafted the six-month added exclusivity incentive for testing off-label uses in pediatric patients in roughly this manner.\(^{35}\)


\(^{34}\) See id. at 577 (“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 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 . . . [n]or does the State argue that the provision challenged here will prevent false or misleading speech.” (citing Pfizer v. W. States Med. Ctr., 535 U.S. 357, 373 (2002))). The dissent objected that “neither of these categories—content-based nor ‘speaker-based’—has ever before justified greater scrutiny when regulatory activity affects commercial speech.” IMS Health Inc., 564 U.S. at 588 (Breyer, J., dissenting).

Delaying generic entry might seem like a steep price for patients and their insurers to pay, but the First Amendment casts serious doubt on the preferred current approach of casually trading away the speech rights of regulated entities. The issuance of “priority review vouchers,” which entitle the holder to expedited processing of a future application for product approval, represents still another type of incentive that Congress has tried in this context.

Why has this aspect of the problem gone entirely unnoticed? At present, and notwithstanding a desire to include new uses on the labeling for their products, generic drug manufacturers have little reason to advertise. As with expenditures for research and development, they free-ride on the marketing efforts of brand-name manufacturers, counting on dramatically lower prices coupled with generic substitution policies to gain market share. Nonetheless, if that business model changed for some reason, then generic sellers

36 Although they require no direct expenditure of public money, such exclusivity incentives come at a price. See Rachel Zimmerman, Child Play: Pharmaceutical Firms Win Big on Plan to Test Adult Drugs on Kids—By Doing Inexpensive Trials, They Gain 6 More Months Free from Generic Rivals—FDA: Law Does Some Good, WALL STREET J., Feb. 5, 2001, at A1 (estimating that the additional six months of market exclusivity on the first twenty-six drugs to receive this extension will generate an extra $4 billion for the brand-name manufacturers, including nearly $1 billion each on Claritin® (loratadine) and Prozac® (fluoxetine)).


38 See Michael A. Fischer & Jerry Avorn, Economic Implications of Evidence-Based Prescribing for Hypertension: Can Better Care Cost Less?, 291 JAMA 1850, 1854 (2004) (“[T]he vigorous marketing of newer, more costly agents compared with virtually no marketing for older, off-patent drugs.”); see also Thomas M. Burton, Hard to Swallow—America’s Soaring Drug Costs—Bested Interests: Why Generic Drugs Often Can’t Compete Against Brand Names—Lower Prices Aren’t Enough to Overcome Demand for ‘New and Improved’—Doctoring the Applesauce, WALL STREET J., Nov. 18, 1998, at A1 ("It is rare for generic-drug companies to dispatch salespeople to visit doctors . . . "). In limited circumstances, however, they may engage in marketing efforts. See Duane M. Kirking et al., Economics and Structure of the Generic Pharmaceutical Industry, 41 J. AM. PHARM. ASS’N 578, 579, 582 (2001); David J. Morrow, International Business: Old Drugs, New Labels: Brand Name Generics and Other Linguistic Anomalies, N.Y. TIMES, June 13, 1998, at D1.

would confront an absolute barrier to communicating any information about new FDA-approved uses during the brand-name manufacturer’s period of market exclusivity. For present purposes, this scenario has powerful explanatory value in highlighting the constitutional flaws of the agency’s policies.

Like the partial market exclusivity granted for SNDAs, the operation of method patents also may pose constitutional questions. Unlike protections granted to an underlying product or process, method-of-use patents arguably squelch the dissemination of information about the utility of something for which other forms of patent protection may have expired. Selling a product with labeling that included reference to a method invented by another entity would infringe their use patent, and advertising a protected use of an unprotected product also would amount to inducement of infringement. A pair of commentators recently noted this parallel, though doing so for purposes of defending the constitutionality of the

