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# Reconciling the Lanham Act and the FDCA: A Comment on Chris Hurley's Note

Christopher B. Seaman\*

## I. Introduction

In *POM Wonderful LLC v. Coca-Cola*,<sup>1</sup> the U.S. Supreme Court unanimously<sup>2</sup> held that a claim for false or misleading advertising under Section 43(a) of the Lanham Act<sup>3</sup> was not preempted by the Federal Food, Drug, and Cosmetics Act<sup>4</sup> (FDCA) simply because the allegedly false or misleading beverage label at issue—which prominently displayed the words “pomegranate blueberry” despite containing less than a thimbleful of either pomegranate juice or blueberry juice<sup>5</sup>—fell within the scope of the Food and Drug Administration’s (FDA) regulatory authority under the FDCA.<sup>6</sup> Rather, the Court concluded that the Lanham Act and the FDCA “complement each other in major respects” because “[a]lthough both statutes touch on food and beverage labeling,” they serve different objectives, as “the Lanham Act protects commercial interest against unfair competition, while the FDCA protects

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\* Associate Professor of Law and Director, Frances Lewis Law Center, Washington and Lee University School of Law. My thanks to Chris Hurley and the Editorial Board of the *Washington and Lee Law Review* for inviting me to participate in the 2017 Notes Colloquium, and my sincere gratitude for their patience with the submission and editing of this Comment.

1. 134 S. Ct. 2228 (2014).

2. The decision in *POM Wonderful* was 8-0; Justice Breyer took no part in consideration or decision of the case. *Id.* at 2242.

3. Pub. L. No. 79-489, 60 Stat. 427 (1946); 15 U.S.C. § 1125 (2012).

4. Pub. L. No. 75-717, 52 Stat. 1046 (1938) (codified as amended at 21 U.S.C. §§ 301–399h).

5. Specifically, Coca-Cola’s Minute Maid juice blend contained only 0.3% pomegranate juice and 0.2% blueberry juice by volume. *POM Wonderful*, 134 S. Ct. at 2233.

6. *Id.* at 2233, 2237–42.

public health and safety.”<sup>7</sup> Furthermore, it explained that the two statutes’ remedial schemes are complementary as well, as the FDA possesses the technical knowledge needed to regulate the health and safety of various consumer products, but it lacks “the expertise in accessing market dynamics that day-to-day competitors possess.”<sup>8</sup> In contrast, the Lanham Act “draws upon this market expertise by empowering private parties to sue competitors” for market harm caused by false advertising.<sup>9</sup>

In particular, the Court’s opinion distinguished between food and beverage labels and other products that are more heavily regulated by the FDA, noting that the FDA did not preapprove juice labels, in contrast with other types of labels, such as prescription drugs.<sup>10</sup> This has led both commentators<sup>11</sup> and courts<sup>12</sup> to question whether *POM Wonderful*’s holding is limited and does not extend to other products, such as pharmaceuticals and medical devices, which are more heavily regulated by the FDA and require preapproval. To date, however, there has been little discussion of an important related issue: whether a drug maker’s promotion of a FDA-approved drug for a non-approved condition, which is commonly known as “off-label use,” also can be subject to claims of false or misleading advertising or promotion under Section 43(a).<sup>13</sup>

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7. *Id.* at 2238.

8. *Id.* at 2238–39.

9. *Id.* at 2238.

10. *See id.* at 2235 (citing 21 U.S.C. § 355(d) and noting “the less extensive role the FDA plays in the regulation of food than in the regulation of drugs”).

11. *See, e.g.,* Peter Meier & Elizabeth Dorsi, *Limiting Lanham Act Claims after POM Wonderful*, ABA SEC. LITIG. (Dec. 17, 2014), <http://apps.americanbar.org/litigation/committees/businessstorts/articles/fall2014-1214-limiting-lanham-act-claims-food-and-drug-products-after-pom-wonderful.html> (last visited Jan. 29, 2018) (“One question left unresolved by *POM Wonderful* is the extent to which its holding applies to drugs regulated by the FDA, as opposed to just food and beverages.”) (on file with the Washington and Lee Law Review).

12. *See, e.g.,* JHP Pharms., LLC v. Hospira, Inc., 52 F. Supp. 3d 992, 999 (C.D. Cal. 2014) (explaining that, in *POM Wonderful*, “the Court suggests a difference between food labeling, which is not subject to FDA pre-approval, and drug labeling, which is,” but ultimately declining to resolve this issue because the plaintiff’s complaint did not adequately plead facts sufficient to plausibly demonstrate false or misleading labeling).

