# After the Juice Wars: The Post-*POM Wonderful* Legal Landscape and its Implications for FDA-Regulated Industries

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## ABSTRACT

Five years have passed since *POM Wonderful LLC v. Coca-Cola Co.* established that the Federal Food, Drug, and Cosmetic Act (FDCA) does not preclude Lanham Act claims targeting FDA-regulated beverages. Few scholars, however, have evaluated the implications of post-*POM Wonderful* doctrinal developments for FDA-supervised industries. This paper fills that gap, demonstrating that courts have consistently invoked *POM Wonderful* to apply a presumption against the preclusion of false advertising claims across all FDCA-covered markets. The opinion has accordingly restricted competitors' ability to defeat such challenges in the early litigation stages, yielding a legal landscape far friendlier to prospective Lanham Act plaintiffs.

## INTRODUCTION

Just over five years ago, a privately held company known for its premium fruit juices took on the nation's leading beverage manufacturer in a courthouse battle over the labeling of a pomegranate-blueberry blend. That dispute eventually culminated in *POM Wonderful LLC v. Coca-Cola Co.*,[1] where the United States Supreme Court addressed an issue that had long befuddled judges and litigants alike: whether private parties could bring Lanham Act[2] claims challenging the marketing or labeling of products subject to the false or misleading labeling provisions of the Federal Food, Drug, and Cosmetic Act (FDCA).[3]

Before *POM Wonderful*, the interaction between these two federal statutes had generated considerable uncertainty. Under § 43 of the Lanham Act, individuals and entities are granted a private right of action for unfair competition arising from false or misleading representations of products.[4] Meanwhile, the FDCA authorizes the Food and Drug Administration (FDA), a federal agency, to exercise authority over the

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1 573 U.S. 102 (2014).

2 15 U.S.C. §§ 1051–1072, 1091–1096, 1111–1127, 1141–1141n (2018).

3 21 U.S.C. §§ 301, 321, 331–337a, 341–363, 371–399g (2018).

4 *See* 15 U.S.C. § 1125(a).

enforcement of regulations governing a range of industries.[5] The two federal laws have bumped up against one another in countless cases, often with defendants insisting that FDA oversight of a product should preclude challenges brought under the Lanham Act. Courts varied significantly in their treatment of those preclusion defenses, leaving prospective litigants with little clarity regarding the viability of their Lanham Act claims.

The Supreme Court's opinion in *POM Wonderful* dispelled some of this confusion. Writing for a unanimous Court, Justice Kennedy concluded that the FDCA did not preclude a Lanham Act claim challenging the labeling of a competitor's juice.[6] In the food and beverage context, the Court explained, the statutes serve complementary purposes: the Lanham Act allows competitors to guard their commercial interests against deceptive economic actors, while the FDCA promotes public health and safety.[7] Operating side by side, the two laws ensure greater overall protection against false and misleading representations on the market.

While *POM Wonderful* did provide some much-needed clarity, the opinion left open a series of questions and prompted several new ones. Lower federal courts have taken on the project of resolving these lingering issues in the years since the release of the opinion. For instance, courts have grappled with the question of whether *POM Wonderful*'s holding should extend beyond the food and beverage context to cover other FDA-regulated industries. Judges have also been left to identify and articulate limitations on the Court's permissive understanding of Lanham Act claims. Additionally, while observers anticipated that *POM Wonderful* would represent a greenlight for Lanham Act litigants, the opinion's actual implications for industry actors have remained largely unclear.

Though several scholars debated the potential significance of *POM Wonderful* shortly after the case was resolved,[8] few have conducted a close evaluation of resulting doctrinal developments in the wake of the decision. This Article aims to fill that gap by canvassing the post-*POM Wonderful* case law and exploring relevant patterns that have emerged through those opinions. The aims of the Article are to shed light on key trends in *POM Wonderful*'s application and to assess their practical significance for actors across all FDA-regulated industries. As for methodology, the research primarily involved collecting and analyzing public court filings and judicial opinions that implicated the intersection between the Lanham Act and the FDCA. The sources in the pages that follow cover a five-year span from mid-2014 through mid-2019.[9]

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5 *See* 21 U.S.C. § 393 (2018); *see also id.* §§ 333–337.

6 *POM Wonderful*, 573 U.S. at 111–20.

7 *Id.* at 106, 115.

