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The Off-Label Use of *POM Wonderful*: Using Section 43(a) to Eliminate Misleading Off-Label Drug Promotion

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The Off-Label Use of *POM Wonderful*: Using Section 43(a) to Eliminate Misleading Off-Label Drug Promotion†

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I. Introduction

On his way home from the hospital with his newborn son, a hit-and-run accident left Jeremy Lew with a severely injured spine.[1] Lew underwent surgery, during which his doctor implanted a device approved by the Food and Drug Administration (FDA) between his cervical vertebrae.[2] The treatment initially appeared successful, but Lew later began suffering from "unrelenting" pain, barely able to pick up his children.[3] Although the FDA approved the device, the agency intended it for use only in the mid-to-lower spinal column.[4] The off-label use of the medical device caused Lew

1. *See* Brian Krans, *The Debate Over "Off-Label" Drug Use*, HUFFINGTON POST, http://www.huffingtonpost.com/entry/the-debate-over-off-label-drug-use_us_588bce2ee4b0cd25e49048b2 (last updated Jan. 30, 2017) (last visited Feb. 18, 2018) (discussing the Lew accident and subsequent treatment) (on file with the Washington and Lee Law Review).

2. *See* Jim Spencer, *Patients Who Received Medtronic's Infuse Product to Get $8.45 Million in Settlements*, STARTRIBUNE (Aug. 2, 2016, 8:25 PM), http://www.startribune.com/patients-who-received-medtronic-product-to-get-8-45-million-in-settlements/388947831/ (last visited Feb. 18, 2018) (reporting that Lew's doctor implanted the "cage device" to hold a synthetic bone growth product in place) (on file with the Washington and Lee Law Review).

3. Krans, *supra* note 1; *see also* Spencer, *supra* note 2 ("Lew ended up with unwanted bone growth in [his spine] that caused nerve damage.").

4. *See* Spencer, *supra* note 2 ("Lew's spine surgery involved placement of Infuse in his neck, where the FDA had warned it could cause nerve and breathing problems.").

unimaginable pain as a result of his nerve injury, and could have further caused sterility, infection, or urinary problems.[5] Nonetheless, the practice of using medications and medical devices for unapproved treatments continues.[6]

Advocates of off-label medication use tout highly successful treatments that have saved lives even when approved treatments have failed.[7] For example, after doctors diagnosed Lisa Rosendahl with a glioblastoma—a highly lethal brain tumor—they estimated that she would live for only another twelve months.[8] Rosendahl's doctor suggested she try chloroquine, a drug indicated for treating malaria and never before used for this type of illness, on the theory that the drug would make the tumor more vulnerable to existing treatments.[9] Ultimately, chloroquine—in conjunction with the continued use of existing treatments—stabilized the tumor, and this use of the drug has since seen similar results in two other patients.[10] This type of last-ditch effort understandably occurs in the treatment of otherwise fatal conditions, but off-label medication use commonly helps patients with less threatening illnesses as well.[11]

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5. *See* Sheila Kaplan, *Whistleblower Case Contends Surgical Device Maker Misled FDA—and Patients Paid the Price*, STAT (Aug. 15, 2016), https://www.statnews.com/2016/08/15/medtronic-medical-device-surgery-fda/ (last visited Feb. 18, 2018) (listing injuries reported by more than 6,000 people who have sued Medtronics over the faulty device) (on file with the Washington and Lee Law Review).

6. *See infra* Part III (discussing the current use of medications for off-label purposes).

7. *See* Dana Dovey, *Glioblastoma Treatment Breakthrough: 'Untreatable' Brain Cancer Tumor Stabilized with Malaria Drug*, MED. DAILY (Jan. 17, 2017, 1:44 PM), http://www.medicaldaily.com/glioblastoma-treatment-breakthrough-untreatable-brain-cancer-tumor-stabilized-408668 (last visited Feb. 8, 2018) (detailing the successful off-label use of a malaria drug for the treatment of a brain tumor) (on file with the Washington and Lee Law Review).

8. *See id.* (explaining that glioblastomas are notoriously difficult to treat).

9. *See id.* (noting that doctors thought chloroquine might disable the tumor's defenses).

10. *See id.* (boasting clinical benefits in all three patients).

11. *See, e.g.*, Lawrence T. Park et al., *Evaluation and Treatment of Poor Sleep*, 9 PRIMARY CARE COMPANION J. CLINICAL PSYCHIATRY 224, 226 (2007) (pointing to Tylenol PM and Nyquil for their off-label treatment of insomnia). For another example sure to arouse your interest, see James O'Reilly & Amy Dalal, *Off-label or Out of Bounds? Prescriber and Marketer Liability for Unapproved Uses of FDA-Approved Drugs*, 12 ANNALS HEALTH L. 295, 298 (2003) (discussing how Viagra originally received approval as a treatment for chest pain before

Typically, the FDA weighs a medication's benefits against potentially harmful side effects as part of its New Drug Application (NDA) process, established by the Food, Drug, and Cosmetic Act (FDCA).[12] Reserving enforcement of off-label medication promotion to the expertise of the FDA, however, has proved somewhat unsuccessful.[13] Because FDA enforcement creates a chilling effect on manufacturers' advertising, pharmaceutical companies have successfully challenged agency enforcement actions as violations of their First Amendment rights.[14] After facing several challenges to its regulations, the FDA reduced the severity of its sanctions in an effort to avoid future lawsuits, but recent lower-court decisions have reinforced the notion that the FDA lacks a sufficient governmental interest to regulate this form of commercial speech.[15]

As an alternative, Section 43(a) of the Lanham Act[16] allows private companies to sue their competitors for false or misleading advertising.[17] The Supreme Court's recent decision in *POM Wonderful LLC v. Coca-Cola Co.*,[18] however, has cast some doubt on pharmaceutical companies' ability to challenge the promotion of products approved by the FDA.[19] Although the Court held that

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doctors began prescribing it for the then off-label treatment of erectile dysfunction).

12. Federal Food, Drug, and Cosmetic Act, Pub. L. No. 75-717, 52 Stat. 1040 (1938). *See* Leonard V. Sacks et al., *Scientific and Regulatory Reasons for Delay and Denial of FDA Approval of Initial Applications for New Drugs 2000–2012*, 311 J. AM. MED. ASS'N 378, 379 (2014) (explaining that manufacturers must provide evidence of a drug's safety and efficacy before the FDA will approve it).

13. *See infra* Part III.A (discussing First-Amendment challenges to the FDA's regulation of off-label drug promotion).

14. *See, e.g.*, United States v. Caronia, 703 F.3d 149, 152 (2d Cir. 2012) ("Caronia argues that he was convicted for his speech—for promoting an FDA-approved drug for off-label use—in violation of his right of free speech under the First Amendment. We agree.").

15. *See* Amarin Pharma, Inc. v. U.S. Food & Drug Admin., 119 F. Supp. 3d 196, 207 (S.D.N.Y. 2015) (noting that the FDA narrowed its interpretation of the FDCA while *Caronia* was on appeal).

16. United States Trademark Act (Lanham Act), Pub. L. No. 79-489, 60 Stat. 427 (1946).

17. *See* 15 U.S.C. § 1125(a)(1) (2012) (codifying the elements for a Section 43(a) claim).

18. 134 S. Ct. 2228 (2014).

19. *See generally id.* (holding that the FDCA does not preclude Lanham Act claims challenging food and beverage labels, but leaving open the possibility that

the FDCA does not preclude challenges to food and beverage labels brought under the Lanham Act, courts have since recognized preclusion in limited situations involving drug labels.[20] Thus, this Note seeks to address whether the current approaches to FDA preclusion of Lanham Act claims effectively bar competitors' actions under Section 43(a), and, if so, whether courts should establish an exception for claims involving the promotion of off-label medication uses.

Part II provides a more in-depth background of the statutes at issue, along with a discussion about how *POM Wonderful* has helped create this potential dilemma.[21] The Note then explores recent trends in litigation under both the FDCA and the Lanham Act to demonstrate how the two statutes complement each other in the regulation of off-label promotion.[22] Part III summarizes current arguments regarding the efficacy of off-label medication use and attempts to determine what level of regulation will best serve the public.[23]

Ultimately, the Note argues that the promotion of off-label drug uses does not fit neatly into the current framework for statutory preclusion that courts have established after *POM Wonderful*.[24] Thus, the question remains whether the FDCA precludes, or should preclude, Lanham Act claims that seek to challenge false or misleading promotion of off-label medication uses.[25] Part IV analyzes off-label promotion under the current preclusion framework to highlight potential problems in application.[26] Part V then argues that while Lanham Act claims

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FDA regulations may preclude drug-related claims).

20. *See infra* note 30 (citing to post-*POM Wonderful* decisions that have barred Lanham Act claims out of deference to the FDA).

21. *See infra* Part II (describing the history of the FDCA and Lanham Act).

22. *See infra* Parts III.A–B (focusing on First Amendment challenges to the FDA's regulations and whether the FDA's drug regulations preclude Lanham Act claims).

23. *See infra* Part III (introducing statistics about current off-label medication use).

24. *See infra* Part IV (outlining two approaches to preclusion that courts have applied since *POM Wonderful*).

25. *See infra* Part IV (applying post-*POM Wonderful* methods of preclusion to off-label promotion).

26. *See infra* Part IV (noting the difficulty of applying current approaches to off-label promotion).

typically cannot challenge a product regulated under the FDA's drug enforcement authority, recent applications of *POM Wonderful* should not extend to Lanham Act claims challenging manufacturers' promotion of drugs for off-label uses.[27]

II. A Comparison of the FDCA and the Lanham Act, and Their Application in POM Wonderful

Although the FDCA and Lanham Act largely serve different purposes, courts previously struggled to find a balance between the "misbranding" provisions of the FDCA and false advertising challenges under the Lanham Act.[28] The Supreme Court eventually provided a definitive statement of the statutes' complementary nature in the regulation of food and beverage labeling in *POM Wonderful*.[29] Nonetheless, courts continue to face confusion as they attempt to apply *POM Wonderful* to cases involving more highly regulated products—specifically, drug labels and advertising.[30]

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27. *See infra* Part V (suggesting a return to the reasoning of *POM Wonderful*).

28. *See, e.g.*, PhotoMedex, Inc. v. Irwin, 601 F.3d 919, 924 (9th Cir. 2010) (reasoning that private parties cannot bring a Lanham Act claim that would require a court to litigate an underlying violation of the FDCA); Schering-Plough Healthcare Prods. v. Schwarz Pharma, Inc., 586 F.3d 500, 510 (7th Cir. 2009) (dismissing plaintiff's claim because the relief sought would amount to a label change requiring FDA approval); Mylan Pharm., Inc. v. Procter & Gamble Co., 443 F. Supp. 2d 453, 455 (S.D.N.Y. 2006) (acknowledging the lack of a private right of action under the FDCA but, nonetheless, permitting a claim brought under Section 43(a)).

29. *See generally* POM Wonderful LLC v. Coca-Cola Co., 134 S. Ct. 2228 (2014) (addressing whether the FDCA's regulation of food and beverage labels precludes Lanham Act claims against manufacturers of food and beverage products).

30. *See, e.g.*, Apotex Inc. v. Acorda Therapeutics, Inc., 823 F.3d 51, 64 (2d Cir. 2016) ("[R]epresentations commensurate with information in an FDA [drug] label generally cannot form the basis for Lanham Act liability."); JHP Pharm., LLC v. Hospira, Inc., 52 F. Supp. 3d 992, 998–1000 (C.D. Cal. 2014) (considering whether the Supreme Court intended *POM Wonderful* to apply to drug labels); *see also* Church & Dwight Co. v. SPD Swiss Precision Diagnostics, GmbH, 843 F.3d 48, 63 (2d Cir. 2016) ("We see no reason why the subjugation of Defendant's [medical device] labeling to FDA regulation . . . should categorically immunize it from Lanham Act claims by competitors . . . .").

A. FDCA

The first major attempt at regulating food and drugs came in 1906 through the enactment of the Food and Drugs Act.[31] In an effort to quell a spike in the interstate shipment of adulterated foods, Dr. Harvey Wiley, then Chief Chemist for the Department of Agriculture, lobbied for the federal act using results of experiments showing the harmful effects of certain food additives.[32] Though this first legislation provided only weak guidance, it established a basis for later national food and drug regulation.[33] Not until 1938, however, did drug manufacturers need approval before marketing their medications.[34]

The FDA attributes its new drug process in part to the marketing of elixir sulfanilamide, a toxic remedy for streptococcal infections developed in 1937 by S.E. Massengill Co.[35] After receiving requests for a liquid form of sulfanilamide, the drug's manufacturer mixed the existing compound with diethylene glycol—a chemical now used in antifreeze.[36] Because no federal regulation existed to ensure the safety and effectiveness of medications before marketing, the new liquid medication resulted in over one hundred deaths throughout the United States that

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31. *See* 1 JAMES T. O'REILLY & KATHARINE A. VAN TASSEL, FOOD AND DRUG ADMINISTRATION § 3:1, Westlaw (database updated June 2017) (noting that Congress had passed several laws attempting to control imported food items, but otherwise left responsibility of regulating adulterated food and drug products to the states).

32. *See id.* § 3:2 (explaining that the experiment tested common food additives and preservatives on volunteer human subjects).

33. *See id.* (characterizing Wiley's proposal as "a weak and administratively cumbersome statute, flawed in significant details," but "a dramatic step forward in consumer protection").

34. *See* Carol Ballentine, *Taste of Raspberries, Taste of Death: The 1937 Elixir Sulfanilamide Incident*, FDA CONSUMER MAG., June 1981 (observing that it was the 1938 FDCA that increased the FDA's regulation of drugs).

35. *See id.* (describing the agony patients faced as a result of taking the elixir).

36. *See id.* (noting that the company did test the elixir for "flavor, appearance, and fragrance and found it satisfactory").

year.[37] Shortly thereafter, Congress enacted the 1938 Federal Food, Drug, and Cosmetic Act.[38]

Though the FDCA continues to evolve, the purpose remains the same: "to protect the health and safety of the public at large" by enabling the FDA to promulgate regulations that seek to eliminate fraud and false claims in the labeling and advertisement of products under its jurisdiction.[39] While food and cosmetics certainly pose health risks, however, it appears drugs have received substantially more attention from the FDA, as Congress has continued to expand the FDCA in ongoing efforts to protect the public from harmful medications.[40] Noted FDCA scholar James O'Reilly highlights several Supreme Court cases that additionally solidify judicial deference to the FDA in the context of drug regulation.[41] Two of these cases, *Wienberger v. Hynson, Westcott & Dunning, Inc.*[42] (*Hynson*) and *United States v. Rutherford*,[43] have significant relevance here.[44] *Hynson* established the FDA's "virtually unreviewable authority to determine whether a product was or was not a 'new drug' and thus within the FDA's regulatory jurisdiction."[45] A few years later, the Court confirmed this authority in *Rutherford* by stating that "[u]nless and until

37. *See id.* (stating that while there was no law illegalizing the selling of toxic drugs at the time, it "was, undoubtedly, bad for business").

38. *See id.* (suggesting that the incident did not merely hasten the FDCA's enactment, but led to the regulation of new drugs).

39. POM Wonderful LLC v. Coca-Cola Co., 134 S. Ct. 2228, 2234 (2014); *see also* O'REILLY & VAN TASSEL, *supra* note 31, § 14:1 (listing some of the methods through which the FDCA impacts drug safety); Federal Food, Drug, and Cosmetic Act, Pub. L. No. 75-717, 52 Stat. 1040 (1938) ("To prohibit the movement in interstate commerce of adulterated and misbranded food, drugs, devices, and cosmetics, and for other purposes.").

40. *See POM Wonderful*, 134 S. Ct. at 2235 (noting the difference between drug and food regulations).

41. *See* James T. O'Reilly, *Losing Deference in the FDA's Second Century: Judicial Review, Politics, and a Diminished Legacy of Expertise*, 93 CORNELL L. REV. 939, 943–45 (2008) (providing a brief history of the cases that have expanded deference to the FDA).

42. 412 U.S. 609 (1973).

43. 442 U.S. 544 (1979).