13. In an important Comment, Kathryn Bi has addressed the issue of what constitutes false or misleading advertising or promotion of off-label uses of drugs,

Fortunately, we have Chris Hurley, who fills this important gap in the literature with his award-winning Note. In particular, Mr. Hurley's Note addresses the difficult question of reconciling the language of two complex statutes, as well as the competing public policy concerns at play: (1) ensuring the safety and efficacy of pharmaceutical drugs through evidence-based regulation, and (2) preserving the ability of physicians and patients to access information about potentially beneficial non-approved uses of such drugs. Ultimately, Mr. Hurley argues the Court's decision in *POM Wonderful* should extend to off-label advertising and promotion that is false or misleading, thus allowing claims against drug makers under Section 43(a) for such conduct.<sup>14</sup> As described further below, while I agree with the Note's main thesis—I similarly would conclude that a Section 43(a) claim against false or misleading statements related to off-label promotion is not preempted by the FDCA—I also contend that courts should be cautious in determining what constituted “false or misleading . . . advertising or promotion” regarding off-label use, for fear of chilling the dissemination of valuable information about potentially efficacious but unapproved uses of FDA-authorized drugs.

The remainder of this Comment proceeds as follows. Part I addresses the issue of “off-label” promotion and explains why off-label use of drugs are both common and beneficial in the practice of modern medicine, but also can be problematic. Part II covers false and misleading advertising under Section 43(a) of the Lanham Act, including past cases where courts permitted claims involving the promotion of regulated pharmaceutical products to go forward despite the FDA's extensive regulatory process for approving for such products under the FDCA. Part III analyzes how the Lanham Act and the FDCA can be reconciled in the

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but it only briefly touches on the *POM Wonderful* decision and its potential impact with no substantive analysis of the potential preemption issue. See Kathryn Bi, Comment, *What is “False or Misleading” Off-Label Promotion?*, 82 U. CHI. L. REV. 975, 989–90 (2015) (stating that “the Supreme Court's decision in *POM Wonderful* . . . eliminated a substantial source of legal uncertainty for prospective plaintiffs and is likely to encourage such private-party suits in the future”).

14. See Christopher A. Hurley, Note, *The Off-Label Use of POM Wonderful: Using Section 43(a) to Eliminate Misleading Off-Label Drug Promotion*, 75 WASH. & LEE L. REV. 593, 632 (2018) (“Applying *POM Wonderful*, then, neither the FDCA nor its accompanying FDA regulations should bar Section 43(a) claims.”).

context of off-label uses of FDA-approved drugs, including the role of physicians as intermediaries in determining whether a particular off-label use is medically appropriate. It then concludes with a few final thoughts regarding the quality and thoughtfulness of Mr. Hurley's Note.

## *II. What are Off-Label Uses, and Why are They Important?*

As a threshold matter, it is important to address what constitutes an "off-label use" of an FDA-approved drug and why such uses are important. As previously mentioned, the FDA is a federal regulatory agency that is part of the U.S. Department of Health and Human Services.<sup>15</sup> The FDA's primary mission is to protect the American public through the regulation of numerous products and services, including but not limited to, drugs, medical devices, vaccines, biologics, food, beverages, dietary supplements, cosmetics, radiation-emitting products, and tobacco products.<sup>16</sup> Within the FDA, the Center for Drug Evaluation and Research (CDER) evaluates the safety and efficacy of prescription drugs through pre-market approval and post-market regulation.<sup>17</sup>

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15. See 21 U.S.C. § 393(a) (2012) ("There is established in the Department of Health and Human Services the Food and Drug Administration . . ."); see also *HHS Organizational Chart*, U.S. FOOD & DRUG ADMIN. (Mar. 8, 2017), <https://www.hhs.gov/about/agencies/orgchart/index.html> (last visited Jan. 29, 2018) (listing the FDA as part of HHS) (on file with the Washington and Lee Law Review).

16. 21 U.S.C. § 393(b); see also *About FDA: What We Do*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/AboutFDA/WhatWeDo> (last updated Dec. 29, 2017) (last visited Jan. 29, 2018).

The Food and Drug Administration is responsible for protecting the public health by ensuring the safety, efficacy, and security of human and veterinary drugs, biological products, and medical devices; and by ensuring the safety of our nation's food supply, cosmetics, and products that emit radiation. FDA also has responsibility for regulating the manufacturing, marketing, and distribution of tobacco products to protect the public health and to reduce tobacco use by minors.