8 *See, e.g.*, Hilary G. Buttrick & Courtney Droms Hatch, *Pomegranate Juice Can Do That? Navigating the Jurisdictional Landscape of Food Health Claim Regulation in a Post-*Pom Wonderful *World*, 49 IND. L. REV. 267 (2016); Matt Busch, Note, POM Wonderful v. Coca-Cola *and the Implications of Granting Competitors the Right to Challenge False or Misleading Food and Beverage Labels Under the Lanham Act*, 48 LOY. L.A. L. REV. 525 (2015); Jennifer Thurswell Radis, Note, *The Lanham Act's Wonderful Complement to the FDCA:* POM Wonderful v. Coca-Cola *Enhances Protection Against Misleading Labeling Through Integrated Regulation*, 47 LOY. U. CHI. L. REV. 369 (2015); Stephen J. White, Jr., Note, *How Far Does the Apple (Pomegranate) Fall from the Tree? Preclusion of Lanham Act Claims by the Food, Drug & Cosmetic Act and* POM Wonderful LLC v. Coca-Cola Co., 15 WAKE FOREST J. BUS. & INTELL. PROP. L. 262 (2015).

9 Before proceeding, it is worth noting that the research conducted here was naturally limited to court documents and opinions that have been made available to the public. The sources surveyed in this Article

To preview, lower courts have generally construed *POM Wonderful* to establish a presumption against the preclusion of Lanham Act claims under the FDCA. Moreover, federal judges have consistently extended this presumption beyond the food and beverage realm: the opinion appears to have emboldened prospective Lanham Act litigants across a variety of FDA-regulated industries, and the courts have repeatedly relied on *POM Wonderful* to evaluate preclusion arguments in those contexts. However, judges have made clear that *POM Wonderful*'s presumption is not absolute, and several limitations on the Court's core holding have developed through case-by-case adjudication. Even with these emerging limits, the trends in the post-*POM Wonderful* case law have been largely plaintiff-friendly—on the whole, the opinion seems to have curtailed the ability of defendants to guard against competitors' Lanham Act claims at the early stages of litigation.

The remainder of this Article proceeds as follows: Part I provides an overview of both the relevant federal statutes and the *POM Wonderful* opinion itself. Part II then evaluates the response to the decision among industry actors, with a particular focus on the predicted uptick in Lanham Act litigation. In Part III, the Article offers a thorough evaluation of significant trends in the post-*POM Wonderful* case law, exploring both the extension of the opinion to other FDA-regulated markets and the emergence of limitations on the Court's central holding. Finally, Part IV turns to the practical implications of these developments for Lanham Act litigants whose products are subject to the FDCA. A brief conclusion ends the analysis.

## I. POMEGRANATES AND PRECLUSION IN THE SUPREME COURT

The Court's *POM Wonderful* decision arose out of a battle over fruit juice that first began in 2008, but the issue at the heart of the opinion—the complex relationship between the FDCA and the Lanham Act—reflects a tension dating back to the enactment of both statutes in the mid-twentieth century. This Part briefly describes each of the relevant federal laws before turning to a summary of the *POM Wonderful* litigation and the resulting Supreme Court opinion.

### *A. A Preview to POM Wonderful: The Lanham Act and the FDCA*

#### *1. The Lanham Act*

Also known as the Trademark Act of 1946, the Lanham Act was drafted and approved to provide commercial actors with greater protections against "unfair competition."[10] This overarching purpose animates the text in § 43 of the statute, which authorizes a private right of action against competitors who achieve a market advantage through the use of "false or misleading representation[s] of fact."[11] To prevail on a claim under § 43, a plaintiff must establish that the "challenged message is (1) either literally or impliedly false, (2) material, (3) placed in interstate commerce,

accordingly represent only a subset of the existing materials relevant to the application of *POM Wonderful*, though the accessible case law provides a sufficient sample for identifying key trends.

[10] *See* 15 U.S.C. § 1127 (2018).