44. *See* O'Reilly, *supra* note 41, at 944 (commenting on how these cases granted the FDA substantial authority over drug regulations).

45. *Id.*; *see also Hynson*, 412 U.S. at 627 ("[The FDA's] jurisdiction to determine whether it has jurisdiction is as essential to its effective operation as is a court's like power.").

Congress [corrects the Court's misinterpretation of the FDCA], we are reluctant to disturb a longstanding administrative policy that comports with the plain language, history, and prophylactic purpose of the Act."[46] Essentially, these cases reflect the Supreme Court's unwillingness to interfere with FDA expertise in the realm of drug regulation.[47] *POM Wonderful* arguably provides yet another example of this deference through the Court's caveat-in-dictum, distinguishing the strict regulation of drugs from the agency's more relaxed approach to food and beverages.[48]

In addition to broad discretion over new drug applications, Congress provided the FDA sole enforcement authority over the FDCA and FDA regulations.[49] Rather than relying merely on the post hoc methods of enforcement used in food and beverage regulation, however, Congress mandated that the FDA approve medications and labels before marketing.[50] The agency also retains post-approval methods of enforcement such as warning letters or enforcement actions against manufacturers, which it may use to police misbranding of medications, unapproved drugs, or other unsafe practices as defined by either the statute or FDA regulations.[51] Through these enforcement actions, the FDA can assign criminal or civil liability resulting in monetary fines,

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46. *Rutherford*, 442 U.S. at 554.

47. *See* O'Reilly, *supra* note 41, at 944 (suggesting that *Hynson* and *Rutherford* granted the FDA the power to determine its own jurisdiction over drug regulation).

48. *See* POM Wonderful LLC v. Coca-Cola Co., 134 S. Ct. 2228, 2235 (2014) ("[T]he FDA does not preapprove juice labels. That contrasts with the FDA's regulation of other types of labels, such as drug labels, and is consistent with the less extensive role the FDA plays in the regulation of food than in the regulation of drugs." (citation omitted)).

49. *See* 21 U.S.C. § 337(a) (2012) ("[A]ll such proceedings for the enforcement . . . of this chapter shall be by and in the name of the United States."). The FDA has allowed petitions by either citizens or "interested persons" if they believe another party has violated the statute or regulations. *See* 21 C.F.R. §§ 10.25, 10.30 (2017) (setting out rules for such petitions).

50. *See* 21 U.S.C. § 355(a) (requiring that "[n]o person shall introduce or deliver for introduction into interstate commerce any new drug" until the drug receives preapproval by the FDA).

51. *See* O'REILLY & VAN TASSEL, *supra* note 31, § 7.1 (providing a brief overview of the FDA's enforcement methods); *see also* Heckler v. Chaney, 470 U.S. 821, 835–38 (1985) (establishing the FDA's broad prosecutorial discretion).

injunctions, exclusion from the market, or withdrawal of drug approval.[52]

As a part of the premarket approval process, the FDCA and its accompanying regulations require drug labels to include certain efficacy information for every intended use of the drug, and the FDA will refuse an application if it discovers any "misbranding."[53] Misbranding occurs, for example, when a drug's label or advertising contains false or misleading information, or when the label does not include adequate warnings and directions for use.[54] Consequently, the FDA has prohibited the promotion of drugs for off-label uses, or those uses for which the drugs have not received approval.[55] For example, because off-label drug promotion advertises unintended uses, for which the labels do not contain adequate directions, the FDA has used such promotion as evidence of mislabeling under the FDCA.[56] This prohibition, however, has led to a dispute over whether the FDA's interpretation violates drug manufacturers' First Amendment rights.[57]

In *Thompson v. Western States Medical Center*,[58] the seminal case challenging FDA limitations on unapproved promotion, the Supreme Court held that the FDA could not prohibit the advertisement of compounded drugs.[59] *Thompson* arose from the FDA's attempt to prohibit a process through which pharmacists would combine drugs to tailor their effects to the needs of individual patients.[60] To prevent harmful side effects, the FDA

52. *See* 21 U.S.C. §§ 332, 333, 335a–c (detailing the penalties available through FDA enforcement actions).

53. *See id.* § 331(b) (prohibiting misbranding).

54. *See id.* § 352 (defining when a drug will be considered "misbranded").

55. *See* United States v. Caronia, 703 F.3d 149, 160–61 (2d Cir. 2012) (deciding that the FDA's evidentiary use of off-label promotion to prove misbranding under the FDCA was an attempt to criminalize the act of off-label promotion).

56. *See id.* at 160 ("Specifically, the government argues that . . . 'the promotion of off-label uses plays an *evidentiary* role in determining whether a drug is misbranded under 21 U.S.C. § 352(f)(1).'").

57. *See id.* at 168 (holding that the FDA cannot prosecute manufacturers for truthful off-label promotion).

58. 535 U.S. 357 (2002).

59. *See id.* at 377 (invalidating the speech-related provisions of the Food and Drug Administration Modernization Act of 1997 § 503A as unconstitutional).

60. *See id.* at 360–61 (describing the process and purpose of drug compounding).

monitored the promotion of these compounded medications until Congress officially criminalized advertising by the pharmacists in the Food and Drug Administration Modernization Act of 1997 (FDAMA).[61] The Supreme Court recognized the utility of such a ban in "[p]reserving the effectiveness and integrity of the FDCA's new drug approval process," but it rejected the notion that the FDA could regulate this commercial speech.[62] Citing the government's concurrent interest in ensuring access to necessary medical treatment, the Court held that the FDA's prohibition "does not appear to directly further any asserted governmental objective."[63] Since *Thompson*, the FDA has encountered additional challenges to its regulations under the First Amendment. This Note revisits the FDA's struggle to find an appropriate regulatory approach to the promotion of off-label medications in Part III.[64]

B. Lanham Act Section 43(a)

At the time of its conception, the Lanham Act purported to create a broad federal law proscribing unfair competition,[65] with Section 43(a) focusing on protecting consumers from the deception of false advertising.[66] Although the drafters of the Lanham Act intended Section 43(a) to play a minor role in the legislation,[67] a wave of cases by creative plaintiffs' attorneys in the 1970s and '80s made it the primary vehicle for protecting consumers from false

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61. Food and Drug Administration Modernization Act of 1997, Pub. L. No. 105-115, 111 Stat. 2296; *see also Thompson*, 535 U.S. at 363–65 (noting that the FDA and the FDAMA did not allow pharmacists to promote compounded drugs).

62. *Thompson*, 535 U.S. at 369.

63. *Id.* at 377.

64. *See infra* Part III.A (detailing several cases in which courts struck FDA regulations for violating the First Amendment).

65. *See* 5 J. THOMAS MCCARTHY, MCCARTHY ON TRADEMARKS AND UNFAIR COMPETITION § 27:7, Westlaw (database updated Sept. 2017) (adding that courts have since declined to recognize the Lanham Act as a comprehensive federal unfair competition law).

66. *See id.* § 27:25 (noting that the broad protections of Section 43(a) lead to several advantages not provided by the common law).

67. *See id.* § 27:7 (explaining that the original draft of Section 43(a) was intended only to "ease the restrictive requirements of proof in the common law false advertising cases").

advertising.[68] Accordingly, Congress amended Section 43(a) in 1989, officially broadening its scope and splitting the provision into two separate "prongs": infringement and false advertising.[69]

While the statute creates a cause of action for "[a]ny person,"[70] courts have determined that only competitors may bring claims under the statute, leaving consumers to rely on private companies to police these unfair trade practices.[71] Considering, however, that "competitors have the greatest interest in stopping misleading advertising, . . . and in many situations . . . the greatest resources to devote to a lawsuit,"[72] the lack of standing for an individual to sue should not lessen the protection provided to consumers. While unfair practices undoubtedly harm consumers, competitors' interests in recovering lost profits or enjoining misleading advertising adequately fulfill Congress's intent "to protect persons engaged in such commerce against unfair competition."[73]

To state a prima facie claim for false advertising, competitors must plead with the requisite specificity[74] that the defendant has used, for the purpose of advertising or promoting in interstate commerce, any false or misleading information that "misrepresents the nature, characteristics, qualities, or geographic origin" of their, or a competitor's, product.[75] Plaintiffs must further demonstrate that they have been or likely will be damaged by these acts.[76]

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68. *See id.* § 27:8 (detailing the expansion of Section 43(a) by courts).

69. *See id.* § 27:9 (observing that before Congress rewrote Section 43(a), both potential claims stemmed from the same language, which prohibited "false designation of origin" and "false description or representation").

70. 15 U.S.C. § 1125(a)(1) (2012).

71. *See, e.g.*, Lexmark Int'l, Inc. v. Static Control Components, Inc., 134 S. Ct. 1377, 1388–90 (2014) ("A consumer who is hoodwinked into purchasing a disappointing product may well have an injury-in-fact cognizable under Article III, but he cannot invoke the protection of the Lanham Act . . . ."); Barrus v. Sylvania, 55 F.3d 468, 470 (9th Cir. 1995) (explaining that standing requires commercial injury "harmful to the plaintiff's ability to compete with the defendant," which excludes individual claims).

72. Coca-Cola Co. v. Procter & Gamble Co., 822 F.2d 28, 31 (6th Cir. 1987).

73. 15 U.S.C. § 1127.

74. *See* MCCARTHY, *supra* note 65, § 27:24 (noting that some courts require more specific pleading for false advertising based on the Federal Rule of Civil Procedure 9(b) standard for claims of fraud).

75. 15 U.S.C. § 1125(a)(1).

76. *See Lexmark Int'l*, 134 S. Ct. at 1384 (quoting 15 U.S.C. § 1125(a) to

Successful claims may result in either preliminary or permanent injunctive relief based upon the likelihood or actual presence of harm, and could include a requirement of corrective advertising to inform consumers of the false or misleading claims.[77] In addition to injunctive relief, plaintiffs may recover the defendant's profits from the unfair marketing campaign, damages sustained by the plaintiff, and costs of litigating.[78] Further, while plaintiffs cannot recover punitive damages under the Lanham Act, "[a] court may enter judgment . . . for any sum above the amount found as actual damages, not exceeding three times such amount," allowing some variance for inadequate or excessive rewards.[79]

Even though the Lanham Act seeks to deter unfair competition, courts have hesitated to allow competitors to bring claims against products regulated by the FDCA.[80] Some courts reasoned that if a product's labeling met the requirements of the FDCA, which sought to prevent the sale of adulterated or misbranded products, then any Lanham Act challenge would inevitably conflict with the FDCA.[81] Others, however, would allow claims that did not require interpretation or application of the

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highlight the elements of damage and proximate cause).

77. *See* MCCARTHY, *supra* note 65, § 27:37 (describing available injunctive relief and the burdens plaintiffs face to obtain such remedy).

78. *See* 15 U.S.C. § 1117(a) (2012) (including attorney fees "in exceptional cases").

79. *See id.* (noting that any variation shall not serve as punitive damages, but as compensation to the plaintiff).

80. *See, e.g.*, Church & Dwight Co. v. SPD Swiss Precision Diagnostics, GmbH, 843 F.3d 48, 73 n.13 (2d Cir. 2016) (recognizing that Lanham Act claims generally cannot challenge FDA labels); Apotex Inc. v. Acorda Therapeutics, Inc., 823 F.3d 51, 64 (2d Cir. 2016) (suggesting that barring Lanham Act claims that challenge drug labels reflects an appropriate deference to the FDA); Alpharma, Inc. v. Pennfield Oil Co., 411 F.3d 934, 939 (8th Cir. 2005) (declining to apply the doctrine of primary jurisdiction); Mylan Labs., Inc. v. Matkari, 7 F.3d 1130, 1139 (4th Cir. 1993) (dismissing a claim of misrepresentation because plaintiffs improperly sought to enforce the FDCA); Sandoz Pharm. Corp. v. Richardson-Vicks, Inc., 902 F.2d 222, 230–32 (3d Cir. 1990) (questioning whether allowing a Lanham Act challenge to defendant's drug label would usurp the FDA's authority); JHP Pharm., LLC v. Hospira, Inc., 52 F. Supp. 3d 992, 998–1000 (C.D. Cal. 2014) (establishing a presumption that Lanham Act claims may challenge products regulated by the FDA).

81. *See* POM Wonderful LLC v. Coca-Cola Co., 679 F.3d 1170, 1178 (9th Cir. 2012) (deferring to the expertise of the FDA by dismissing a claim challenging a drink label that appeared to comply with FDA regulations), *rev'd*, 134 S. Ct. 2228 (2014).

FDCA or FDA regulations.[82] This disagreement reached its peak when the Supreme Court attempted to resolve the debate in *POM Wonderful v. Coca-Cola*.[83]

C. A Comparison of the Lanham Act and the FDCA in POM Wonderful

In 2014, the Lanham Act and the FDCA collided after Coca-Cola began marketing its new pomegranate-blueberry juice.[84] While Coca-Cola's label contained the words "pomegranate blueberry" in large font and all capital letters, along with a vignette that showed blueberries, grapes, raspberries, and a halved pomegranate, the juice itself contained only 0.3% pomegranate juice and 0.2% blueberry juice.[85] POM Wonderful LLC (POM), a competitor of Coca-Cola as a grower and distributor of pomegranate juices, sued Coca-Cola under Section 43(a) of the Lanham Act.[86] POM challenged the label as misleading, explaining that consumers "have no way on God's green earth of telling that the total amount of blueberry and pomegranate juice in this product can be dispensed with a single eyedropper."[87]

Coca-Cola contested the suit, asserting that the FDCA's prohibition on misbranded food and drinks and the juice label's

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82. *See* PhotoMedex, Inc. v. Irwin, 601 F.3d 919, 924 (9th Cir. 2010) (barring a Lanham Act claim as an attempt to enforce the FDCA); Schering-Plough Healthcare Prods. v. Schwarz Pharma, Inc., 586 F.3d 500, 510 (7th Cir. 2009) (suggesting that a direct conflict between a Lanham Act claim and FDA regulations may create a preclusive effect).

83. *See generally* POM Wonderful LLC v. Coca-Cola Co., 134 S. Ct. 2228, 2234 (2014) (resolving whether the FDCA precludes a Lanham Act challenge to a food or beverage regulation).

84. *See id.* at 2235 (laying out a summary of the facts).

85. *See id.* ("Below those words, Coca-Cola placed the phrase 'flavored blend of 5 juices' in much smaller type.").

86. *See id.* ("POM alleged that the name, label, marketing, and advertising . . . mislead consumers into believing the product consists predominantly of pomegranate and blueberry juice when it in fact consists predominantly of less expensive apple and grape juices.").

87. *See* Oral Argument at 15:23, POM Wonderful LLC v. Coca-Cola Co., 134 S. Ct. 2228 (2014) (No. 12-761), https://apps.oyez.org/player/#/roberts6/oral_argument_audio/23517 (adding that "[i]t amounts to a teaspoon in a half gallon").

compliance with FDA regulations precluded POM's claim.[88] The District Court granted partial summary judgment for Coca-Cola, explaining that "the 'FDA has directly spoken on the issues that form the basis of POM's Lanham Act claim against the naming and labeling of' Coca-Cola's product, but has not prohibited any, and indeed expressly has permitted some, aspects of Coca-Cola's label."[89] The Ninth Circuit affirmed the decision, reasoning that "the Lanham Act may not be used as a vehicle to usurp, preempt, or undermine FDA authority."[90]

On appeal to the Supreme Court, the parties tasked the Court with choosing between competing canons of statutory interpretation.[91] POM suggested that courts "give full effect to both statutes unless they are in 'irreconcilable conflict,'" whereas Coca-Cola sought to have the more specific FDCA narrow the scope of the Lanham Act.[92] The Court declined to accept either argument.[93] Instead, it first searched both the FDCA and the Lanham Act for a provision expressly limiting their coequal application before considering whether the statutes were

88. *See POM Wonderful*, 134 S. Ct. at 2239 (pointing to a congressional goal of "national uniformity in food and beverage labeling"). When discussing preclusion of one federal statute's cause of action by another federal statute, the Note uses the term "statutory preclusion." This is not to be confused with legislative preclusion of judicial review in the context of administrative law. *See* ALFRED C. AMAN, JR. & WILLIAM T. MAYTON, ADMINISTRATIVE LAW § 12.5 (2d ed. 2001) (detailing generally the limitations to judicial review of agency action through express legislative statements included in organic statutes).