(on file with the Washington and Lee Law Review).

17. See *About the Center for Drug Evaluation and Research*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/default.htm> (last updated Dec. 9, 2014) (last visited Jan. 29, 2018).

The Center for Drug Evaluation and Research (CDER) performs an essential public health task by making sure that safe and effective

Pre-market approval is a rigorous process with several stages. First, a product sponsor (i.e., a pharmaceutical company) must submit an Investigational New Drug (IND) application to the FDA.<sup>18</sup> If approved for investigation, the drug goes through three phases of clinical trials to evaluate safety, dosing, efficacy, and adverse reaction (side effects).<sup>19</sup> The final stage, Phase III, is the most rigorous, typically lasting multiple years and involving thousands of subjects (patients).<sup>20</sup> After clinical trials are complete, the company files a New Drug Application (NDA), which the FDA investigates with the assistance of physicians and scientists from various disciplines and sub-disciplines, including pharmacologists, statisticians, and medical officers.<sup>21</sup> If approved, FDA also considers what information must be included on the drug's label, such as dosing information and warnings about

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drugs are available to improve the health of people in the United States. As part of the U.S. Food and Drug Administration (FDA), CDER regulates over-the-counter and prescription drugs, including biological therapeutics and generic drugs.

(on file with the Washington and Lee Law Review).

18. See 21 C.F.R. § 312.3(b) (2017) (“Investigational new drug means a new drug or biological drug that is used in a clinical investigation.”); *id.* § 312.20(a) (“A sponsor shall submit an [investigational new drug application] to FDA if the sponsor intends to conduct a clinical investigation with an investigational new drug.”).

19. These clinical trials are known as Phase I, Phase II, and Phase III. *Id.* §§ 312.21(a)–(c).

20. *Step 3: Clinical Research*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/ForPatients/Approvals/Drugs/ucm405622.htm> (last updated Jan. 4, 2018) (last visited Jan. 29, 2018) (on file with the Washington and Lee Law Review); see also Kyle D. Ross et al., *Drug Use, Access, and the Role of the Pharmaceutical Industry*, in INTRODUCTION TO HEALTH CARE DELIVERY: A PRIMER FOR PHARMACISTS 141, 150 tbl. 5-1 (Robert L. McCarthy et al. eds., 5th ed. 2012) (stating that Phase III clinical trials have a length of 3–4 years and involve between 2000–3000 patients in clinical settings).

21. *New Drug Application (NDA)*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/NewDrugApplicationNDA/default.htm> (last updated Mar. 29, 2016) (last visited Feb. 5, 2018) (on file with the Washington and Lee Law Review); see also Earlene E. Lipowski & Marcus Long, *Government Involvement in Healthcare* (“The drug developer files a new drug application (NDA) after it completes Phase III trials with the drug. The FDA reviews a summary of results from all clinical trials and the procedures planned for the drug’s manufacture, formulation, and quality control.”), in INTRODUCTION TO HEALTH CARE DELIVERY: A PRIMER FOR PHARMACISTS, *supra* note 20, at 401, 413.

potential side effects.<sup>22</sup> The median time from start of clinical trial to FDA approval is approximately eight years.<sup>23</sup> The process of drug approval is also incredibly expensive. According to a recent study by researchers at the Tufts Center for the Study of Drug Development, the average industry cost of new prescription drugs (including failed applications) is over \$2.5 billion, and only 12% of drugs that enter clinical trials are eventually approved.<sup>24</sup> In short, the drug approval process is costly, lengthy, and uncertain.

Once a drug is approved, physicians are generally free to prescribe it without restriction. But in order to market the drug (“promotion” in FDA lingo), the pharmaceutical company must have obtained approval for a particular use.<sup>25</sup> Prescription for a condition other than the ones approved by the FDA is called an “off-label” use.<sup>26</sup>

There are numerous reasons why a drug may be prescribed off-label. First, pharmaceutical companies may not believe it is cost-effective to apply for FDA approval via a supplemental drug application for additional uses.<sup>27</sup> This may occur, for example, if

22. See generally 21 C.F.R. § 201.56 (explaining the requirements governing labels for drugs, including warnings regarding adverse reactions).

23. Thomas J. Hwang et al., *The FDA’s Expedited Programs and Clinical Development Times for Novel Therapeutics, 2012-2016*, 318 J. AM. MED. ASSOC. 2137, 2137 (2017).