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40 See Tahir Amin & Aaron S. Kesselheim, Secondary Patenting of Branded Pharmaceuticals: A Case Study of How Patents on Two HIV Drugs Could Be Extended for Decades, 31 HEALTH AFF. 2286, 2291 (2012) (“The 108 patents we identified could extend the market exclusivity of [Abbott’s] ritonavir and lopinavir/ritonavir to at least 2028—twelve years after the expiration of the patents on their base compounds . . . .”); Andrew Pollack, New Patents Aim to Delay Generics of Biologics, N.Y. TIMES, July 16, 2016, at B1 (“The main patent on the composition of Humira expires at the end of this year. But AbbVie, the company behind Humira, has amassed more than 70 newer patents, mostly in the last three years, covering formulations of the drug, manufacturing methods and use for specific diseases. It says these ancillary patents should protect its crown jewel . . . until at least 2022.”). They only work, however, if the ANDA filer seeks approval for the patented additional use, which would not occur if, for instance, the pioneer never had secured FDA approval for that use. See Warner-Lambert Co. v. Apotex Corp., 316 F.3d 1348, 1352, 1354–55 (Fed. Cir. 2003) (rejecting a claim by the manufacturer of Neurontin® (gabapentin), which was labeled only for treating epilepsy but widely used in patients with neurodegenerative diseases, that approval of a generic version would infringe (or induce infringement of) its method patent covering such off-label uses).

41 See, e.g., AstraZeneca LP v. Apotex, Inc., 633 F.3d 1042, 1060 (Fed. Cir. 2010) (affirming the district court’s finding that “Apotex had the requisite specific intent to induce infringement because Apotex included instructions in its proposed label that will cause at least some users to infringe the asserted method claims”); cf. King Pharma., Inc. v. Eon Labs., Inc., 616 F.3d 1287, 1279 (Fed. Cir. 2010) (first citing In re Ngai, 367 F.3d 1336, 1338, 1339 (Fed. Cir. 2004); then citing In re Gulack, 703 F.2d 1381, 1385 (Fed. Cir. 1983); and then citing General Electric Co. v. Jewel Incandescent Lamp Co., 326 U.S. 242, 249 (1945)) (holding that a claim element of “informing” a patient of a drug’s effect was unpatentable as printed matter).

42 See Chiuminatta Concrete Concepts, Inc. v. Cardinal Indus., 145 F.3d 1303, 1311–12 (Fed. Cir. 1998); see also Wyeth v. Sandoz, Inc., 703 F. Supp. 2d 508, 511, 521 (E.D.N.C. 2010) (granting summary judgment to brand-name drug manufacturer on induced infringement claim because the generic’s “label provides instructions for and encourages direct infringement, thereby establishing the requisite intent for active inducement of infringement” (footnote omitted)); James R. Whittle, Note, Tailored Treatment, Tailored Enforcement: Protecting Innovation in Personalized Medicine from a Patent-Protection Loophole, 84 GEO. WASH. L. REV. 480, 486 (2016) (“[A] generic drug maker who markets a drug covered only by a method patent may induce infringement of that patent by providers even though it will never directly infringe the patent by administering the drug.”).
FDA's prohibition on off-label promotion insofar as no one has questioned the constitutionality of liability for induced infringement of method patents.\textsuperscript{43} I derive precisely the opposite lesson from this insight: the agency’s embargo on promoting generic drugs for new uses deemed on-label only for the brand-name version cannot possibly pass muster under commercial speech doctrine, which no longer tolerates pursuit of collateral goals such as incentivizing research, and this suggests that the threat of liability for the same conduct as induced infringement of a method patent might raise constitutional difficulties as well.

Over the years, an occasional commentator has wondered about possible First Amendment problems with granting and enforcing certain patents.\textsuperscript{44} Strangely, however, some of them seem to doubt that state action exists.\textsuperscript{45} Given the U.S. Supreme Court’s well entrenched pattern of invoking rights of free speech to limit defamation and related tort claims,\textsuperscript{46} I find this puzzling, especially insofar as patents originate from a federal agency while protection against harms to reputation and the like represent little more than

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\item See Christopher Robertson & Victor Laurion, Tip of the Iceberg II: How the Intended-Uses Principle Produces Medical Knowledge and Protects Liberty, 11 N.Y.U. J.L. & LIBERTY 770, 792–93 (2017). They put it as follows:

It would be ironic if, in the pharmaceutical industry, innovator-companies . . . successfully pled the First Amendment to give them a right to market off-label, but when they become plaintiffs in patent cases, were unable to enforce their use-patents because generic makers . . . claimed a First Amendment right to promote on-label in ways that infringed the innovator’s patent.