89. *POM Wonderful*, 134 S. Ct. at 2236 (quoting POM Wonderful LLC v. Coca-Cola Co., 727 F. Supp. 2d 849, 871 (C.D. Cal. 2010), *aff'd*, 679 F.3d 1170 (9th Cir. 2012), *rev'd*, 134 S. Ct. 2228 (2014)).

90. POM Wonderful LLC v. Coca-Cola Co., 679 F.3d 1170, 1176 (9th Cir. 2012), *rev'd*, 134 S. Ct. 2228 (2014).

91. *See* POM Wonderful LLC v. Coca-Cola Co., 134 S. Ct. 2228, 2236–37 (2014) (explaining that the problem of competing interpretive maxims is not unique to *POM Wonderful*).

92. *Id.* at 2237.

93. *See id.* (noting that the "Court does not need to resolve this dispute" because, in either case, the FDCA does not preclude POM's claim). Although the Court declined to apply either rule in *POM Wonderful*, it hinted at the idea that a direct conflict between the statutes would create a preclusive effect. *See id.* at 2240 ("Because, as we have explained, the FDCA and the Lanham Act are complementary and have separate scopes and purposes, this greater specificity would matter only if the Lanham Act and the FDCA cannot be implemented in full at the same time.").

conflicting or complementary in nature.[94] Through this approach, the Court determined that the FDCA does not expressly preclude the Lanham Act, and that, instead, the two statutes complement each other through their distinct scopes and purposes.[95] Moreover, the Court warned that the ability of the FDA's sole enforcement power to police unfair market practices pales in comparison to the expertise of market competitors.[96]

Ultimately, however, the Court narrowed its holding to food and beverage regulations, leaving open the possibility that the FDCA might still preclude Lanham Act claims challenging products more heavily regulated by the FDA, such as drugs.[97] Significantly, labels for drugs and some medical devices require preapproval by the FDA, which involves a detailed description of the products' quality, safety, and effectiveness, and a review of the proposed labeling.[98] Because the FDCA and its accompanying regulations involve a more comprehensive examination of the claims made by pharmaceutical companies as compared to those

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94. *See id.* at 2237–38 (pointing to the lack of an express provision as "'powerful evidence that Congress did not intend FDA oversight to be the exclusive means' of ensuring proper food and beverage labeling" (quoting Wyeth v. Levine, 555 U.S. 555, 575 (2009))).

95. *See id.* at 2241 (rejecting Coca-Cola's preclusion argument because "Congress did not intend the FDCA to preclude Lanham Act suits like POM's").

96. *See id.* at 2238 ("The FDA, however, does not have the same perspective or expertise in assessing market dynamics that day-to-day competitors possess. . . . [Competitors'] awareness of unfair competition practices may be far more immediate and accurate than that of agency rulemakers and regulators.").

97. *See id.* at 2233 ("[T]he FDCA and the Lanham Act complement each other in the federal regulation of misleading food and beverage labels."); *see also* Andrew Baum, *Supreme Court Holds that Lanham Act False Advertising Claims Are Not Preempted by FDCA*, HEALTH CARE L. TODAY (June, 20, 2014), https://www.healthcarelawtoday.com/2014/06/20/supreme-court-holds-that-lanham-act-false-advertising-claims-are-not-preempted-by-fdca/ (last visited Feb. 18, 2018) (observing that "the Court might take a different view if drug labeling were at issue") (on file with the Washington and Lee Law Review).

98. *See* 21 U.S.C. § 355(b) (2012) (listing requirements for preapproval of drugs through the FDA's NDA process); *FDA Regulation of Drugs Versus Dietary Supplements*, AM. CANCER SOC'Y, https://www.cancer.org/treatment/treatments-and-side-effects/complementary-and-alternative-medicine/dietary-supplements/fda-regulations.html (last updated Mar. 31, 2015) (last visited Feb. 18, 2018) [hereinafter *FDA Regulation*] (outlining the approval process of new drugs, and the conditions placed on the manufacturer by the FDA) (on file with the Washington and Lee Law Review).

made by food and beverage manufacturers,[99] the FDA sees fewer instances of mislabeling.[100] Nonetheless, lower courts have continued to rely on pre-*POM Wonderful* precedent for drug-related cases, demonstrating an unwillingness to interfere with FDA regulations.[101]

For example, in *Perez v. Nidek Co.*,[102] the Southern District of California dismissed state-law claims of unfair competition against a defendant medical device promoter, noting that "it was not proper for a district court to 'usurp administrative agencies' responsibility for interpreting and enforcing potentially ambiguous [FDA] regulations.'"[103] Though *Perez* did not involve the Lanham Act, courts resolving state-law claims have typically relied on the same precedent that formed the basis of post-*POM Wonderful* preclusion arguments.[104] Similarly, the Central District of California has held that "insofar as Plaintiffs' claims are based solely on allegations that Defendants promoted [their drug] for off-label purposes, they constitute an impermissible attempt to

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99. *See FDA Regulation*, *supra* note 98, at 5–7 (comparing regulation of drugs versus dietary supplements, which more closely resembles food).

100. *See Comments on FDA Enforcement of Drug Advertising Regulations*, PUB. CITIZEN (Oct. 28, 2002), http://www.citizen.org/Page.aspx?pid=3336#_ftnref3 (last visited Feb. 18, 2018) (showing a decline in the number of drug enforcement actions after the FDA began regulating the advertising of unapproved drug and medical device uses) (on file with the Washington and Lee Law Review). *But see id.* (expressing concern over the insufficient number of employees available to review advertisements).

101. *See, e.g.*, Apotex Inc. v. Acorda Therapeutics, Inc., 823 F.3d 51, 64, 64 n.9 (2d Cir. 2016) (barring Lanham Act claims challenging statements consistent with FDA-approved labeling (citing Mylan Pharm., Inc. v. Proctor & Gamble Co., 443 F. Supp. 2d 453 (S.D.N.Y. 2006))); JHP Pharm., LLC v. Hospira, Inc., 52 F. Supp. 3d 992, 999–1005 (C.D. Cal. 2014) (suggesting that primary jurisdiction, affirmative policy decision, conflict with an FDA-preapproved labeling scheme, and potentially drug labels in general may require preclusion (citing PhotoMedex, Inc. v. Irwin, 601 F.3d 919 (9th Cir. 2010))); Catheter Connections, Inc. v. Ivera Med. Corp., No. 2:14-CV-70-TC, 2014 WL 3536573, at *6 (D. Utah July 17, 2014) (leaving enforcement of the FDCA to the FDA (citing PhotoMedex, Inc. v. Irwin, 601 F.3d 919, 922 (9th Cir. 2010))).

102. 657 F. Supp. 2d 1156 (S.D. Cal. 2009).

103. *Id.* at 1165 (quoting Sandoz Pharm. Corp. v. Richardson-Vicks, Inc., 902 F.2d 222, 231 (3d Cir. 1990)).

104. *See, e.g.*, *id.* at 1165 (citing PhotoMedex, Inc. v. RA Med. Sys. Inc., No. 04CV24JLS (CAB), 2007 WL 3203039 (S.D. Cal. Oct. 29, 2007), *aff'd sub nom.*, PhotoMedex, Inc. v. Irwin, 601 F.3d 919 (9th Cir. 2010)).

bring a private suit for violations of the FDCA."[105] The court continued, however, to say that if "Plaintiffs can identify specific representations . . . that are literally false, misleading or contain material omissions, the claims are actionable" under California's consumer fraud laws.[106]

Conversely, the Eighth Circuit allowed a Section 43(a) claim where the manufacturer of a drug approved to treat only hypertension advertised its product as a "miracle drug" for the treatment of angina.[107] Likewise, the Southern District of New York has held that although "courts have rejected attempts . . . to create a private cause of action to challenge a manufacturer or distributor's sale of an FDA approved drug for off-label use," certain claims involving false assertions of FDA approval could proceed.[108] Thus, it appears that whether the FDCA or FDA regulations preclude Lanham Act claims challenging off-label promotion remains largely undecided, as courts vary on how strictly they apply *POM Wonderful*.

III. The Rise of Off-Label Medication Use and Issues Inhibiting Regulation

As the stories of Jeremy Lew and Lisa Rosendahl illustrate, the potential gain from off-label drug use might offset many of the associated public health risks, but such use could also result in devastating pain and suffering.[109] These conflicting results have led to a substantial debate among both lawyers and medical professionals about the safety of off-label treatments.[110] Studies

105. *In re* Epogen & Arenesp Off-Label Mktg. & Sales Practices Litig., 590 F. Supp. 2d 1282, 1292 (C.D. Cal. 2008).

106. *Id.*

107. *See* Rhone-Poulenc Rorer Pharm., Inc. v. Marion Merrell Dow, Inc., 93 F.3d 511, 513 (8th Cir. 1996) (upholding the finding that defendant violated the Lanham Act).

108. Mylan Pharm., Inc. v. Proctor & Gamble Co., 443 F. Supp. 2d 453, 460 (S.D.N.Y. 2006) (citing PDK Labs v. Friedlander, 103 F.3d 1105 (2d Cir. 1997); Mylan Labs., Inc. v. Matkari, 7 F.3d 1130 (4th Cir. 1993)).

109. *See supra* Part I (discussing Lew's nerve damage and the life-saving treatment of Rosendahl, both resulting from off-label treatments).

110. *See* Teresa Carr, *Off-Label Use: Should Drugs Do Double Duty?*, CONSUMER REP. (Jan. 4, 2017), http://www.consumerreports.org/drugs/off-label-use-should-drugs-do-double-duty/ (last visited Feb. 18, 2018) (reporting that drug

have shown that off-label uses account for approximately 20% of all prescribed treatments,[111] and that up to about 75% of those medications lack scientific evidence of efficacy.[112] In some cases, these uses provide hope for otherwise helpless patients, targeting cancers or rare diseases that may have no existing treatments.[113] As such, supporters of off-label use seek to increase the availability of drugs and efficacy data for unapproved uses.[114]

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companies seek to relax rules about off-label use and promotion while consumers typically want the FDA involved to prevent misleading advertising) (on file with the Washington and Lee Law Review).

111. *See* Tracy Hampton, *Experts Weigh in on Promotion, Prescription of Off-Label Drugs*, 297 J. AM. MED. ASS'N 683, 683 (2007) ("21% of the 725 million total drug prescriptions reported . . . lacked FDA approval for the condition they were used to treat."); Timothy O'Shea, *10 Surprising Off-Label Uses for Prescription Medications*, PHARMACYTIMES (Jan. 5, 2016), http://www.pharmacytimes.com/contributor/timothy-o-shea/2016/01/10-surprising-off-label-uses-for-prescription-medications (last visited Feb. 18, 2018) ("It is estimated that up to 20% of all medications prescribed are for indications that are not approved by the FDA.") (on file with the Washington and Lee Law Review); Randall S. Stafford, *Regulating Off-Label Drug Use—Rethinking the Role of the FDA*, 358 NEW ENG. J. MED. 1427, 1427 (2008) ("[F]or the 3 leading drugs in each of the 15 leading drug classes, off-label use accounted for approximately 21% of prescriptions.").

112. *See* Carr, *supra* note 110 ("[M]ore than 80 percent of off-label prescribing by doctors lacked strong scientific evidence."); Hampton, *supra* note 111, at 683 ("[Seventy-three percent] of off-label uses lacked evidence of clinical efficacy, and only 27% were supported by strong scientific evidence."); Stafford, *supra* note 111, at 1427 ("[M]ost off-label drug uses (73%) were shown to have little or no scientific support."); Christopher M. Wittich et al., *Ten Common Questions (and Their Answers) About Off-Label Drug Use*, 87 MAYO CLINIC PROC. 982, 983 (2012) ("[Seventy-three percent] of medications prescribed for an off-label use had poor or no scientific support.").

113. *See* Hampton, *supra* note 111, at 1427 ("[Fifty percent] to 75% of all uses of drugs in cancer care in the United States are off-label . . . . [A]pproximately 90% of patients with rare diseases are given at least one drug that is off-label."); *see also* Kelli Miller, *Off-Label Drug Use: What You Need to Know*, WEBMD (2009), http://www.webmd.com/a-to-z-guides/features/off-label-drug-use-what-you-need-to-know#1 (last visited Feb. 18, 2018) ("According to the American Cancer Society, cancer treatment often involves using certain chemotherapy drugs off-label, because a chemotherapy drug approved for one type of cancer may actually target many different types of tumors.") (on file with the Washington and Lee Law Review).

114. *See* Stafford, *supra* note 111, at 1427 (acknowledging that off-label promotion gives doctors and patients the benefit of "earlier access to potentially valuable medications"). *See generally* James M. Spears et al., *Embracing 21st Century Information Sharing: Defining a New Paradigm for the Food and Drug Administration's Regulation of Biopharmaceutical Company Communications with Healthcare Professionals*, 70 FOOD DRUG L.J. 143 (2015) (arguing for a

Not all uses stem from a lack of alternative treatments, however, and some result merely from incomplete clinical testing.[115] For example, "three fourths of the prescription drugs on the market do not have labeling indications for children, leaving their use in children to physicians' discretion."[116] Psychiatric medications also often lack sufficient clinical data, as "[p]atients with psychiatric disorders are often excluded from clinical trials, and these disorders are inherently difficult to study."[117] So, while some off-label uses might treat otherwise untreatable conditions, opponents of off-label use suggest that the benefits do not outweigh the potential negative side effects of using a medication with limited clinical efficacy information.[118] Instead, they argue that the promotion of such uses serves only to increase profits of the pharmaceutical companies.[119] As such, they push for increased regulation and postmarket enforcement of prohibitions on off-label use and promotion.[120]

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relaxation of FDA regulation of off-label promotion, among other things, so that physicians can receive the most recent information about the medications they prescribe and to avoid violating First Amendment rights).

115. *See* Hampton*, supra* note 111, at 683 (explaining that treatments can be difficult to test on some populations).

116. *Id.*

117. Wittich et al., *supra* note 112, at 983; *see also* Hampton, *supra* note 111, at 683 (noting that 96% of the off-label uses of psychiatric prescriptions had little or no support—the greatest disparity in support of studied medications); Susan Ipaktchian, *14 Drugs Identified as Most Urgently Needing Study for Off-Label Use, Stanford Professor Says*, STAN. MED. (Nov. 24, 2008), https://med.stanford.edu/news/all-news/2008/11/14-drugs-identified-as-most-urgently-needing-study-for-off-label-use-stanford-professor-says.html (last visited Feb. 18, 2018) (listing fourteen drugs in need of clinical testing for off-label use, nine of which are most commonly used to treat psychiatric disorders) (on file with the Washington and Lee Law Review); Stafford, *supra* note 111, at 1427 (observing that 60% of antipsychotics are prescribed off-label).

118. *See* Carr, *supra* note 110 ("[P]atients were 54 percent more likely to experience some kind of harm . . . compared with those taking the same drug for an approved use."); O'Shea, *supra* note 111 ("[T]he rate of side effects for off-label drugs was 44% higher than on-label ones.").

119. *See* Carr, *supra* note 110 (suggesting that, contrary to pharmaceutical companies' claims, their ultimate goal is "to sell products").

120. *See id.* (observing that "allowing drug companies to distribute off-label marketing materials . . . isn't helpful because it's likely to be biased," and "consumers want the FDA involved" so they know of any side effects and of the efficacy of suggested uses); Hampton, *supra* note 111, at 684 ("Experts note that changes may be needed. 'It might be helpful to adopt a more aggressive postmarket surveillance system, and that could be done using data collected

Certainly, the FDA should attempt to regulate the negative effects of off-label prescribing; but, at some point, the benefit from unapproved use likely outweighs the risk. Two issues have gained momentum over recent years that will ultimately play a role in determining the best method for regulating off-label promotion: First, the FDA's efforts to criminalize the misbranding of drugs by companies marketing them for off-label uses have led to litigation over First Amendment violations, as the regulations limit manufacturers' ability to promote their products.[121] Second, courts have distinguished *POM Wonderful*'s holding—that the FDCA does not preclude the Lanham Act—when Section 43(a) claims challenge medication labels.[122] When viewed together, the two issues create a potential paradox: FDA drug regulations preclude Lanham Act claims, but the FDA cannot effectively punish manufacturers who peddle drugs for off-label uses.[123] Thus, the best method of regulating off-label promotion might be to carve out an exception to the modern application of *POM Wonderful* in order to allow competitors to sue under Section 43(a), effectively supporting the FDA's goal of protecting consumer safety.