24. Joseph A. DiMasi et al., *Innovation in the Pharmaceutical Industry: New Estimates of R&D Costs*, 47 J. HEALTH ECON. 20, 25–26 (2016).

25. See Michael Ollove, *Pressure mounts to lift FDA restrictions on off-label drugs*, WASH. POST (Oct. 8, 2017), [https://www.washingtonpost.com/national/health-science/pressure-mounts-to-lift-fda-restrictions-on-off-label-drugs/2017/10/06/568204a0-a2f6-11e7-8cfe-d5b912fab99\\_story.html?utm\\_term=.c5a78f297441](https://www.washingtonpost.com/national/health-science/pressure-mounts-to-lift-fda-restrictions-on-off-label-drugs/2017/10/06/568204a0-a2f6-11e7-8cfe-d5b912fab99_story.html?utm_term=.c5a78f297441) (last visited Feb. 5, 2018) (“[F]or decades drugmakers have been barred from promoting their drugs for uses that hadn’t gone through clinical trials.”) (on file with the Washington and Lee Law Review).

26. See Christopher M. Wittich et al., *Ten Common Questions (and Their Answers) About Off-Label Drug Use*, 87 MAYO CLINIC. PROC. 982, 982 (2012) (“The most common form of [off-label drug use] involves prescribing currently available and marketed medications but for an indication that has never received Food and Drug Administration (FDA) approval. Hence, the specific use is ‘off-label’ (ie, not approved by the FDA and not listed in FDA-required drug-labeling information).”).

27. See *id.* at 985

Obtaining a new FDA approval for a medication can be costly and time-consuming. To add additional indications for an already approved medication requires the proprietor to file a supplemental drug application, and, even if eventually approved, revenues for the new

the off-label use is to treat a rare condition with few patients (called “orphan conditions”).<sup>28</sup> Second, if the drug in question has become generic by falling outside of patent protection, it may lack a corporate sponsor to bear the required expenses of the FDA approval process because, if successful, other companies can “free ride” off the approval because the sponsoring firm lacks exclusivity.<sup>29</sup> Third, off-label use may occur when the condition is otherwise likely to be untreatable (i.e., last-resort therapy), or when there is emerging but not yet conclusive evidence of effectiveness.<sup>30</sup> These types of treatments “can provide valuable data about the effects of the drug for different conditions and populations,” which “can then be used to inform future clinical practice.”<sup>31</sup>

Empirical evidence demonstrates that off-label uses of FDA-approved drugs is widespread. A 2006 study based on nationally representative prescribing data found that approximately 21% of all drugs were prescribed off label.<sup>32</sup> One of the most common off-label uses was for cardiac medications, representing nearly half (46%) of all prescriptions for these drugs.<sup>33</sup> Another frequent off-label use is for psychiatric disorders (approximately 40% according to one study), where existing medications may not be effective for certain patients or may have

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indication may not offset the expense and effort of obtaining approval.

28. See Randall S. Stafford, *Regulating Off-Label Drug Use—Rethinking the Role of the FDA*, 358 N. ENGL. J. MED. 1427, 1427 (2008) (explaining that off-label uses “can provide the only available treatments for ‘orphan’ conditions”); see also Wittich et al., *supra* note 26, at 989 (“Orphan drugs are medications that are developed and used for rare, or orphan, diseases. Owing to a drug’s limited clinical use for an orphan indication, it will typically generate insufficient profitability for the drug’s sponsor to seek FDA approval for the narrow indication.”).

29. Stafford, *supra* note 28, at 1427; see also Henry Grabowski, *Patents, Innovation and Access to New Pharmaceuticals*, 5 J. INT’L ECON. L. 849, 851 (2002) (“Absent patent protection, or some equivalent barrier, imitators could free ride on . . . FDA approval and duplicate the compound for a small fraction of the originator’s costs.”).

30. See Stafford, *supra* note 28, at 1427 (noting that “off-label use includes . . . last-resort therapy” and that it permits “physicians to adopt new practices based on emerging evidence”).

31. Ryan Abbott & Ian Ayres, *Evidence and Extrapolation: Mechanisms for Regulating Off-Label Uses of Drugs and Devices*, 64 DUKE L.J. 377, 390 (2014).

32. David C. Radley et al., *Off-Label Prescribing Among Office-Based Physicians*, 166 ARCHIVES INTERNAL MED. 1021, 1023 (2006).