[11] *Id.* § 1125(a)(1) (imposing civil liability on "any person who . . . uses . . . false or misleading representation[s] of fact, which . . . misrepresent[] the nature, characteristics, qualities, or geographic origin of his or her or another person's goods, services, or commercial activities").

and (4) the cause of actual or likely injury."[12] The stakes are often quite high for competitors defending against these claims, as litigants who prevail on their Lanham Act challenges may be entitled to both monetary damages and injunctive relief.[13]

### *2. The Federal Food, Drug, and Cosmetic Act (FDCA)*

Eight years before the passage of the Lanham Act, Congress enacted the FDCA to establish a new framework for the regulation of foods, medical devices, drugs, and cosmetics.[14] The statute overhauled the existing standards for food and drug safety,[15] mandated new premarket approval processes for pharmaceuticals, and authorized FDA to promulgate additional requirements.[16] In contrast with the Lanham Act, the FDCA did not provide for any private right of action against parties who violated its provisions; Congress instead gave FDA nearly exclusive authority to enforce both the statute itself and its associated regulations.[17] The law has been amended and updated on multiple occasions since 1938, producing the complex apparatus currently in place for the protection of consumer health and safety.[18]

The dispute in *POM Wonderful* specifically implicated an FDCA provision imposing a prohibition on "misbranded" foods and beverages.[19] To avoid "misbranding" a particular item, industry actors must adhere to a variety of product-specific labeling requirements. For example, manufacturers of juice blends—such as the pomegranate-blueberry product at issue in *POM Wonderful*—are required to include specific details about the names, quantities, and purposes of the component juices on the labels for the company's mix.[20] In the pre-*POM Wonderful* era, the key question was whether compliance with regulations of this sort would prevent a competitor from challenging the content of a label under the Lanham Act. The Court's answer to that question is explored at length in the following section.

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[12] Church & Dwight Co. v. SPD Swiss Precision Diagnostics, GmBH, 843 F.3d 48, 65 (2d Cir. 2016); *see also* Lexmark Int'l, Inc. v. Static Control Components, Inc., 572 U.S. 118, 136 (2014) ("To invoke the Lanham Act's cause of action for false advertising, a plaintiff must plead . . . and ultimately prove . . . an injury to a commercial interest in sales or business reputation proximately caused by the defendant's misrepresentations.").

[13] *See* 15 U.S.C. §§ 1117, 1125(a).

[14] *See* 21 U.S.C. §§ 301, 321, 331–337a, 341–363, 371–399g (2018).

[15] *See The 1938 Food, Drug, and Cosmetic Act*, U.S. FOOD & DRUG ADMIN. (Jan. 31, 2018), https://www.fda.gov/about-fda/histories-product-regulation/1938-food-drug-and-cosmetic-act [https://perma.cc/3GQT-5DXA].

[16] *See Part II: 1938 Food, Drug, Cosmetic Act*, U.S. FOOD & DRUG ADMIN. (Nov. 27, 2018), https://www.fda.gov/about-fda/fdas-evolving-regulatory-powers/part-ii-1938-food-drug-cosmetic-act [https://perma.cc/3PLZ-YG8M].

[17] *See, e.g.*, 21 U.S.C. §§ 333–337.

[18] *See Selected Amendments to the FD&C Act*, U.S. FOOD & DRUG ADMIN. (Mar. 29, 2018), https://www.fda.gov/regulatory-information/laws-enforced-fda/selected-amendments-fdc-act [https://perma.cc/UJU5-LDUM] (listing all major amendments to the FDCA chronologically).

[19] *See, e.g.*, 21 U.S.C. § 331. A food or drink may be "misbranded" if, for example, its "labeling is false or misleading," *id.* § 343(a), information required on the label "is not prominently placed thereon," *id.* § 343(f), or the label does not indicate "the common or usual name of the food," *id.* § 343(i).

[20] *See, e.g.*, 21 C.F.R. § 102.33(d) (2019). For example, where the "named juice" on a juice blend's label is "not the predominant juice," that label must either "indicate that the name of the juice is present as a flavor or flavoring" or "include the amount of the named juice" as a percentage. *Id.*

### *B. A Labeling Battle in the Lower Courts*

Back in 2002, a pair of billionaire industrial agriculturalists founded POM Wonderful LLC to develop and market a variety of fruit products for health-conscious consumers.[21] The private company invested heavily in its initial research and product development efforts, hoping to create a set of "super premium" fruit juices that would deliver the "nutritional qualities and health benefits associated with pomegranate[s]."[22] POM Wonderful quickly evolved into the nation's largest distributor and leading seller of pomegranate juices,[23] with a recorded $70 million in annual supermarket sales just six years after the brand reached the market.[24]