A. Pharmaceutical Companies Challenge FDA Regulations as Violating the First Amendment

Although the FDCA does not expressly prohibit off-label drug marketing, the FDA has interpreted the statute's misbranding

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by other players in the healthcare system—for instance, insurance companies or HMOs . . . ."); Stafford, *supra* note 111, at 1429 (warning against a relaxation of FDA regulations, and recommending that the agency "take an active role in fostering evidence-based practice . . . and requiring a balanced and fair presentation of scientific evidence").

121. *See infra* Part III.A (summarizing recent First-Amendment challenges to FDA regulations).

122. *See infra* Part III.B (outlining post-*POM Wonderful* approaches to preclusion in the context of drug labels).

123. *See infra* Parts III.A–B (detailing these two issues). If the information in a promotion or advertisement is false, both methods may provide legal recourse; however, courts have interpreted the phrase "false and misleading" differently for the FDCA and the Lanham Act. *See* Kathryn Bi, Comment, *What is "False or Misleading" Off-Label Promotion?*, 82 U. CHI. L. REV. 975, 999 (2015) (arguing that courts should interpret "false or misleading" uniformly across statutes with this language).

provisions to criminalize the practice.[124] Attempts to enforce the criminal provisions, however, have led to several recent court decisions admonishing the regulations as violations of the First Amendment.[125] The Supreme Court's decision in *Thompson* signaled the beginning of a decrease in FDA enforcement authority by holding that criminal prosecution for advertising compounded drugs did not directly advance a substantial governmental interest.[126] But, even after the FDA amended its sanctions in an effort to prevent future constitutional challenges, the agency has largely continued its criminal prohibition on off-label promotion of medications.[127] Despite the FDA's shift in regulations, the Supreme Court found in *Sorrell v. IMS Health, Inc.*[128] that "[s]peech in aid of pharmaceutical marketing . . . is a form of expression protected by the Free Speech Clause of the First Amendment."[129] Moreover, the conflicting government interests asserted in *Thompson* remain, as some pharmaceuticals have

124. *See* 21 C.F.R. § 202.1(j) (2008) (considering off-label promotion to be misbranding under the FDCA); United States v. Caronia, 703 F.3d 149, 153–55 (2d Cir. 2012) (outlining the FDA's argument that off-label promotion of a medication amounts to evidence of misbranding because the drug's label does not include adequate directions for the unapproved use); *In re* Epogen & Aranesp Off-Label Mktg. & Sales Practices Litig., 590 F. Supp. 2d 1282, 1288 (C.D. Cal. 2008) (providing a detailed roadmap of relevant FDCA and FDA rules through which the agency has sought to prohibit off-label promotion).

125. *See, e.g.*, *Caronia*, 703 F.3d at 152 (agreeing with appellant that his conviction for promoting an off-label use violated the First Amendment); Amarin Pharma, Inc. v. U.S. Food & Drug Admin., 119 F. Supp. 3d 196, 198 (S.D.N.Y. 2015) ("Amarin claims that the FDA's threat of a misbranding action is chilling it from engaging in constitutionally protected truthful speech."); *see also* Sorrell v. IMS Health Inc., 564 U.S. 552, 580 (2011) (declaring a Vermont law unconstitutional because it limited the ability of pharmaceutical manufacturers to engage in protected speech); Thompson v. W. States Med. Ctr., 535 U.S. 357, 377 (2002) (striking speech-related provisions of the Food and Drug Administration Modernization Act of 1997 as unconstitutional for prohibiting promotion of compounded drugs without directly furthering a government interest).

126. *See Thompson*, 535 U.S. at 369 (noting that the government has competing interests of "[p]reserving the effectiveness and integrity of the FDCA's new drug approval process" and "permitting the continuation of the practice . . . so that patients with particular needs may obtain medications suited to those needs").

127. *See Amarin Pharma*, 119 F. Supp. 3d at 207–08 (discussing the FDA's attempt to limit Amarin's promotion under the agency's narrower regulations).

128. 564 U.S. 552 (2011).

129. *Id.* at 557.

commonly known and effective off-label uses.[130] As the government has conceded, "because obtaining FDA approval for a new drug is a costly process, requiring FDA approval . . . for the particular needs of an individual patient would, as a practical matter, eliminate the practice . . . and thereby eliminate availability of . . . drugs for those patients who have no alternative treatment."[131] Consequently, the FDA has recently faced additional challenges to its regulation of off-label drug promotion.[132]

In *United States v. Caronia*,[133] the Second Circuit overturned the conviction of a pharmaceutical representative for off-label promotion and ruled that the FDA's prosecution violated the First Amendment.[134] Orphan Medical, Inc. hired Alfred Caronia to promote Xyrem, a central nervous system depressant used to treat narcolepsy patients with cataplexy[135] or excessive daytime sleepiness.[136] Because of Xyrem's side effects,[137] the FDA required

130. *See Thompson*, 535 U.S. at 368 (weighing the government's interests in preserving the integrity of the NDA process and maintaining access to individualized drug treatments unavailable through FDA-approved uses); *Caronia*, 703 F.3d at 166–67 (examining the government's interests in preserving the "integrity of the FDA's drug approval process and reducing patient exposure to unsafe and ineffective drugs" while recognizing that the FDA has acknowledged the benefit of off-label use and promotion); *see also* U.S. FOOD & DRUG ADMIN., PUBLIC HEALTH INTERESTS AND FIRST AMENDMENT CONSIDERATIONS RELATED TO MANUFACTURER COMMUNICATIONS REGARDING UNAPPROVED USES OF APPROVED OR CLEARED MEDICAL PRODUCTS 3 (2017) (asserting eleven government interests that seem to be covered broadly by those asserted in *Thompson* and *Caronia*).

131. *Thompson*, 535 U.S. at 369 (citing Brief for Petitioner at 19, Thompson v. W. States Med. Ctr., 535 U.S. 357 (2002) (No. 01-344)).

132. *See supra* note 125 (providing examples of challenges to the FDA's regulations).

133. 703 F.3d 149 (2d Cir. 2012).

134. *See id.* at 169 (concluding that "the government cannot prosecute pharmaceutical manufacturers and their representatives under the FDCA for speech promoting the lawful, off-label use of an FDA-approved drug").

135. *See id.* at 155 (defining cataplexy as "a condition associated with weak or paralyzed muscles").

136. *See id.* (noting that the two different uses of the drug were approved at different times, showing that off-label uses may eventually qualify for approval).

137. *See id.* ("Xyrem can cause serious side effects, including difficulty breathing while asleep, confusion, abnormal thinking, depression, nausea, vomiting, dizziness, headache, bedwetting, . . . sleepwalking[,] . . . seizures, dependence, severe withdrawal, coma, and death. Xyrem's active

the drug to carry a "black box" warning[138] and limited its distribution.[139] After launching an investigation of Orphan Medical, Inc., the FDA recorded a conversation in which Caronia promoted Xyrem for "insomnia, Fibromyalgia[,] periodic leg movement, restless leg, . . . Parkinson's and . . . other sleep disorders."[140] In later meetings, Caronia also offered evidence of safe use in patients younger than the population approved by the FDA.[141]

The court began its discussion by acknowledging the validity of the FDA's regulation prohibiting mislabeling, but ultimately determined that the agency could not use commercial speech as evidence of a violation of that regulation.[142] Under the agency's interpretation of the FDCA, off-label promotion evidences a company's intended use of the promoted drug.[143] As such, the agency sought to categorize a drug as mislabeled when the manufacturer advertised a use other than those indicated on the label.[144] The court distinguished mislabeled medications from off-label promotion, finding that "the government clearly prosecuted Caronia for his . . . speech."[145]

As the Second Circuit analyzed the FDA's prohibition, it applied the heightened scrutiny owed to content-based restrictions, but suggested that this application of the regulation

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ingredient . . . has been federally classified as the 'date rape drug . . . .'").

138. *See id.* ("The black box warning is the most serious warning placed on prescription medication labels.").

139. *See id.* (allowing only one pharmacy to distribute the medication across the United States).

140. *Id.* at 156 (alteration in original).

141. *See id.* at 156–57 (quoting Caronia as stating, "[T]here have been reports of patients as young as fourteen using it").

142. *See id.* at 161–62 (suggesting that the use of Caronia's speech as evidence of misbranding effectively amounted to the FDA's prosecution of speech).

143. *See id.* at 160 ("[T]he government argues that '[p]romoting an approved drug for off-label uses is not itself a prohibited act under the FDCA' and 'the promotion of off-label uses plays an *evidentiary* role in determining whether a drug is misbranded under 21 U.S.C. § 352(f)(1).'" (second alteration in original) (quoting Gov't Br. 51)).

144. *See* 21 C.F.R. § 202.1(e)(4) (2008) ("An advertisement . . . shall not recommend or suggest any use that is not in the labeling accepted in such approved new-drug application or supplement . . . .").

145. United States v. Caronia, 703 F.3d 149, 161 (2d Cir. 2012).

would fail even an intermediate-scrutiny test.[146] The court noted that the prohibition failed to advance directly a government interest as required for the government to limit protected speech.[147] Though the FDA sought to "preserv[e] the efficacy and integrity of the FDA's drug approval process and reduc[e] patient exposure to unsafe and ineffective drugs," the agency also knew "that approved drugs [would] be used in off-label ways."[148] The court found that this contradictory approach "interferes with the ability of physicians and patients to receive potentially relevant treatment information," inhibiting the public's ability to make informed treatment decisions.[149]

Several years after *Caronia*, Amarin Pharma, Inc. (Amarin) sought review in the Southern District of New York for "preliminary relief to ensure its ability to engage in truthful and non-misleading speech free from the threat of a misbranding action."[150] In *Amarin Pharma, Inc. v. U.S. Food & Drug Administration*,[151] the plaintiff presented a list of disclosures about off-label uses of its drug Vascepa that the company intended to disseminate to medical professionals.[152] Along with test results suggesting the safety and efficacy of the drug, Amarin agreed to release statements disclaiming that the medicine had not received FDA approval for the suggested uses.[153] The court, citing the same

146. *See id.* at 164 ("[W]e conclude the government cannot justify a criminal prohibition of off-label promotion even under *Central Hudson's* less rigorous intermediate test."). *But see id.* at 182 (Livingston, J., dissenting) (finding no reason to overturn Caronia's conviction, and noting that "the majority's decision today extends heightened scrutiny further than the Supreme Court ever has").

147. *See id.* at 167 ("[T]he government's prohibition of off-label promotion by pharmaceutical manufacturers 'provides only ineffective or remote support for the government's purpose.'" (quoting 44 Liquormart, Inc. v. Rhode Island, 517 U.S. 484, 504–05 (1996))).

148. *Id.* at 166.

149. *Id.*; *see also* U.S. FOOD & DRUG ADMIN., *supra* note 130, at 26 (acknowledging that the FDA's interest are "sometimes competing").

150. Amarin Pharma, Inc. v. U.S. Food & Drug Admin., 119 F. Supp. 3d 196, 198 (S.D.N.Y. 2015).

151. 119 F. Supp. 3d 196 (S.D.N.Y. 2015).

152. *See id.* at 212 (seeking a judgment that the FDA cannot keep the pharmaceutical company "from making completely truthful and non-misleading statements about its product to sophisticated healthcare professionals").

153. *See id.* at 215 (listing five disclosures that would inform medical professionals of the lack of FDA approval and other potential downsides to the

conflicting interests present in *Thompson* and *Caronia*, found that the FDA could not prosecute Amarin based on the presented statements.[154] Ultimately, the parties agreed that Amarin could promote the drug in a truthful and nonmisleading way.[155]

By acknowledging the potential validity of mislabeling prohibitions, courts have established that misbranding remains actionable, although the evidentiary use of truthful speech likely does not.[156] How much the agency will compromise on its effective prohibition, however, remains unclear.[157] In November of 2016, after facing defeat in both *Caronia* and *Amarin*, the FDA considered another shift from its strict prohibition on off-label promotion to avoid violating the First Amendment.[158] The

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drug's off-label use).

154. *See id.* at 237 (granting Amarin preliminary relief).

155. *See* Deborah Mazer & Gregory Curfman, *FDA Sanctions Off-Label Drug Promotion*, HEALTH AFF. BLOG (July 19, 2016), http://healthaffairs.org/blog/2016/07/19/fda-sanctions-off-label-drug-promotion/ (last visited Feb. 18, 2018) (reporting that the FDA ultimately settled with Amarin, in part because the agency had worked with the drug company to develop the medication, and Amarin could promote it based "almost entirely on statements by the FDA itself") (on file with the Washington and Lee Law Review).

156. *See* United States v. Caronia, 703 F.3d 149, 167 (2d Cir. 2012) ("While some off-label information could certainly be misleading or unhelpful, this case does not involve false or misleading promotion. . . . [I]t only furthers the public interest to ensure that decisions about the use of prescription drugs, including off-label usage, are intelligent and well-informed." (citations omitted)).

157. *See* Elizabeth Graham Minerd, *Guest Post—Midnight Madness—The FDA Continues to Discount First Amendment Implications of Restrictions on Off-Label Promotion*, JD SUPRA (Jan. 27, 2017), http://www.jdsupra.com/legalnews/guest-post-midnight-madness-the-fda-60305/ (last visited Feb. 18, 2018) (suggesting that cases like *Caronia* have not deterred the FDA from prosecuting even truthful off-label promotion) (on file with the Washington and Lee Law Review).

158. *See* Ryan Basen, *FDA Mulls New Policy on Off-Label Promotion*, MEDPAGETODAY (Nov. 9, 2016), http://www.medpagetoday.com/publichealthpolicy/fdageneral/61323 (last visited Feb. 18, 2018) (discussing a public hearing hosted by the FDA to hear comments on whether and how the agency should regulate off-label promotion) (on file with the Washington and Lee Law Review); Liz Minerd, *Guest Post – The FDA's Two-Day Meeting on Manufacturer Off-Label Communications*, DRUG & DEVICE L. (Nov. 15, 2016), https://www.drugandmanufacturer-off-label-communications.html (last visited Feb. 18, 2018) (summarizing comments made for and against increased regulations during the FDA's two-day meeting on November 9–10, 2016) (on file with the Washington and Lee Law Review).

following January, the FDA released a memorandum that seemed to double down on the agency's current approach of prohibiting off-label promotion, rather than relaxing its regulations.[159] After dismissing alternatives to regulation,[160] the memorandum merely restated the FDA's current approach,[161] while leaving open the possibility that the regulations may change under the Trump administration.[162]

B. POM Wonderful*'s Application to Drug-Related Claims*

When the Supreme Court found that the Lanham Act and FDCA complemented each other in *POM Wonderful*, it essentially dismissed any future arguments that the FDCA precludes Lanham Act claims.[163] As a result, if the Court intended FDA preapproval to bar Section 43(a) claims, it must have envisioned a different conflict necessitating such a bar.[164] Yet, courts attempting to

159. *See* U.S. FOOD & DRUG ADMIN., *supra* note 130, at 21 (maintaining the agency's argument that "the government's reliance on speech as evidence of intended use under the FD&C Act does not infringe the right of free speech under the First Amendment"); *see also* Minerd, *supra* note 157 ("[T]he Agency concludes that the restrictions on off-label promotion advance substantial government interests . . . and are therefore constitutional . . . . The Agency dismisses the Second Circuit's contrary analysis of the off-label promotion restrictions . . . in *United States v. Caronia* . . . .").

160. *See* U.S. FOOD & DRUG ADMIN., *supra* note 130, at 26 ("Although many of these proposed approaches address one or more of the interests identified above, FDA is concerned that none of them appear to integrate the complex mix of numerous, and sometimes competing, interests at play and thus do not best advance those multiple interests.").