33. *Id.*



substantial negative side effects.<sup>34</sup> Off-label use is also common for advanced-stage cancer where other treatments have failed; by one estimate, one-half to three-quarters of all drugs used in chemotherapy were prescribed off label.<sup>35</sup> Finally, pediatric applications of drugs are another area where off-label use is frequent, in part because the drugs that are effective in adults are often effective in children as well, but for safety reasons clinical trials are not feasible.<sup>36</sup> In sum, off-label uses of approved drugs are common and may be beneficial,<sup>37</sup> but they also carry potential risks, including lack of efficacy and potentially serious side effects.<sup>38</sup>

### *III. Section 43(a) and Claims of False or Misleading Advertising Involving FDA-Approved Drugs Before POM Wonderful*

This Comment will now turn to Section 43(a) of the Lanham Act. Congress's purpose in enacting the Lanham Act was, *inter alia*, "to regulate commerce within the control of Congress" by "prevent[ing] fraud and deception."<sup>39</sup> Although the Lanham Act is

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34. Darshan Kharadi et al., *Off-Label Drug Use in Psychiatry Outpatient Department: A Prospective Study at a Tertiary Care Teaching Hospital*, 6 J. BASIC & CLINICAL PHARMACY 45, 46 (2015).

35. C. Daniel Mullins et al., *Recommendations for Clinical Trials of Off-Label Drugs Used to Treat Advanced-Stage Cancer*, 30 J. CLINICAL ONCOLOGY 661, 661 (2012) (citing Michael Soares, "Off-Label" Indications for Oncology Drug Use and Drug Compendia: History and Current Status, 1 J. ONCOLOGY PRAC. 102, 104 (2005)).

36. See generally, e.g., American Academy of Pediatrics, *Policy Statement: Off-Label Uses of Drugs in Children*, 133 PEDIATRICS 563 (2014); Jennifer Corny et al., *Unlicensed and Off-Label Drug Use in Children Before and After Pediatric Governmental Initiatives*, 20 J. PEDIATRIC PHARMACOLOGY & THERAPEUTICS 316 (2015). Congress has passed legislation, including the Best Pharmaceuticals for Children Act of 2007, Pub. L. No. 110-85, 121 Stat. 876, and the Pediatric Research Equity Act of 2003, Pub. L. No. 108-155, 117 Stat. 1936, to help address this issue.

37. See Bi, *supra* note 13, at 983 ("[O]ff-label prescriptions can have tangible public health benefits—the medical community considers some off-label uses to be 'state of the art' procedures for treating certain conditions.").

38. See Rebecca Dresser & Joel Frader, *Off Label Prescribing: A Call for Heightened Professional and Government Oversight*, 37 J.L. MED. & ETHICS 476, 476 (2009) ("Off-label prescribing is an integral part of contemporary medicine . . . . Off-label prescribing can also harm patients, however.").

39. *Lexmark Int'l, Inc. v. Static Control Components, Inc.*, 134 S. Ct. 1377

best known as the federal law governing trademarks,<sup>40</sup> Section 43(a) sweeps significantly broader by creating a federal remedy against unfair competition.<sup>41</sup> Specifically, Section 43(a) prohibits and creates a civil cause of action against:

[A]ny person who, on or in connection with any goods or services, or any container for goods, uses in commerce any word, term, name, symbol, or device, or any combination thereof, or any false designation of origin, false or misleading description of fact, or false or misleading representation of fact which—

(A) is likely to cause confusion, or to cause mistake, or to deceive as to the affiliation, connection, or association of such person with another person, or as to the origin, sponsorship, or approval of his or her goods, services, or commercial activities by another person, or

(B) in commercial advertising or promotion, misrepresents the nature, characteristics, qualities, or geographic origin of his or her or another person's goods, services, or commercial activities . . . .<sup>42</sup>

Initially, Section 43(a) was narrowly interpreted “as forbidding only ‘passing-off,’ or the infringement or unauthorized use of a trademark.”<sup>43</sup> Indeed, Judge Charles Edward Clark of the U.S. Court of Appeals for the Second Circuit—a former Dean of Yale Law School—noted in a concurring opinion a decade after the Lanham Act’s enactment that Section 43(a) was an “extensive

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(2014) (quoting 15 U.S.C. § 1127 (2012)).