\textit{Id.} at 793; see also id. (“Patent law’s prohibition on the marketing of infringing uses and the FDCA’s prohibition on the marketing of unapproved uses both create incentives for the production of scientific knowledge.”).


\textsuperscript{46} See Lars Noah, Does the U.S. Constitution Constrain State Products Liability Doctrine?, 92 TEMPLE L. REV. (forthcoming Dec. 2019) (manuscript at 32–33) (on file with author); Adam Liptak, Justice Thomas Calls for Reconsideration of a Landmark 1964 Libel Ruling, N.Y. TIMES, Feb. 20, 2019, at A16 (explaining the apparent lack of interest among most members of the current Court to revisit the question).
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inventions of state common law. Moreover, even if private litigation to enforce intellectual property (IP) rights against those claiming to exercise their freedom of speech fails to qualify as state action, market exclusivities granted by the FDA plainly would do so for a pair of reasons. First, such exclusivities operate to prevent the agency from issuing licenses to competitors, and the failure to honor this restriction would trigger a right of judicial review against the FDA rather than against the competitor. Second, labeling or advertising a generic product for a new use during the pioneer’s partial exclusivity period covering that use would trigger federal prosecution rather than (or in addition to) private litigation asserted by a competitor.

In any event, given their constitutional heritage, patents arguably differ from statutory awards of market exclusivity when it comes to objections arising under the First Amendment, especially in light of the fact that commercial speech enjoyed no protection until relatively recently. In contrast, when Congress crafted quasi-IP protections for new drugs, it knew that the Supreme Court had begun to take seriously claims that even advertising enjoyed constitutional status. Whatever one thinks about the continued enforcement of

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47 See Burk, supra note 44, at 235–38; Chiang, supra note 44, at 331–38, 343–44; cf. id. at 348 (“[A] private patent owner’s choices in enforcement do not constitute state action and cannot violate the First Amendment.”). Unfortunately, these commentators give no attention to commercial speech principles as a possible constraint on patent doctrine.


49 See, e.g., Southern v. Pfizer, Inc., 471 F. Supp. 2d 1207, 1212–13 (N.D. Ala. 2006) (discussing the company’s guilty plea to federal criminal charges for off-label promotion of Neurontin® ( gabapentin)); Alex Berenson, Indictment of Doctor Tests Drug Marketing Rules, N.Y. TIMES, July 22, 2006, at A1 (reporting the arrest of a psychiatrist accused of conspiring with the manufacturer of Xyrem® ( gamma hydroxybutyrate) to publicize off-label uses of this narcolepsy drug at continuing medical education events); see also United States v. Harkonen, 510 F. Appx. 635–37 (9th Cir. 2013) (holding that the First Amendment did not protect the CEO of InterMune from a wire fraud conviction for issuing a press release that offered a favorable interpretation (based on post-hoc subgroup analysis of a secondary endpoint) of an unsuccessful study of Actimmune® ( interferon gamma-1b) in the treatment of pulmonary fibrosis, an off-label use); David Brown, Jury Said Guilty, but What Did He Do?, WASH. POST, Sept. 24, 2013, at E1 (reporting that, in addition to six months of home detention, Scott Harkonen got debarred by the FDA and CMS, adding that his “case has gotten little attention” though some “view it as a sleeping monster, a threat to free speech in science”).

50 See U.S. CONST. art. I, § 8, cl. 8. If nothing else, this would seem to endorse the substantial nature of the interest pursued by the government. Even so, legislation to implement this power would not enjoy immunity from First Amendment scrutiny.
method patents, the FDA’s system of granting newly approved uses of previously approved drugs partial protection from generic competition effectively embargoes truthful and nonmisleading speech. Given the ready availability (if not necessarily the desirability) of less-speech-restrictive mechanisms for incentivizing research into new uses of pharmaceutical products, this system strikes me as plainly inconsistent with the high court’s latest commercial speech decisions.