161. *See id.* at 22 (arguing that the FDA does not prohibit off-label speech, but merely uses speech as evidence to establish an element of the agency's prohibition on misbranding). *But see* Nathan Brown, *FDA Offers Some Clarity (But Few Concessions) on Off-Label Communication of Medical Products*, JD SUPRA (Jan. 30, 2017), http://www.jdsupra.com/legalnews/fda-offers-some-clarity-but-few-12036/ (last visited Feb. 18, 2018) ("With its pair of draft guidance documents, FDA slightly broadens the scope of permissible communications related to approved or cleared medical products . . . .") (on file with the Washington and Lee Law Review).

162. *See* Minerd, *supra* note 157 (noting that the comment period for changes in FDA regulations closes April 2017).

163. *See* POM Wonderful LLC v. Coca-Cola Co., 134 S. Ct. 2228, 2240 (2014) (stating that the statutes' separate scopes and purposes allow courts to implement them at the same time).

164. *See, e.g.*, *id.* at 2241 (leaving available the possibility of preclusion when

reconcile the Supreme Court's narrow holding in *POM Wonderful* with precedent that recognizes broad deference to the FDA have demonstrated little disagreement over how *POM Wonderful* applies to Lanham Act claims involving drugs.[165] Rather, a consensus seems to have formed among courts that deference to the FDA's strict drug regulation might create a preclusive effect in limited circumstances.[166] Ultimately, this has led to some conflict about when, but not whether, drug regulation under the FDCA bars Section 43(a) claims.[167]

Judicial deference to the FDA in this area of regulation is vital to the agency's continued success, as a lack of consistent deference may dilute the agency's authority in the eyes of those regulated by the FDA.[168] In the context of drugs and medical devices, which have a large impact on public health and safety, an agency's inability to regulate effectively could lead to disastrous results. Considering the onus placed on manufacturers to keep their labeling accurate as new efficacy data becomes available,[169] the FDA must command respect from pharmaceutical companies.[170]

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a lawsuit would undermine an agency judgment or policy (citing Geier v. Am. Honda Motor Co., 529 U.S. 861 (2000))); *see also* JHP Pharm., LLC v. Hospira, Inc., 52 F. Supp. 3d 992, 999 (C.D. Cal. 2014) (contending that the Supreme Court intended preclusion in cases where an agency provided multiple options for manufacturers to reach compliance with regulations or where a Lanham Act claim would conflict with an affirmative FDA policy judgment like preapproval).

165. *See, e.g.*, Apotex Inc. v. Acorda Therapeutics, Inc., 823 F.3d 51, 64 (2d Cir. 2016) ("[R]epresentations commensurate with information in an FDA label generally cannot form the basis for Lanham Act liability.").

166. *See id.* at 64 n.10 ("Lanham Act liability might arise if an advertisement uses information contained in an FDA-approved label that does not correspond substantially to the label, or otherwise renders the advertisement literally or implicitly false.").

167. *Compare* Church & Dwight Co. v. SPD Swiss Precision Diagnostics, GmbH, 843 F.3d 48, 73 n.13 (2d Cir. 2016) (recognizing only limited circumstances in which FDA action precludes Lanham Act claims), *with JHP Pharm.*, 52 F. Supp. 3d at 1005 (suggesting that claims involving drug labeling may be broadly precluded).

168. *See* O'Reilly, *supra* note 41, at 942 (arguing that a lack of judicial deference to agencies leads regulated entities to "deem the agency less potent").

169. *See supra* Part II.B (discussing the FDA's ability to withdraw approval of drugs and medical devices based on noncompliance with agency regulations).

170. *See* 21 C.F.R. § 314.70 (2016) (outlining the FDA's reapproval of drugs and medical devices after manufacturers make label changes to update safety information).

Importantly, this is not to say that the FDA may override congressional acts through its powers of rulemaking and enforcement.[171] Rather, it is a recognition that courts intended to yield to the FDA's broad authority in the area of drug and medical device approval, and that decisions requiring interpretation of the FDA's regulations are best left to the agency's expertise.[172] As the Supreme Court established in *POM Wonderful*, the FDA's regulation of food and beverage labels set a base level of requirements for manufacturers.[173] But, when the FDA takes an active role in preapproving a label, rather than passively listing required information that manufacturers may satisfy with a wide array of vignettes, the agency creates a greater possibility of direct conflict with the Lanham Act.[174] In those cases, courts should give greater weight to the agency's expertise and enforcement power.[175]

Thus, considering that the Court broadly declined to find a statutory conflict, yet alluded to the possibility that more stringent FDA procedures may bar Lanham Act claims, the logical conclusion is the existence of some sort of preclusion based on deference to agency expertise.[176] Although the Supreme Court has

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171. *See* POM Wonderful LLC v. Coca-Cola Co., 134 S. Ct. 2228, 2241 (2014) ("An agency may not reorder federal statutory rights without congressional authorization.").

172. *See* O'Reilly, *supra* note 41, at 942 ("A historic strength of the FDA has been the deference received from courts during enforcement actions; indeed, the FDA has long nurtured its aura of expertise in order to win the accommodating acceptance of judges.").

173. *See POM Wonderful*, 134 S. Ct. at 2240 (noting that Congress did not intend the FDCA to act as a ceiling on the regulation of food and beverage labels).

174. *See* JHP Pharm., LLC v. Hospira, Inc., 52 F. Supp. 3d 992, 1000 n.5 (C.D. Cal 2014) (identifying the common requirement in the Supreme Court's preclusion analysis as "positive regulatory action" by the FDA).

175. *See id.* at 1003 (suggesting that determining whether a defendant misleadingly represents a product as "safe" or "effective" may require resolution by the FDA); *see also* Par Sterile Prods., LLC v. Fresenius Kabi USA LLC, No. 14 C 3349, 2015 WL 1263041, at *4 n.5 (N.D. Ill. Mar. 17, 2015) (agreeing with *JHP Pharm.* that some cases involving "complex inquiry" into matters of FDA expertise may be precluded); Catheter Connections, Inc. v. Ivera Med. Corp., No. 2:14-CV-70-TC, 2014 WL 3536573, at *6 (D. Utah July 17, 2014) (deferring to the FDA to resolve whether updates to an FDA-approved label requires reapproval in order to avoid misleading consumers).

176. *See POM Wonderful*, 134 S. Ct. at 2241 (suggesting that a direct conflict with an agency's policy may warrant preclusion to avoid undermining the agency's judgment).

shown considerably high regard for FDA expertise, it is highly unlikely that the Court intended to create an outright ban in *Hynson* or *Rutherford* on any claims involving the agency—especially considering that the legislature never took such action.[177] Instead, several post-*POM Wonderful* cases demonstrate a more plausible reason for this deference by attempting to reconcile the Supreme Court's holding with its caveat-in-dictum concerning FDA preapproval.[178] Similar to *POM Wonderful*, these cases acknowledge that the FDCA does not generally preclude the Lanham Act,[179] yet they go one step farther to bar claims based on pre-*POM Wonderful* principles of agency deference.[180]

For example, a few years before *POM Wonderful*, federal courts agreed that some questions regarding the safety or efficacy of medical devices and pharmaceuticals may be better resolved by the FDA's expertise.[181] In *POM Wonderful*, the Supreme Court also

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177. *See id.* at 2235 (pointing to the lack of legislative action establishing the FDCA's preclusion of the Lanham Act as evidence that the statutes should not have such effect); *see also supra* Part II.B (outlining the holdings of *Hynson* and *Rutherford*, which helped establish a strong judicial deference to the FDA).

178. *See supra* note 175 (providing examples of post-*POM Wonderful* cases recognizing preclusion or otherwise dismissing claims based on deference to the FDA).

179. *See Par Sterile Prods.*, 2015 WL 1263041, at *4 (observing that as long as the Lanham Act does not require a manufacturer to disobey an FDA requirement, Section 43(a) claims will not be precluded); *Catheter Connections*, 2014 WL 3536573, at *6 ("[T]he simple fact that a matter touches upon an area dealt with by the FDA is not a bar to proceedings with a claim under the Lanham Act." (quoting Pom Wonderful LLC v. Ocean Spray Cranberries, Inc., 642 F. Supp. 2d 1112, 1118 (C.D. Cal. 2009))).

180. *See, e.g.*, *Catheter Connections*, 2014 WL 3536573, at *6 (relying on *PhotoMedex, Inc. v. Irwin* to dismiss the claim out of deference to the FDA's exclusive enforcement authority).

181. *See* PhotoMedex, Inc. v. Irwin, 601 F.3d 919, 924 (9th Cir. 2010) (acknowledging the FDA's primary jurisdiction over FDCA violations); Schering-Plough Healthcare Prods. v. Schwarz Pharma, Inc., 586 F.3d 500, 512 (7th Cir. 2009) (affirming dismissal of a claim that would require the court to interpret FDA regulations); Alpharma, Inc. v. Pennfield Oil Co., 411 F.3d 934, 939 (8th Cir. 2005) (declining to defer to the FDA, but recognizing that questions requiring "expert consideration and uniformity of resolution" may necessitate agency intervention (quoting United States v. McDonnell Douglass Corp., 751 F.2d 220, 224 (8th Cir. 1984))); PDK Labs, Inc. v. Friedlander, 103 F.3d 1105, 1113 (2d Cir. 1997) (denying the availability of Section 43(a) as a method to enforce the FDCA); Mylan Labs., Inc. v. Matkari, 7 F.3d 1130, 1139 (4th Cir. 1993) (holding that Mylan could not independently enforce the FDCA through a Section 43(a) claim); Sandoz Pharm. Corp. v. Richardson-Vicks, Inc., 902 F.2d

recognized the potential for courts to undermine agency judgment by failing to consider adequately the ramifications of overruling agency action.[182] Citing *Geier v. American Honda Motor Co.*,[183] the Court explained that courts may bar an action if the ensuing litigation would conflict with an agency's affirmative policy choice.[184] Thus, while the Court's holding broadly rejected Coca-Cola's theory of complete statutory preclusion, the Court likely did not intend to prevent an FDA policy decision from barring certain Lanham Act claims.[185] Instead, the Court created a presumption against preclusion that defendants in drug-related Lanham Act actions may rebut by demonstrating that proper resolution requires deference to FDA expertise.[186] Since *POM Wonderful*, courts have attempted to define exactly when FDA actions should preclude Section 43(a) claims.[187] In the next Part, this Note analyzes the established methods of preclusion and applies them to Section 43(a) claims involving promotion of off-label drug uses in order to determine whether existing case law would allow competitors to police off-label promotion through the Lanham Act.[188]

222, 231 (3d Cir. 1990) ("[The cited cases] provide no support for the theory that it is appropriate for a court in a Lanham Act case to determine preemptively how a federal administrative agency will interpret and enforce its own regulations.").

182. *See* POM Wonderful LLC v. Coca-Cola Co., 134 S. Ct. 2228, 2241 (2014) (addressing the government's claim that the FDA intended to provide flexibility in labeling for food and drinks).

183. 529 U.S. 861 (2000).

184. *See POM Wonderful*, 134 S. Ct. at 2241 (stating that the court barred the action in *Geier* because it "directly conflicted with the agency's policy choice").

185. *See id.* (suggesting that *Geier*'s holding may preclude future Lanham Act claims that would require a court to undermine FDA judgments).

186. *See* JHP Pharm., LLC v. Hospira, Inc., 52 F. Supp. 3d 992, 1000 (C.D. Cal 2014) (reasoning that the Court created a presumption against preclusion and suggesting two ways of rebutting this presumption).

187. *Compare infra* note 190 (providing examples of situations in which courts have allowed claims to continue), *with supra* note 181 (listing the reasons courts have provided for precluding Lanham Act claims).

188. *See infra* Part IV (testing the ability of Section 43(a) claims involving off-label promotion to survive the direct-conflict and usurpation approaches to preclusion).

IV. FDA Regulations Preclude Lanham Act Claims Challenging Off-Label Promotion

Some courts have suggested that Lanham Act claims challenging drug labels fall under a broad exception to the Supreme Court's holding in *POM Wonderful*, precluding them altogether.[189] For the most part, however, courts have allowed Section 43(a) claims involving drugs so long as the resolution of relevant issues does not require FDA expertise.[190] Because the FDA has assumed such a large role in prohibiting the promotion of off-label drug uses, courts must now determine whether the FDA's involvement bars competitors' claims of false or misleading off-label advertising under Section 43(a).[191]

While courts have uniformly held that FDA drug regulation may preclude Lanham Act claims after *POM Wonderful*, each court tends to cite different reasons for such preclusion.[192] In application, however, several trends have emerged, suggesting that any difference in language merely reflects the absence of a guiding

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189. *See, e.g.*, *JHP Pharm.*, 52 F. Supp. 3d at 1005 (suggesting that because "the area of drug labeling was specifically singled out by the *POM Wonderful* Court as being one where the FDA takes a particularly active role . . . drug labeling might be an area where Lanham Act claims *are* precluded").

190. *See* Church & Dwight Co. v. SPD Swiss Precision Diagnostics, GmbH, 843 F.3d 48, 73 (2d Cir. 2016) (affirming the denial of defendant's motion to dismiss because the issue was whether advertising could be misunderstood, and did not require FDA expertise to resolve); PhotoMedex, Inc. v. Irwin, 601 F.3d 919, 924–25 (9th Cir. 2010) (suggesting that FDCA questions simple enough for courts to resolve would not preclude private Lanham Act claims); *see also JHP Pharm.*, 52 F. Supp. 3d. at 1001 ("In this instance, it takes no special expertise to determine whether the FDA has granted approval or not . . . .").

191. *See, e.g.*, Mylan Pharm., Inc. v. Proctor & Gamble Co., 443 F. Supp. 2d 453, 460 (S.D.N.Y. 2006) (acknowledging the lack of a private right to enforce off-label drugs under the FDCA, but allowing a Lanham Act claim to challenge whether defendant's advertising misleads consumers to believe the drug is safe and effective for unapproved uses).

192. *See, e.g.*, Apotex Inc. v. Acorda Therapeutics, Inc., 823 F.3d 51, 64 (2d Cir. 2016) (barring Lanham Act claims challenging statements consistent with FDA-approved labeling); *JHP Pharm.*, F. Supp. 3d at 1005 (suggesting that primary jurisdiction, affirmative policy decision, conflict with an FDA-preapproved labeling scheme, and potentially drug labels in general may require preclusion); Catheter Connections, Inc. v. Ivera Med. Corp., No. 2:14-CV-70-TC, 2014 WL 3536573, at *6 (D. Utah July 17, 2014) (leaving enforcement of the FDCA to the FDA).

authority on the issue.[193] Two of these trends—barring direct conflicts and usurpations of FDA authority—have received particularly wide acceptance among courts applying *POM Wonderful* in the context of drugs or medical devices.[194]

This Note first seeks to determine whether the current approaches to FDA preclusion of Lanham Act claims effectively bar competitors' actions under Section 43(a).[195] This inquiry alone cannot provide a dispositive answer to the issue, however, as *POM Wonderful*'s application to drug claims remains uncertain.[196] Thus, the Author also offers a general argument in favor of allowing competitors to sue for unfair competition on the basis of off-label promotion.[197]

A. Direct Conflict with FDA Policy Decisions

Though the Supreme Court declined to adopt a steadfast rule for statutory preclusion in *POM Wonderful*, it suggested that a

193. *See JHP Pharm.*, 52 F. Supp. 3d at 1000 n.5 (speculating as to what portions of the Supreme Court's dicta in *POM Wonderful* might clarify the Court's intention to preclude Section 43(a) claims involving drug labels and promotion). The apparent confusion between the doctrine of primary jurisdiction and courts' deference to the interpretation and enforcement powers of the FDA exemplifies this difference in language. *Compare id.* at 1001 (discussing whether the primary jurisdiction doctrine should require dismissal of such Lanham Act claims), *with Catheter Connections*, 2014 WL 3536573, at *6 (precluding a claim based on deference to the FDA's sole enforcement authority). This Note will not attempt the feat of expounding upon the differences between primary jurisdiction and deference to the interpretation or enforcement powers of the FDA. *See* RICHARD HENRY SEAMON, ADMINISTRATIVE LAW: A CONTEXT AND PRACTICE CASEBOOK 753 (Michael Hunter Schwartz ed., 2013) ("Because primary jurisdiction is a rather rare bird, some familiarity with the doctrine is the mark of a well-educated administrative lawyer.").