40. See *Overview of Trademark Law*, <https://cyber.harvard.edu/metaschool/fisher/domain/tm.htm> (last visited Feb. 5, 2018) (“Trademarks are governed by both state and federal law. . . . The main federal statute is the Lanham Act, which was enacted in 1946 . . . . Today, federal law provides the main, and by and large the most extensive, source of trademark protection . . . .”) (on file with the Washington and Lee Law Review).

41. See Joseph P. Bauer, *A Federal Law of Unfair Competition: What Should Be the Reach of Section 43(a) of the Lanham Act?*, 31 UCLA L. REV. 671, 672 (1984) (noting that “Section 43(a) is . . . a major weapon in the fight against ‘unfair competition’”); J. Thomas McCarthy, *Lanham Act § 43(a): The Sleeping Giant is Now Wide Awake*, 59 L. & CONTEMP. PROBS. 45, 45 (1996) (“Today, section 43(a) of the Lanham Act is the preeminent federal law for asserting claims in private litigation against two distinct types of ‘unfair competition’ . . . .”).

42. 15 U.S.C. § 1125(a)(1) (2012).

43. Ethan Horwitz & Benjamin Levi, *Fifty Years of the Lanham Act: A Retrospective of Section 43(a)*, 7 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 59, 59–60 (1996).

provision covering the false description or representation of goods introduced into commerce,” but lamented that “there is indication here and elsewhere that the bar has not yet realized [its] potential impact.”<sup>44</sup> But over time, “through case law interpretation and in some times erratic spurts of growth, Section 43(a) began to fulfill the role” as “the primary source of private remedies against several important types of unfair competition.”<sup>45</sup> As Professor J. Thomas McCarthy has explained, “by the 1980s, Section 43(a) had become a much-used and potent statute” to combat multiple forms of unfair competition, including false or misleading statements in the advertising and promotion of goods.<sup>46</sup>

Notably, there are numerous examples of cases brought under Section 43(a) regarding alleged false or misleading advertising about FDA-regulated drugs prior to *POM Wonderful* that were not found to be preempted. For example, in *McNeilab, Inc. v. American Home Products Corp.*,<sup>47</sup> McNeilab, Inc. (McNeil), the manufacturer of Tylenol, sued American Home Products (AHP), the maker of competing product Advil, under Section 43(a) regarding AHP commercials which claimed Advil did not cause stomach upset as a side effect more frequently than Tylenol.<sup>48</sup> The District Court granted McNeil a preliminary injunction against AHP based in part on survey evidence,<sup>49</sup> which was affirmed on appeal by the Second Circuit.<sup>50</sup> There was no assertion that the FDCA preempted McNeil’s Section 43(a) claim, even though both Advil and Tylenol are FDA-regulated over-the-counter (OTC) drugs.

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44. *Maternally Yours, Inc. v. Your Maternity Shop, Inc.*, 234 F.2d 538, 546 (2d Cir. 1956) (Clark, J., concurring).

45. McCarthy, *supra* note 41, at 51.

46. *Id.* at 52.

47. 848 F.2d 34 (2d Cir. 1988).

48. *Id.* at 35. This was preceded by an earlier lawsuit by AHP against McNeil, which alleged that McNeil had engaged in false advertising under Section 43(a) by disseminating to physicians a safety profile that visually compared ibuprofen to aspirin and “suggest[ed] that ibuprofen shared aspirin’s high propensity to irritate the stomach.” *Id.* at 36. McNeil counterclaimed, alleging that AHP’s advertising campaign concealed Advil’s side effects. *Id.* At trial, the district court held that both parties had violated Section 43(a) and enjoined a variety of their advertising. *Id.* (citing *Am. Home Prods. Corp. v. Johnson & Johnson*, 654 F. Supp. 568 (S.D.N.Y. 1987)).

49. *Id.* at 37 (citing *McNeilab, Inc. v. Am. Home Prods. Corp.*, 675 F. Supp. 819 (S.D.N.Y. 1987)).

50. *Id.* at 37–39.

Similarly, in *Ortho Pharmaceutical Corp. v. Cosprophar, Inc.*,<sup>51</sup> the FDA approved the plaintiff's prescription drug, Retin-A, for treating acne.<sup>52</sup> After its approval, the *Journal of the American Medical Association*, a leading medical publication, published an article by researchers who discovered that the active ingredient in Retin-A (tretinoin) was also effective in treating photodamaged skin from sun exposure.<sup>53</sup> In the wake of this publicity, prescriptions for off-label use of Retin-A increased dramatically.<sup>54</sup> Cosprophar then began marketing a skin cream with an advertisement asserting that it contained a chemical which "belonged to the same family" as Retin-A and compared the two products' side effects in an allegedly misleading manner.<sup>55</sup> Ortho Pharmaceutical then sued Cosprophar, asserting that its advertisements were false or misleading under Section 43(a) of the Lanham Act. Although the District Court ultimately dismissed Ortho's complaint because it could not prove competitive injury and thus lacked standing, which was affirmed by the Second Circuit on appeal,<sup>56</sup> neither court held that plaintiff's claims were preempted despite the involvement of an FDA-regulated drug.

In addition, there are several cases where lower federal courts rejected claims of preemption over the manufacturing and marketing of "knock-off" drugs prior to *POM Wonderful*.<sup>57</sup> For instance, in *Schwarz Pharma, Inc. v. Breckenridge Pharmaceutical, Inc.*,<sup>58</sup> the district court held that defendant's claim that its product was bioequivalent to plaintiff's prescription drug was actionable under Section 43(a) and not preempted under

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51. 32 F.3d 690 (2d Cir. 1994).

52. *Id.* at 692.

53. *Id.* (referring to Jonathan S. Weiss et al., *Topical Tretinoin Improves Photoaged Skin: A Double-Blind Vehicle-Controlled Study*, 259 J. AM. MED. ASS'N 527 (1988)).

54. *See id.* (according to plaintiff's own estimate, nearly half of Retin-A's sales were for off-label use).

55. *Id.* at 692–93.

56. *Id.* at 694–97.

57. *See generally* Solvay Pharms., Inc., v. Glob. Pharms., 298 F. Supp. 2d 880 (D. Minn. 2004).

58. 388 F. Supp. 2d 967 (E.D. Wis. 2005).

the FDCA.<sup>59</sup> Likewise, in *Mylan Laboratories, Inc. v. Matkari*,<sup>60</sup> the Fourth Circuit reversed the district court's decision to dismiss plaintiff's Section 43(a) claim that defendant had falsely alleged that its drug was bioequivalent to plaintiff's.<sup>61</sup>

Despite this body of case law, Congress has failed to amend Section 43(a) to expressly exclude claims for regulated drugs under the FDCA, despite enacting numerous other changes to the Lanham Act since the mid-1980s (including amendments to other parts of Section 43).<sup>62</sup> As a result, Congress's failure to amend either the Lanham Act or the FDCA to overturn these decisions and expressly preempt Section 43(a) claims involving advertising for FDA-regulated drugs means that Congress has likely acquiesced in allowing such claims. Under the so-called "acquiescence rule," "if Congress does not overturn a judicial or administrative interpretation it probably acquiesces in it."<sup>63</sup> As the Supreme Court explained in *Apex Hosiery Co. v. Leader*,<sup>64</sup> "[t]he long time failure of Congress to alter [a statute] after it had been judicially construed . . . is persuasive of legislative recognition that the judicial construction is the correct one."<sup>65</sup> The acquiescence rule thus provides further support for Mr. Hurley's thesis that the FDCA does not preempt Section 43(a) claims regarding advertising and promotion of off-label uses.

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59. *Id.* at 973–75.

60. 7 F.3d 1130 (4th Cir. 1993).

61. *Id.* at 1137–38.

62. *See generally, e.g.*, Trademark Law Revision Act of 1988, Pub. L. No. 100-667, 102 Stat. 3935; Federal Trademark Revision Act of 1995, Pub. L. No. 104-98, 120 Stat. 1730; Madrid Protocol Implementation Act, Pub. L. 107-273, 116 Stat. 1758 (2002); Trademark Dilution Revision Act, Pub. L. No. 109-312, 120 Stat. 1730 (2006); Prioritizing Resources and Organization for Intellectual Property Act of 2008 (PRO-IP Act), Pub. L. No. 110-403, 122 Stat. 4256.

63. William N. Eskridge, Jr., *Interpreting Legislative Inaction*, 87 MICH. L. REV. 68, 69 (1988).

64. 310 U.S. 469 (1940).

65. *Id.* at 488–89; *see also* *Flood v. Kuhn*, 407 U.S. 258, 283–84 (1972) ("Congress, by its positive inaction, has allowed those decision to stand for so long and, far beyond mere inference and implication, has clearly evinced a desire not to approve of them legislatively.").