194. *See* JHP Pharm., LLC v. Hospira, Inc., 52 F. Supp. 3d 992, 1000 n.5 (C.D. Cal 2014) (suggesting that a conflict with an agency's policy decision, as in *Geier*, would preclude a Lanham Act claim); *Catheter Connections*, 2014 WL 3536573, at *6 (holding that the plaintiff's first claim was precluded because it impermissibly sought to enforce the FDCA).

195. *See infra* Parts IV.A–B (applying both methods of preclusion to Lanham Act claims challenging the promotion of off-label drug uses).

196. *See supra* Part III.B (addressing a conflict between courts, which have acknowledged various levels of preclusive effect, and scholars, who suggest a broad application of *POM Wonderful*'s holding).

197. *See infra* Part V (suggesting that the Supreme Court's reasoning in *POM Wonderful* should apply to off-label promotion).

direct conflict between the FDCA and the Lanham Act would create a preclusive effect.[198] Similarly, the Court alluded to the possibility that a direct conflict with an agency's policy judgment may also preclude actions under Section 43(a).[199] Because the Court has established that the FDCA and Lanham Act complement each other, the former should not become an issue unless Congress amends either act.[200]

As for when the Lanham Act conflicts with an FDA policy judgment, however, the Court provides only superficial guidance.[201] In *POM Wonderful*, the Court uses the term "policy judgment" merely to distinguish its precedent in *Geier*.[202] After suffering an injury in a car accident, the plaintiff in *Geier* sued Honda for not installing an airbag in her 1987 automobile.[203] The Department of Transportation had promulgated a rule allowing manufacturers to choose from a set of active and passive safety measures that would meet the agency's standards.[204] Coca-Cola argued that its pomegranate-blueberry juice similarly met FDA-required safety and ingredient labeling standards.[205] The Court distinguished the two cases, however, by asserting that the Department of Transportation made an affirmative decision to

198. *See* POM Wonderful LLC v. Coca-Cola Co., 134 S. Ct. 2228, 2237 (2014) (observing that neither the Lanham Act nor the FDCA "forbids or limits Lanham Act claims challenging labels that are regulated by the FDCA"); *see also* MCCARTHY, *supra* note 65, § 27:65.50 ("Only if there is a direct conflict between a clear mandate of FDCA regulation's [sic] and Lanham Act enforcement would there be a conflict.").

199. *See POM Wonderful*, 134 S. Ct. at 2241 (suggesting that a court could bar a claim if the cause of action directly conflicts with an agency's policy judgment).

200. *See id.* at 2240 ("[N]either the statutory structure nor the empirical evidence of which the Court is aware indicates there will be any difficulty in fully enforcing each statute . . . .").

201. *See id.* at 2241 (providing only a bare assertion that this case does not undermine an agency judgment).

202. *See id.* (pointing to a lack of any affirmative policy choice by the FDA).

203. *See* Geier v. Am. Honda Motor Co., 529 U.S. 861, 864–65 (2000) (bringing suit under a state tort law).

204. *See id.* at 875 (outlining the intended progression of the Department of Transportation's Standard 208, which listed the available safety devices).

205. *See POM Wonderful*, 134 S. Ct. at 2236 (addressing the district court's reasoning that the FDA "has not prohibited any, and indeed expressly has permitted some, aspects of Coca-Cola's label").

allow each of the safety measures, whereas the FDA merely set a floor for the information required.[206]

Another more relevant example of a conflicting policy judgment occurred before *POM Wonderful* in *Schering-Plough Healthcare Products v. Schwarz Pharma, Inc.*[207] Schering-Plough Healthcare Products (Schering), which manufactured the over-the-counter laxative "MiraLAX," brought a Lanham Act suit seeking to have the defendant manufacturers of similar generic drugs remove the symbol "Rx only" from their products' labels.[208] Schering claimed that the symbol misled consumers who may believe that all laxatives using the active ingredient polyethylene glycol 3350 required a prescription.[209] The Seventh Circuit affirmed the dismissal of Schering's claim because of a conflict between Section 43(a) of the Lanham Act and FDA regulations.[210] Per FDA requirements, generic medications requiring prescriptions must have the symbol "Rx only," which would prevent the court from granting Schering's request to have it removed.[211]

FDA preapproval alone should not suffice to disqualify a claim under the Lanham Act, however, as the FDA allows manufacturers to make minor or moderate changes to a product's label after approval so long as they subsequently notify the agency.[212] While the regulations permit only "editorial" label changes or changes that strengthen consumer knowledge about a product—such as the addition of warnings or removal of misleading information—*POM*

206. *See id.* at 2241 (explaining that the Department of Transportation "deliberately" provided a choice to manufactures, rather than merely enacting a flexible regulation).

207. Schering-Plough Healthcare Prods. v. Schwarz Pharma, Inc., 586 F.3d 500, 503 (7th Cir. 2009) (involving a medication that was simultaneously challenged in an FDA enforcement proceeding).

208. *See id.* at 502–03 (noting that all of the medications involved had the same active ingredient of polyethylene glycol 3350 as well as the same dosage, strength, and route of administration).

209. *See id.* at 503 (detailing Schering's argument that the defendants' labels falsely claimed that polyethylene glycol was available by prescription only).

210. *See id.* at 510 (affirming dismissal without prejudice so that Schering could refile depending on the results of the open FDA enforcement proceeding).

211. *See id.* (explaining that removing the symbol would constitute a "major" change under FDA regulations, requiring further FDA approval).

212. *See* 21 C.F.R. § 314.70 (2016) (describing the notification requirements for minor, moderate, and major drug label changes).

Wonderful shows that a change as slight as font size may mislead consumers.[213] Additionally, as the Seventh Circuit explained in *Schering*, "it might take years for the agency to get around to prohibiting a misleading label."[214] Because an intervening change to the label of an FDA-preapproved drug or medical device might allow an unapproved label to enter the market, preapproval of a product is likely necessary but not sufficient to establish a preclusive effect.[215] Furthermore, because promotion of off-label uses exclusively involves benefits unapproved by the FDA, courts should be unable to identify any conflicting policy decision.[216]

Proponents of preclusion would likely argue that the FDA's acknowledgement and acceptance of off-label prescribing evidence an affirmative policy decision to allow such uses.[217] Although the allowance of Section 43(a) claims would certainly deter off-label promotion, no direct conflict would exist unless the FDA adopted a policy requiring off-label use of medications.[218] Moreover, the agency's own criminal prohibition on the advertising of these potential benefits opposes this theory.[219] At best, the FDA has

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213. *See* POM Wonderful LLC v. Coca-Cola Co., 134 S. Ct. 2228, 2235 (2014) (focusing on the misleading nature of the font and vignette on Coca-Cola's pomegranate-blueberry juice).

214. *Schering-Plough Healthcare Prods.*, 586 F.3d at 510.

215. *See POM Wonderful*, 134 S. Ct. at 2240–41 (rejecting the government's argument that the FDA specifically requiring or authorizing aspects of a label precludes a Lanham Act challenge to that label).

216. *See* JHP Pharm., LLC v. Hospira, Inc., 52 F. Supp. 3d 992, 1005 (C.D. Cal. 2014) (considering that the lack of FDA approval might effectively remove a product from the preclusion argument altogether).

217. *See* United States v. Caronia, 703 F.3d 149, 153 (2d Cir. 2012) ("[T]he FDA generally does not regulate how physicians use approved drugs."); U.S. Food & Drug Admin., *FDA Drug Bulletin*, 12 FDA DRUG BULL. 1, 5 (1982) ("Once a product has been approved for marketing, a physician may prescribe it for uses or in treatment regimens or patient populations that are not included in approved labeling."); *see also "Off-Label" and Investigational Use of Marketed Drugs, Biologics, and Medical Devices – Information Sheet*, U.S. FOOD & DRUG ADMIN., http://www.fda.gov/RegulatoryInformation/Guidances/ucm126486.htm (last updated Jan. 25, 2016) (last visited Feb. 18, 2018) (listing six conditions that manufacturers must meet in order to begin clinical testing of an off-label use without an Investigational New Drug Application) (on file with the Washington and Lee Law Review).

218. *See POM Wonderful*, 134 S. Ct. at 2240 (suggesting that a conflict would arise "only if the Lanham Act and the FDCA cannot be implemented in full at the same time").

219. *See Caronia*, 703 F.3d at 155 (noting that the FDA has equated off-label

mired its policy in contradiction by asserting the competing goals of providing necessary medical treatment and limiting off-label promotion.[220] Thus, allowing competitors to bring Lanham Act suits challenging the off-label promotion of drugs will create a vehicle complementary to, not in conflict with, the FDA's affirmative policy choice to prohibit this advertising.

B. Usurpation of FDA Authority

Because the FDCA lacks a private cause of action, competitors often seek to enforce FDCA provisions through Section 43(a) suits or bring claims that require interpretation of the FDCA or FDA regulations.[221] Courts have agreed, however, that "a private action brought under the Lanham Act may not be pursued when . . . the claim would require litigation of the alleged underlying FDCA violation in a circumstance where the FDA has not itself concluded that there was such a violation."[222] Additionally, "claims that require direct interpretation and application of the FDCA are not properly recognized because such matters are appropriately addressed by the FDA, especially in light of Congress's intention to repose in that body the task of enforcing the FDCA."[223] Consequently, before the Supreme Court decided *POM Wonderful*, courts typically disallowed Section 43(a) suits in which plaintiffs sought indirectly to enforce the FDCA or where courts would have to apply or interpret the FDCA—functions reserved to the FDA.[224]

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marketing with misbranding, which is illegal under the FDCA).

220. *See id.* at 166 ("[T]he government asserts an interest in preserving the effectiveness and integrity of the FDCA's drug approval process, and an interest in reducing patient exposure to unsafe and ineffective drugs.").

221. *See* Healthpoint, Ltd. v. Stratus Pharm., 273 F. Supp. 2d 769, 786 (W.D. Tex. 2001) ("[C]ourts have held not only that a plaintiff may not seek to enforce directly the FDCA through the Lanham Act but also that a plaintiff may not maintain a Lanham Act claim if the claim requires direct application or interpretation of the FDCA or FDA regulations.").

222. PhotoMedex, Inc. v. Irwin, 601 F.3d 919, 924 (9th Cir. 2010).

223. Cottrell, Ltd. v. Biotrol Int'l, Inc., 191 F.3d 1248, 1255 (10th Cir. 1999) (quoting Braintree Labs., Inc. v. Nephro-Tech, Inc., No. 96-2459-JWL, 1997 WL 94237, at *6 (D. Kan. Feb. 26, 1997)).

224. *See, e.g.*, *PhotoMedex*, 601 F.3d at 924 (finding that plaintiff could not privately enforce the FDCA); Mylan Labs., Inc. v. Matkari, 7 F.3d 1130, 1139 (4th Cir. 1993) (same). Although interpreting and enforcing are arguably different

Since *POM Wonderful*, courts have continued to recognize that attempts to enforce the FDCA through Lanham Act claims might be precluded.[225] Typically, defendants must show that the court would have to engage not only in fact finding, but also interpretation or application of the FDCA.[226] For example, in *PhotoMedex, Inc. v. Irwin*,[227] PhotoMedex, Inc. filed suit against Ra Medical Systems, Inc. (RMS) for claiming that the FDA had cleared its excimer laser[228] for marketing.[229] Rather, RMS had received the manufacturing rights for the laser from SurgiLight, another developer that had received FDA 510(k) clearance for its design.[230] Before filing a Lanham Act suit, PhotoMedex, Inc. filed a complaint with the FDA reporting RMS for marketing a new

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functions, the intertwined nature of the two actions necessitate simultaneous consideration. For example, suppose that MedInc markets a medication as "safe and effective" without FDA approval under the grandfather clause of the FDCA. Pharmaco introduces a new medication that has the same medical indications, but that has received preapproval from the FDA. Rather than submitting a citizen petition to the FDA, Pharmaco sues MedInc for advertising its drug as "safe and effective." Pharmaco would, in effect, ask the court to enforce the FDCA by seeking to invoke the section of the statute that requires the FDA to determine the safety and effectiveness of new medications. In order to make such a determination, however, the FDA must interpret the FDCA to decide what level of safety and effectiveness to require. As such, in order to decide the claim on its merits, the court would have to both enforce and interpret the FDCA.

225. *See, e.g.*, Innovative Health Sols., Inc. v. DyAnsys, Inc., No. 14-cv-05207-SI, 2015 WL 2398931, at *6–8 (N.D. Cal. May 19, 2015) (recognizing the FDA's sole authority over FDCA enforcement); Par Sterile Prods., LLC v. Fresenius Kabi USA LLC, No. 14 C 3349, 2015 WL 1263041, at *4 n.5 (N.D. Ill. Mar. 17, 2015) (noting that *POM Wonderful* left open the possibility "that a Lanham Act claim might be precluded in certain cases that fall within the exclusive purview of the FDA"); JHP Pharm., LLC v. Hospira, Inc., 52 F. Supp. 3d 992, 997–1000 (C.D. Cal. 2014) (providing a detailed analysis for future preclusion of Lanham Act claims).

226. *See Innovative Health Sols.*, 2015 WL 2398931, at *7 (holding that the plaintiff's claim over misuse of an FDA clearance number did not circumvent FDA enforcement when the FDA had already spoken on the issue); *Par Sterile Prods.*, 2015 WL 1263041, at *4 n.5 (noting that litigating the fact of FDA approval does not require FDA expertise).

227. 601 F.3d 919 (9th Cir. 2010).

228. *See id.* at 922, 925 (explaining that excimer lasers are Class II medical devices used to treat skin disorders).

229. *See id.* at 923 ("Defendants distributed a brochure which proclaimed that Ra Medical's [laser] was 'FDA Approved . . . .'").

230. *See id.* at 922 (noting that SurgiLight gave RMS manufacturing rights in exchange for royalties).

product without 510(k) clearance.[231] Noting that the FDA investigated RMS and failed to determine that the new design required further clearance, the Ninth Circuit affirmed the district court's grant of summary judgment for lack of standing.[232] The court reasoned that "PhotoMedex is not permitted to circumvent the FDA's exclusive enforcement authority by seeking to prove that Defendants violated the FDCA, when the FDA did not reach that conclusion."[233] Further, the court recognized that "[t]esting the truth of PhotoMedex's claim would . . . require a court to usurp the FDA's prerogative to enforce the FDCA" because it would require interpretation of the statute.[234]

In *Catheter Connections, Inc. v. Ivera Medical Corp.*,[235] the District of Utah attempted to provide further clarity and guidance for determining when a claim usurps the FDA's enforcement authority.[236] There, the court held that the plaintiff improperly sought to bring a claim under the FDCA, explaining, "The initial decision [that its device was covered by Section 510(k) clearance of a similar device] lay in Ivera's hands. If that decision was wrong, the next step lies with the FDA, which may enforce the section and require a new submission by Ivera."[237] Conversely, the court allowed Catheter Connections' remaining claims to proceed, reasoning that the challenges were fact-based, rather than an "interpretation or application of FDA policy or regulatory requirements."[238]

Typically, claims that fall into the category of "seeking to enforce the FDCA" resemble attempts to circumvent the FDA's enforcement authority.[239] As the Ninth Circuit explained in

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231. *See id.* at 926 ("The issue was presented to the FDA, but it does not appear that the agency ever reached the conclusion sought by PhotoMedex.").

232. *See id.* at 923 (stating that the district court granted summary judgment because the FDA has "exclusive jurisdiction over FDCA enforcement").

233. *Id.* at 928.

234. *Id.*

235. No. 2:14-CV-70-TC, 2014 WL 3536573 (D. Utah July 17, 2014).

236. *See id.* at *5–7 (distinguishing between interpretation of the FDCA and fact finding).

237. *Id.* at *6.

238. *See id.* at *7 (suggesting that requiring the court to inquire into the nature of the product, rather than interpret the FDCA, distinguished the remaining claims).

239. *See, e.g.*, PhotoMedex, Inc. v. Irwin, 601 F.3d 919, 924 (9th Cir. 2010)

PhotoMedex, the enforcement issue arises when "the claim would require litigation of the alleged underlying FDCA violation."[240] Because the FDA has sought to prohibit nearly all instances of off-label promotion, any challenge to such promotion under Section 43(a) would resemble a private attempt to enforce the FDA's prohibition.[241] Thus, it appears that the current preclusion jurisprudence might completely bar Lanham Act claims challenging off-label promotion, as competitors would inevitably usurp the FDA's enforcement power.[242]

V. A Return to POM Wonderful*: Allowing Enforcement Through Section 43(a)*

Although courts often bar Section 43(a) claims under the current preclusion framework, they should create an exception for off-label drug promotion. Two considerations support this idea. First, the regulation of off-label promotion more closely resembles a function of the Lanham Act's protection against unfair competition than the FDCA's protection of public health and safety against adulterated drugs.[243] Applying *POM Wonderful*, then, neither the FDCA nor its accompanying FDA regulations should bar Section 43(a) claims.[244] Second, the FDA has asserted two competing governmental interests in its attempts to regulate off-label promotion, which courts and the agency alike have had

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(noting that the court would not allow PhotoMedex's claim when the FDA already determined there was no violation of the FDCA's provisions regarding FDA clearance).

240. *Id.*

241. *See supra* Part III.B (discussing the FDA's attempts to prosecute even truthful promotion under the FDCA's misbranding provisions).

242. *See* Minerd, *supra* note 157 (interpreting the FDA's latest guidance memorandum as merely "set[ing] forth the Agency's justification for their current restrictions on off-label promotion").

243. *See* Bi, *supra* note 123, at 999 (recommending the FDA adopt the same definition of "false or misleading" as the Lanham Act for evaluating off-label speech because the agency's off-label promotion regulations so closely resemble false advertising regulations).

244. *See* POM Wonderful LLC v. Coca-Cola Co., 134 S. Ct. 2228, 2238 (2014) (noting that the Lanham Act, and not the FDCA, focuses on protecting commercial interests against unfair competition).

difficulty balancing.[245] Lanham Act claims, however, rely on certain assumptions that will ultimately help balance the FDA's conflicting goals, "tak[ing] advantage of synergies among multiple methods of regulation" to support the FDA's interests in maintaining validity of its NDA process and protecting public health and safety.[246] Thus, returning to the Supreme Court's reasoning in *POM Wonderful* provides an answer for the instant regulatory dilemma—the Lanham Act complements the FDCA and FDA regulations. Deference to the FDA may occasionally mandate the preclusion of Section 43(a) claims, but that preclusion should not extend to disputes concerning the promotion of medications for off-label uses.

A. Off-Label Promotion is Unfair Competition

Viewing off-label promotion through the lens of *POM Wonderful* and its progeny, it appears that a private right of action to prevent misleading advertisement falls squarely under the scope of Section 43(a) as the regulation of unfair competition.[247] And, while off-label advertising certainly affects public health and safety so as also to implicate the FDCA, the Supreme Court in *POM Wonderful* explicitly relied upon the Lanham Act's distinct and complementary purpose to hold that the FDCA did not preclude claims under Section 43(a).[248] Courts have largely distinguished *POM Wonderful*'s holding when deciding Section 43(a) claims involving pharmaceuticals based on the FDA's regulation of those products through premarket approval.[249] But,

245. *See* United States v. Caronia, 703 F.3d 149, 166 (2d Cir. 2012) (weighing the FDA's interests in preserving the NDA process and reducing marketing of unsafe products against the FDA's allowance of off-label use and the ability to make informed treatment decisions).

246. *POM Wonderful*, 134 S. Ct. at 2239.

247. *See* 15 U.S.C. § 1127 (2012) ("The intent of this chapter is to . . . protect persons engaged in [interstate] commerce against unfair competition . . . ."); *POM Wonderful*, 134 S. Ct. at 2233–34 (describing the intent and purpose of the Lanham Act).

248. *See POM Wonderful*, 134 S. Ct. at 2238 ("Although both statutes touch on . . . labeling, the Lanham Act protects commercial interests against unfair competition, while the FDCA protects public health and safety.").

249. *See, e.g.*, Apotex Inc. v. Acorda Therapeutics, Inc., 823 F.3d 51, 64 (2d Cir. 2016) ("[A]n FDA label generally cannot form the basis for Lanham Act

regardless of whether *POM Wonderful*'s "complementary" holding applies to products preapproved by the FDA, off-label promotion concerns exclusively *unapproved* uses of medications.[250] Thus, the fact that the FDA sought to criminalize off-label promotion under the FDCA should not preclude similar civil claims under the Lanham Act.[251]

As Professor O'Reilly suggests, the FDA holds a unique quality as a government agency, departing from the typical approach to "agencies as vehicles for populist control of an important aspect of the economy."[252] Rather, the agency's founders sought to provide an administration of "passionate consumer advocates who used the power of a dispassionate scientific approach to address safety issues."[253] In fact, this scientific-expertise-based and consumer-oriented approach helped establish the deference to the FDA with which courts often treat matters arising under the FDCA.[254] As a result, public safety depends on the FDA's NDA process, the validity of which the agency has sought to protect through its prohibition of off-label promotion.[255] But, the agency further identifies a contradictory goal, which highlights its inability to pinpoint the best regulatory approach to this problem.[256]

During its litigation of First Amendment challenges, the FDA asserted that it indirectly banned off-label promotion for public

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liability."); JHP Pharm., LLC v. Hospira, Inc., 52 F. Supp. 3d 992, 1005 (C.D. Cal. 2014) ("*POM Wonderful* suggested, at least obliquely, that drug labeling might be an area where Lanham Act claims *are* precluded.").

250. *See Caronia*, 703 F.3d at 152 (defining off-label promotion as being "for a purpose not approved by the U.S. Food and Drug Administration").

251. *See POM Wonderful*, 134 S. Ct. at 2239 ("A holding that the FDCA precludes Lanham Act claims . . . would lead to a result that Congress likely did not intend.").

252. O'Reilly, *supra* note 41, at 948.

253. *Id.*

254. *See id.* at 949 (crediting the FDA's "reputation for superior science and expertise" as the reason for courts' willingness to give deference to the agency).

255. *See* United States v. Caronia, 703 F.3d 149, 166 (2d Cir. 2012) (recognizing that the government's "interest in preserving the effectiveness and integrity of the FDCA's drug approval process" is substantial).

256. *See* Thompson v. W. States Med. Ctr., 535 U.S. 357, 369–70 (2002) (discussing the difficulty of drawing the line between protecting the FDCA's approval process and the continuing need to provide appropriate treatment through drug compounding).

health and safety, while also conceding the importance of maintaining access to drugs for off-label use.[257] For that reason, the agency has not criminalized the prescribing or use of drugs for unapproved uses, but solely their promotion.[258] Consequently, the FDA's attempt to criminalize off-label promotion does not so much serve the FDCA's purpose of protecting public health and safety from adulterated medications as it does the Lanham Act's purpose of preventing unfair competition. Rather, the pecuniary incentive that Section 43(a) creates for competitors would provide a more appropriate avenue for preventing the unfair advertising.[259] Although Professors O'Reilly and Van Tassel correctly contend that the FDA will provide necessary control over pharmaceutical companies' greed,[260] that same greed provides competing manufacturers with a compelling incentive to regulate off-label promotion.[261] Indeed, while the FDA permits citizens to petition for

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257. *See Caronia*, 703 F.3d at 153 ("Off-label use is an 'accepted and necessary corollary of the FDA's mission to regulate in this area without directly interfering with the practice of medicine.'" (quoting Buckman Co. v. Plaintiffs' Legal Comm., 531 U.S. 341, 350 (2001))).

258. *See* U.S. FOOD & DRUG ADMIN., *supra* note 217, at 5 (allowing off-label prescribing of unapproved drug uses); *see also* 21 U.S.C. § 396 (2012) ("Nothing in this Act shall be construed to limit or interfere with the authority of a health care practitioner to prescribe or administer any legally marketed device to a patient for any condition or disease within a legitimate health care practitioner-patient relationship.").

259. *See* POM Wonderful LLC v. Coca-Cola Co., 134 S. Ct. 2228, 2238–39 (2014) ("By 'serv[ing] a distinct compensatory function that may motivate injured persons to come forward,' Lanham Act suits, to the extent they touch on the same subject matter as the FDCA, 'provide incentives' for manufacturers to behave well." (quoting Wyeth v. Levine, 555, U.S. 555, 579 (2009))). The FDCA also allows the FDA to fine manufacturers for criminal violations of the statute's misbranding provisions, but these punishments still lack the monetary reward that entices competing manufacturers to help police off-label promotion. *See* 21 U.S.C. § 333 (punishing criminal violations of the FDCA's misbranding provisions with potential fines of up to $1 million after the second offense in ten years).

260. *See* O'REILLY & VAN TASSEL, *supra* note 31, § 3:2 ("Whether regulatory enforcement can control greed is an issue debated to this day in the food and drug regulation field. Good faith on the part of the manufacturers is a necessary ideal but until that perfect world can be achieved, a strong [FDA] is justified.").

261. *See POM Wonderful*, 134 S. Ct. at 2238

> The FDA, however, does not have the same perspective or expertise in assessing market dynamics that day-to-day competitors possess. Competitors who manufacture or distribute products have detailed knowledge regarding how consumers rely upon certain sales and marketing strategies. Their awareness of unfair competition practices

enforcement, it lacks the pecuniary interest that Section 43(a) provides to competitors who might have better knowledge about competing drugs.[262]

Additionally, *POM Wonderful* suggested that barring Lanham Act claims might require the FDA to spread its resources too thin, preventing the agency from fully enforcing its regulations.[263] Admittedly, *POM Wonderful* concerned food and beverage regulations, which, as the Supreme Court acknowledged, receive much less attention than drug regulations.[264] Nonetheless, the Court counseled against preclusion, in part because competitors have greater resources to challenge misleading advertising.[265] Potential fluctuations in FDA resources and enforcement following changes in the executive branch also warrant a backstop in the form of Lanham Act liability.[266] For example, at the time this Note was written, President Trump's leading candidate to head the FDA supported a drastic decline in the NDA process and other safeguards that could result in unsafe drugs reaching the market.[267] As the Supreme Court stated in *POM Wonderful*, "[t]his

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> may be far more immediate and accurate than that of agency rulemakers and regulators. Lanham Act suits draw upon this market expertise by empowering private parties to sue competitors to protect their interests on a case-by-case basis.

262. *See id.* at 2238–39 (noting that the Lanham Act provides incentives for competing manufacturers to help regulate market practices otherwise regulated by the FDCA).

263. *See id.* at 2239 (implying that the FDA lacks the resources to pursue enforcement regarding all objectionable labels).

264. *See id.* (recognizing that the FDA does not preapprove food and beverage labels like it does drug labels).

265. *See id.* at 2238 ("The FDA, however, does not have the same perspective or expertise in assessing market dynamics that day-to-day competitors possess.").

266. *See* O'Reilly, *supra* note 41, at 959–62, 977 (observing that the executive branch has enormous discretion over the NDA process, and arguing that a renewed FDA independence would help the agency regain deference); *see also* John D. Loike & Jennifer Miller, *Opinion: Improving FDA Evaluation Without Jeopardizing Safety and Efficacy*, SCIENTIST (Feb. 1, 2017), http://www.the-scientist.com/?articles.view/articleNo/48280/title/Opinion--Improving-FDA-Evaluations-Without-Jeopardizing-Safety-and-Efficacy/ (last visited Feb. 18, 2018) (considering what changes a new head of the FDA would bring to the agency's NDA process) (on file with the Washington and Lee Law Review).

267. *See* Drew Armstrong et al., *Trump Team Said to Consider Thiel Associate O'Neill for FDA*, BLOOMBERG POL. (Dec. 7, 2016, 12:01 PM), https://www.bloomberg.com/politics/articles/2016-12-07/trump-team-is-said-to-consider-thiel-associate-o-neill-for-fda (last visited Feb. 18, 2018) ("In a 2014

is quite consistent with the congressional design to enact two different statutes, each with its own mechanisms to enhance the protection of competitors and consumers."[268]

B. Section 43(a) Claims Will Protect the FDA's Stated Interests

Since its inception in the 1930s, the FDA has faced the difficult task of pursuing the FDCA's goal of protecting public health and safety from adulterated drugs.[269] Successful administration of its own strict standards for new drugs and clinical testing, however, has led to a new dilemma. Protecting public safety requires the continuation of the NDA process that has ensured safe and effective treatment and increased monitoring of dangerous medications.[270] But, public health may require treatment options that lack FDA approval—possibly because a drug lacked insufficient supporting data from clinical trials for a particular use at the NDA stage, or because the FDA determined that the potential side effects outweighed the benefits and declined to grant approval.[271] In either case, the requirements of Section 43(a) will incidentally lead to an appropriate balancing of the FDA's end goals.

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speech, he said he supported reforming FDA approval rules so that drugs could hit the market after they've been proven safe, but without any proof that they worked, something he called 'progressive approval.'") (on file with the Washington and Lee Law Review); Loike & Miller, *supra* note 266 ("O'Neill has publicly proposed eliminating the FDA's requirement for Phase 2 and Phase 3 trials, in an effort to lower drug development costs.").

268. POM Wonderful LLC v. Coca-Cola Co., 134 S. Ct. 2228, 2239 (2014).

269. *See* Federal Food, Drug, and Cosmetic Act, Pub. L. No. 75-717, 52 Stat. 1040 (1938) (providing that the act's purpose is to protect the public from misbranding).

270. *See* United States v. Caronia, 703 F.3d 149, 166 (2d Cir. 2012) (recognizing that the FDA's interest in preserving its NDA process is "substantial").

271. *See id.* at 153 ("[O]ff-label uses or treatment regimens may be important and may even constitute a medically[-]recognized standard of care." (alterations in original) (quoting U.S. FOOD & DRUG ADMIN., DRAFT GUIDANCE, GOOD REPRINT PRACTICES FOR THE DISTRIBUTION OF MEDICAL JOURNAL ARTICLES AND MEDICAL OR SCIENTIFIC REFERENCE PUBLICATIONS ON UNAPPROVED NEW USES OF APPROVED DRUGS AND APPROVED OR CLEARED MEDICAL DEVICES 3 (2009))).

1. Maintaining Validity of the NDA Process

Section 43(a), by dissuading competitors from placing a drug on the market for an unapproved and unintended use, exemplifies the complementary nature of the Lanham Act and FDCA praised by the Supreme Court in *POM Wonderful*.[272] Under this scheme, manufacturers must choose either to promote a newly discovered off-label use—and face the threat of paying monetary damages to their competitors—or to put that money toward a supplemental application for FDA approval.[273] Moreover, if manufacturers face both civil liability to their competitors and criminal liability through the FDA, the cost of any misleading promotion increases.[274]

Granted, the reported estimates of bringing a new drug to the market might seem exorbitant, but pharmaceutical companies often include the cost of research in these estimates.[275] Significantly, the truthful marketing of drugs for off-label purposes presupposes the existence of efficacy data for the medications.[276]

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272. *See POM Wonderful*, 134 S. Ct. at 2238–39 (finding the Lanham Act and FDCA to be complementary because they serve different functions with overlapping subject matter).

273. *Compare* J. SHAWN MCGRATH & KATHLEEN M. KEDROWSKI, DAMAGES TRENDS IN PATENT AND LANHAM ACT CASES 9, http://apps.americanbar.org/litigation/committees/corporate/docs/2010-cle-materials/05-hot-topics-ip-remedies-injunctions/05b-damages-trends-ga-bar.pdf (showing that the average award for false advertising cases from 2004 and 2008 was between $2.5–3 million, with the largest damages award being over $16 million), *with Standard Costs (in Thousands of Dollars) for Components of the Process for the Review of Human Drug Applications*, U.S. FOOD & DRUG ADMIN., http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm093484.htm (last updated Oct. 2, 2017) (last visited Feb. 18, 2018) (listing the average cost of new drug application with clinical data at about $1.8 million, and the cost of a supplement with clinical data at about $473,000 in 2016) (on file with the Washington and Lee Law Review).

274. *See* 21 U.S.C. § 333 (2012) (punishing manufacturers who violate the FDCA's misbranding provisions with fines from fifty thousand to one million dollars).