*IV. Reconciling Section 43(a) and the FDCA Regarding  
Promotion of Off-Label Uses*

In short, I agree with the primary thesis in Mr. Hurley's Note that claims under Section 43(a) of the Lanham Act regarding off-label uses of drugs are not barred as a matter of law, based in part on the history of such claims prior to *POM Wonderful* as described in the previous section, as well as the analysis in *POM Wonderful* itself that explains how the two statutes are complementary rather than competing in their objective to prevent false or misleading statements regarding FDA-regulated products. For policy reasons, however, I recommend that courts tread with some caution in this area, as an overly-broad reading of what constitutes false or misleading advertising may chill the dissemination of valuable information by a drug maker regarding potentially life-saving off-label uses.

Some claims regarding off-label use would clearly run afoul of Section 43(a). For instance, an allegation that a drug has been approved by the FDA to treat a certain condition, when it has not in fact been so approved, would clearly be a false statement that violates Section 43(a). Similarly, if a drug maker claims that an FDA-approved drug is efficacious for treating another, unapproved condition, but then-existing clinical data in the medical literature does not support this claim, then it would likely be false or misleading under Section 43(a).<sup>66</sup>

Other assertions, however, may present a more difficult case. For instance, the FDA defines "misbranding" under the FDCA as any promotion by drug makers of an off-label use.<sup>67</sup> But this sort of "misbranding" does not necessarily involve false or misleading statements under Section 43(a). For example, if a reliable post-approval study or trial found that a drug was efficacious and safe for treating an unapproved condition, the maker of the drug should be able to communicate that result to physicians.<sup>68</sup> To hold

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66. See generally Bi, *supra* note 13, at 1015–18.

67. See Wittich et al., *supra* note 26, at 988 ("[T]he FDA prohibits 'misbranding' of medications. Misbranding includes labeling a medication with misleading information, including off-label uses.").

68. The 1997 FDA Modernization Act, Pub. L. No. 105-115, 111 Stat. 2296, provides support for this outcome, as it "allow[s] manufacturers to distribute to health care providers peer-reviewed journal articles about unapproved uses of

otherwise would limit the ability of drug companies to disseminate important information.

Furthermore, there is an important difference between a Section 43(a) claim of a false or misleading statement—which generally involves advertising aimed to an ordinary consumer—and promotion of an off-label use of an approved drug, which are typically directed at highly-trained and educated physicians. To borrow a term from tort law, these physicians operate as “learned intermediaries”<sup>69</sup> who can use the information provided by drug makers to exercise their professional judgment about whether to prescribe an off-label use for their patients.<sup>70</sup>

### V. Conclusion

Despite these modest qualifications, Mr. Hurley’s Note is a model of student scholarship—it rigorously addresses a timely, important, and difficult problem; it demonstrates a deep understanding of multiple intersecting areas of law; it takes a normative position on the dispute; and it supports that position with both legal authority and well-reasoned argument.<sup>71</sup> Future

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medications.” Wittich et al., *supra* note 26, at 988. The FDA also revised its guidelines in 2009 to allow distribution of off-label use by pharmaceutical firms if specific regulations were followed. *Id.*; see also Bi, *supra* note 13, at 983 (explaining the “scientific-exchange exception to the general bar on off-label speech” “permit[s] drugmakers and physicians to communicate the underlying science about off-label uses”).

69. The learned intermediary doctrine is a defense to a product liability claim, wherein a manufacturer of a product can discharge its duty to warn consumers by communicating such information to a learned third party, such as a physician. See RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 6(d) (AM. LAW INST. 1998); see also Timothy S. Hall, *Reimagining the Learned Intermediary Rule for the New Pharmaceutical Marketplace*, 35 SETON HALL L. REV. 193, 196 (2004) (explaining that under the learned intermediary doctrine, “the mere fact that a prescription drug is at issue in a failure-to-warn case automatically vitiates the manufacturer’s duty to warn the end user of dangers posed by the product” with only a few limited exceptions).

70. See Bi, *supra* note 13, at 1008 (“[T]he audience for an off-label claim should . . . include any medical professional who makes prescribing decisions.”).

71. See also Christopher B. Seaman, Comment, *Comment on “Groove is in the Hart”: A Workable Solution for Applying the Right of Publicity to Video Games*, 72 WASH. & LEE L. REV. 399, 407 (2015) (praising another Note as “an excellent piece of student scholarship—it is clearly written, well organized, and makes a valuable contribution to the resolution of a difficult problem that has perplexed

*Law Review* staffwriters working on their own Notes would do well to carefully study what Mr. Hurley has done and emulate it in their own scholarship.