275. *See* A. Gordon Smith, *Price Gouging and the Dangerous New Breed of Pharma Companies*, HARV. BUS. REV. (July 6, 2016), https://hbr.org/2016/07/price-gouging-and-the-dangerous-new-breed-of-pharma-companies (last visited Feb. 18, 2018) (estimating the price of research and development to be anywhere from millions of dollars to over $2.6 billion) (on file with the Washington and Lee Law Review).

276. *See* 21 U.S.C. § 352(a)(1) (noting that clinical data is not false or

Thus, regardless of whether manufacturers market an approved or off-label use, the vast majority of effective marketing will require testing and efficacy data.[277] The availability of Section 43(a) will not limit a pharmaceutical company's ability to gather real-world clinical data, however, as long as the company clearly disclaims the insufficiency of supporting efficacy and safety information as part of the advertising.[278] After *Amarin*, companies may disclaim a drug's risks and lack of FDA approval to promote truthfully an off-label use and avoid Lanham Act liability.[279] In effect, this would allow companies to promote an off-label use and receive clinical data from treatment results instead of paying for additional testing. By contrast, then, companies could potentially pay less to submit a new use to the FDA than to face civil liability from their competitors.[280]

Arguably, this could lead to an increase in healthcare costs, rather than an increase in NDAs.[281] Instead of deterring off-label promotion, pharmaceutical companies might continue their current practice of merely passing the price of litigation on to consumers.[282] Any increase in price due to litigation costs of claims arising under the Lanham Act, however, presupposes the

misleading if it "is based on competent and reliable scientific evidence").

277. *See* Hampton, *supra* note 111, at 683 (stating that physicians prescribing off-label uses "have the responsibility to be well-informed about the product, to base its use on firm scientific rationale and on sound medical advice").

278. *See* Amarin Pharma, Inc. v. U.S. Food & Drug Admin., 119 F. Supp. 3d 196, 235 (S.D.N.Y. 2015) (allowing Amarin to promote its medication based on the transparency of the advertisements and disclosures).

279. *See id.* (identifying a method by which to avoid liability under Section 43(a)).

280. *See supra* note 273 (comparing the price of Lanham Act damages to the price of FDA approval).

281. *See* Elizabeth Richardson, *Health Policy Brief: Off-Label Drug Promotion*, HEALTHAFFAIRS (June 30, 2016), https://www.healthaffairs.org/do/10.1377/hpb20160630.920075/full/ (last visited Mar. 4, 2018) ("[P]reventing a manufacturer from communicating about an off-label use or the comparative value of its products might . . . increase health costs.") (on file with the Washington and Lee Law Review).

282. *See* Trisha Marczak, *Multimillion-Dollar Settlement for Misleading Consumers: Just Another Day at Pfizer*, MINTPRESS NEWS (Aug. 1, 2013), http://www.mintpressnews.com/pfizer-settlement-misleading-consumers/166292/ (last visited Feb. 18, 2018) ("[W]hen it comes to paying for costs associated with lawsuits and settlements against drug makers, consumers are likely to carry the tab.") (on file with the Washington and Lee Law Review).

availability of some alternative drug for the same treatment—a drug company cannot successfully bring a claim under the Lanham Act unless it has suffered losses from a competing product.[283] If a company hikes the price of their drug to pass litigation costs on to its consumers, then those consumers have the option of purchasing medications from the competitor, whose product likely received approval from the FDA.[284] As a result, the availability of Lanham Act claims should provide incentives for manufacturers to seek FDA approval for their supplemental uses.

2. Balancing Necessary Treatments with a Potential for Dangerous Side Effects

Both the FDCA and the Lanham Act seek to protect consumers—the FDCA from adulterated or misbranded drugs, and the Lanham Act from unfair competition.[285] Since the FDA began interpreting off-label promotion as evidence of misbranding, however, the two statutes largely coincide.[286] As *POM Wonderful* suggests, despite the difference in legislative intent, the FDCA and Lanham Act provide distinct and complementary avenues to protect consumers from both unfair competition and adulterated or misbranded drugs.[287] By focusing on unfair competition, the Lanham Act supports the FDCA in the area of off-label promotion

283. *See* Lexmark Int'l, Inc. v. Static Components, Inc., 134 S. Ct. 1377, 1390 (2014) (requiring that a plaintiff fall within the "zone of interest" by asserting loss to either their reputation, or sales as a result of the defendant's acts).

284. *See* Richardson, *supra* note 281 ("Rising prescription drug costs have led to an increased emphasis on the comparative value of treatments on the market . . . which allows individuals to assess the price of a given drug relative to its value.").

285. *See* 15 U.S.C. § 1127 (2012) ("The intent of this chapter is to . . . protect persons engaged in [interstate] commerce against unfair competition . . . ."); Federal Food, Drug, and Cosmetic Act, Pub. L. No. 75-717, 52 Stat. 1040 (1938) ("To prohibit the movement in interstate commerce of adulterated and misbranded food, drugs, devices, and cosmetics, and for other purposes.").

286. *See* Perez v. Nidek Co., 657 F. Supp. 2d 1156, 1166 (S.D. Cal. 2009) (drawing a parallel between plaintiff's off-label claims and the FDA's enforcement of off-label claims).

287. *See* POM Wonderful LLC v. Coca-Cola Co., 134 S. Ct. 2228, 2238 (2014) ("The two statutes impose 'different requirements and protections.'" (quoting J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc., 122 S. Ct. 593, 605 (2001))).

where FDA regulation may decrease access to necessary treatment options.[288]

a. Section 43(a) Does Not Limit Access to Necessary Treatments

Often patients rely on off-label treatments as options of last resort, whether because other treatments have failed, or because no medication specifically targets a particular illness.[289] For example, the story of Lisa Rosendahl shows that off-label uses can treat rare or otherwise incurable conditions—an important reason not to prevent access to information about off-label options.[290] Where the FDA seeks to limit off-label promotion in all instances, however, the Lanham Act likely would not prevent access to treatment options in either of these situations.

In order to prove a prima facie case under Section 43(a), a competitor must show losses by demonstrating that sales of its own product decreased because of unfair competition.[291] Rosendahl's tumor did not respond to traditional treatment options, which her doctors exhausted before moving on to the experimental use of chloroquine.[292] Hypothetically, then, if the manufacturer of the chloroquine used to help Rosendahl sought to promote this newly discovered use of its drug, the companies selling traditional treatments could not establish a prima facie case under the Lanham Act. The existing treatments serve a different function medically, by targeting glioblastomas directly rather than preventing autophagy as chloroquine did.[293] Moreover, Rosendahl

288. *See* United States v. Caronia, 703 F.3d 149, 166 (2d Cir. 2012) (stating that the FDA's regulation of off-label promotion "interferes with the ability of physicians and patients to receive potentially relevant treatment information").

289. *See* Hampton, *supra* note 111, at 683 (reporting that up to 75% of all cancer drugs are used for off-label treatments, and 90% of rare diseases are treated with off-label medications).

290. *See* Dovey, *supra* note 7 (noting that Rosendahl's doctors used chloroquine on a "hunch," and not based on an approved use).

291. *See* Lexmark Int'l, Inc. v. Static Components, Inc., 134 S. Ct. 1377, 1390 (2014) (explaining that unfair competition "was understood to be concerned with injuries to business reputation and present and future sales").

292. *See* Dovey, *supra* note 7 ("[H]er brain tumor proved unresponsive to all known treatments.").

293. *See id.* (indicating that the doctors knew chloroquine could prevent autophagy, the process "used by many brain cancers to help them avoid

still required traditional medications, as the chloroquine merely increased the existing drugs' effects.[294] As a result, the competitor would lack the damage and causation required by Section 43(a).[295]

Taking a broader look, Lanham Act claims likely cannot succeed in challenging the off-label promotion of drugs for treatment of rare or otherwise untreatable illnesses. Pharmaceutical companies typically focus on profitable medications, often choosing to ignore rare conditions in pursuit of drugs that will sell more consistently.[296] Thus, a doctor prescribing an off-label use to a patient who suffers from a rare disease likely does so, at least in part, because no other options exist.[297] If the manufacturer of that drug then seeks to promote the medication's newly discovered use, it will have no competitors to bring suit under Section 43(a) because other pharmaceutical companies have not sought to develop treatments for such a rare condition.[298]

Even if another treatment option exists, the off-label use of drugs as last-ditch efforts often follows exhaustion of existing treatments, like in the case of Rosendahl.[299] In those situations,

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treatment").

294. *See id.* ("[W]ithout its greatest defense, the tumor would be more vulnerable to traditional treatments used to destroy it.").

295. *See Lexmark Int'l*, 134 S. Ct. at 1390 (requiring a plaintiff to establish proximate cause under Section 43(a)).

296. *See* Aaron S. Kesselheim, *Innovation and the Orphan Drug Act, 1983–2009: Regulatory and Clinical Characteristics of Approved Orphan Drugs*, *in* RARE DISEASES AND ORPHAN PRODUCTS: ACCELERATING RESEARCH AND DEVELOPMENT 291, 291 (Marilyn J. Field & Thomas F. Boat eds., 2010) ("If a disease affects a limited number of patients and does not allow recovery of private research investment, then therapeutic products for that condition may be developed slowly or not at all."). *But see id.* at 292 (explaining that the Orphan Drug Act of 1983 sought to encourage pharmaceutical companies to develop treatments for rare diseases).

297. *See* Robert H. Pritchard, *Off-Label Uses of Approved Drugs: A New Compromise is Needed*, LEDA HARV. L. SCH., https://dash.harvard.edu/bitstream/handle/1/8965544/rpritcha.html?sequence=2 (last visited Feb. 18, 2018) ("In some situations, an off-label prescription is the only treatment available to a patient, . . . because a more targeted drug is [sic] does not exist . . . .") (on file with the Washington and Lee Law Review).

298. *See* Stafford, *supra* note 111, at 1427 (recognizing that off-label uses may be the only treatments available for "orphan" (rare) conditions).

299. *See* Pritchard, *supra* note 297 (suggesting that an off-label treatment might be the only option when "other methods of treatment are ineffective or unavailable to patient intolerance").

the off-label treatment most likely applies a different medical approach to the problem and, therefore, does not take profits from other companies' products.[300] If a doctor decides that an experimental or newly discovered off-label treatment may better suit their patients than existing treatments, then companies with competing products might have standing under Section 43(a).[301] But, that ultimately serves the FDA's purpose of eliminating dangerous off-label treatments, as discussed below.

b. Section 43(a) Will Help Eliminate Dangerous Off-Label Treatments

The FDA's NDA process weeds out potentially dangerous drugs, while granting approval to those found safe and effective for particular treatments.[302] Often a denial of approval may result from insufficient data or a risky side effect.[303] Consequently, the agency may approve a drug for only one of a number of potential treatments, balancing the potential risks with the benefits for each indicated condition.[304] This weighing process leads to the approval of drugs like many chemotherapeutic agents—necessary for the treatment of several cancers, but with potentially painful and fatal side effects.[305] On the other end of the spectrum, a nighttime cough medicine might be approved as a decongestant, while the potential

300. *See* Wittich et al., *supra* note 112, at 982 (noting that doctors might resort to "any treatment that is logical and available" to treat life-threatening conditions).

301. *See id.* (acknowledging that doctors may prescribe drugs that fall in the same class as other common treatments, even if those drugs have not received approval for the same indications).

302. *See* Sacks et al., *supra* note 12, at 379 (claiming that rejection of an NDA helps keep ineffective or harmful drugs off the market).

303. *See id.* at 380–82 (listing common reasons for delay or denial of an NDA).

304. *See* Wittich et al., *supra* note 112, at 982 (discussing how drugs may lack evidence of efficacy for a particular class of patients, leading to FDA approval of the studied class only).

305. *See* Jeff Roberts, *The Most Dangerous & Heavily Promoted Prescription Drugs & Their Potential Natural Alternatives*, COLLECTIVE EVOLUTION (Oct. 14, 2014), http://www.collective-evolution.com/2014/10/14/the-most-dangerous-heavily-promoted-prescription-drugs-possible-natural-alternatives/ (last visited Feb. 18, 2018) (stating that chemotherapeutic agents may cause liver and kidney toxicity, lung disease, problems with immune systems and bone marrow, and could lead to death) (on file with the Washington and Lee Law Review).

negative effects of long-term use prevent its approval as a sleep aid.[306] Nobody would suggest that cough syrup poses more of a threat to health than a chemotherapeutic agent, but when weighed against the benefits of an extra hour of sleep or the treatment of cancer, respectively, the risk of the cough medicine's side effects likely does not outweigh the benefit.

Here, the Lanham Act's requirements provide balanced regulation of off-label claims by allowing well-established off-label use to continue, while providing an avenue to challenge unsupported off-label promotion. Competitors might have standing under Section 43(a) in cases where drugs lack sufficient clinical support for the claims made during advertising, but if scientific clinical trials support the efficacy and safety of an off-label use then the medical community, not the manufacturer, often promotes that use.[307] The FDA has even provided guidance for when Continuing Medication Education programs are sufficiently independent from pharmaceutical companies to allow discussion of off-label uses.[308]

In cases where the medical community, and not a manufacturer, provides "statements of scientific conclusions about unsettled matters of scientific debate,"[309] the First Amendment protects the dissemination of efficacy information, even from private actions under the Lanham Act. Presumably, if the medical community has endorsed a particular use, then medical professionals have witnessed the potential risks and benefits and formed their own opinion that the off-label use is sufficiently safe and effective.[310] Doctors and patients will then continue to receive supporting data for well-established, off-label treatment options

306. *See* Park et al., *supra* note 11, at 226 ("In general, [antihistamines] are not FDA-approved for the treatment of insomnia, though their use is supported by a large body of patient and clinical experience.").

307. *See* Wash. Legal Found. v. Friedman, 13 F. Supp. 2d 51, 56 (D.D.C. 1998) (identifying sources the FDA has allowed to disseminate information about off-label uses, like textbooks, medical colleagues, and educational programs).

308. *See id.* at 57 (providing twelve factors to determine whether education programs are "independent").

309. ONY Inc. v. Cornerstone Therapeutics, Inc., 720 F.3d 490, 492 (2d Cir. 2013).

310. *See id.* at 497 (explaining that where an opinion is based on truthful and nonmisleading scientific discourse, it is protected).

even without promotion by the manufacturer.[311] Conversely, if competitors can show that a pharmaceutical company has a role in promotion, and that the claims have misled consumers, such advertising might give rise to liability under the Lanham Act.[312] As such, availability of Section 43(a) to challenge off-label promotion should not eliminate necessary or widely beneficial off-label drug use and promotion. Rather, it should effectively regulate manufacturers' claims of experimental or secondary uses that have yet to receive proper attention in clinical trials.

VI. Conclusion

Both the Lanham Act and the FDCA seek to "protect consumers," albeit within different spheres of the law and through distinct means. Yet, while Congress and the Supreme Court have allowed the statutes to continue working in tandem to support a unified goal, lower courts have nonetheless found that questions of law requiring FDA expertise often bar Lanham Act claims challenging a drug's label. The problem remains that although the FDA deserves deference in regulating drug products, the agency's limited resources prevent it from effectively protecting public health from false or misleading off-label promotion on its own.

Instead, courts should follow *POM Wonderful* and allow competitors to help police off-label promotion with Section 43(a) claims. As the Supreme Court acknowledged in *POM Wonderful*, the Lanham Act creates an incentive for competitors to police false or misleading marketing and would not conflict with the FDA's goals. Rather, Section 43(a) complements the FDA's regulations by ensuring access to necessary treatment, reducing the prevalence of dangerous off-label use, and maintaining the validity of the FDA's NDA process. As such, *POM Wonderful* stands for the proposition that the best approach to eliminating false or misleading off-label promotion requires the FDCA to work in conjunction with

311. *See Wash. Legal Found.*, 13 F. Supp. 2d at 73 (assuring that manufacturers still may not distribute certain off-label promotional materials even though the medical community may recognize a use).

312. *See id.* (limiting the court's holding to allow dissemination only through "independent program providers").

pharmaceutical companies that use Section 43(a) to challenge unfair competition.