Among the company's early products was a pomegranate-blueberry juice, which POM Wonderful continues to advertise as a "berry blend combin[ing] two bright, healthy juices into one tasty antioxidant powerhouse."[25] The product's labeling supports this assertion: the sole ingredients listed for the blend are pomegranate juice and blueberry juice from concentrate and natural flavors.[26] POM Wonderful's executives were confident in the steady pace of the product's sales until 2007, when the Coca-Cola Company announced that it would launch a similarly labeled "Pomegranate Blueberry" blend through its Minute Maid subsidiary.[27] The Coca-Cola product would be marketed to consumers at a price five times cheaper than that of its POM Wonderful counterpart.[28]

When the Coca-Cola juice hit grocery store shelves, the product's labeling revealed the reason for its significantly lower cost—at least to those customers who were willing to read closely. The bottle prominently featured the words "*pomegranate blueberry*" in large capital letters, with smaller text printed lower on the label indicating that the product was actually a "*flavored blend of 5 juices*."[29] Though the labeling seemed to imply otherwise, neither pomegranate juice nor blueberry juice was the primary ingredient in the Coca-Cola product; those juices comprised only 0.3%

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[21] Complaint for False Advertising Under Lanham Act 43(A) at 3, Pom Wonderful LLC v. Coca Cola Co., 727 F. Supp. 2d 849 (C.D. Cal. 2010) (No. 2:08-cv-06237); *see also* Nina Totenberg, *POM Wonderful Wins a Round in Food Fight with Coca-Cola*, NPR: THE SALT (June 21, 2014, 6:41 PM), https://www.npr.org/sections/thesalt/2014/06/12/321390014/pom-wonderful-wins-a-round-in-food-fight-with-coca-cola [https://perma.cc/QW2H-PT23]; Amanda Fortini, *Pomegranate Princess*, NEW YORKER (Mar. 31, 2008), https://www.newyorker.com/magazine/2008/03/31/pomegranate-princess [https://perma.cc/T2LP-AB6K].

[22] Complaint for False Advertising Under Lanham Act 43(A) at 4, *Pom Wonderful LLC*, 727 F. Supp. 2d 849 (No. 2:08-cv-06237).

[23] *Id.*

[24] *Id.*

[25] *Pomegranate Blueberry 100% Juice*, POM WONDERFUL LLC, https://www.pomwonderful.com/products/pomegranate-blueberry-juice [https://perma.cc/PD8V-5N5E].

[26] *Nutritional Facts: Pomegranate Blueberry 100% Juice*, POM WONDERFUL LLC, https://www.pomwonderful.com/products/pomegranate-blueberry-juice/nutritionfacts [https://perma.cc/S4X7-TMBL].

[27] Complaint for False Advertising Under Lanham Act 43(A) at 5, *Pom Wonderful LLC*, 727 F. Supp. 2d 849 (No. 2:08-cv-06237); *see also Minute Maid Adds Pomegranate Blueberry Variety to Enhanced Juices Line*, BEVNET (Sept. 24, 2007), https://www.bevnet.com/news/2007/09-24-2007-Minute_Maid_Pom.asp [https://perma.cc/G3P9-KCLS].

[28] *See* Totenberg, *supra* note 21.

[29] POM Wonderful LLC v. Coca-Cola Co., 573 U.S. 102, 110 (2014).

and 0.2% of the blend, respectively.[30] Instead, over 99% of the blend consisted of apple and grape juices,[31] two economically inferior ingredients that allowed Coca-Cola to lower production costs and sell the juice at a reduced price.[32]

Soon after Coca-Cola introduced its product to consumers, POM Wonderful witnessed a decline in the sales of its own pomegranate-blueberry juice.[33] The company suspected that its shoppers, duped into believing that Coca-Cola had produced a similar blend, were replacing its juice with the cheaper alternative.[34] POM Wonderful turned to the federal courts for a solution, filing a complaint in the U.S. District Court for the Central District of California alleging that Coca-Cola's "false or misleading" advertisements violated § 43 of the Lanham Act.[35] The plaintiff specifically asserted that "[p]urchasers . . . [were] likely to be misled and deceived by Coca Cola's product labeling," which conveyed the false impression that the "primary ingredients" in the competitor's blend were "pomegranate and blueberry juice."[36] In reality, POM Wonderful explained, Coca-Cola had "substituted much of the valuable and beneficial substance of pure pomegranate juice with . . . juices such as apple and grape," leaving consumers with a nutritionally inferior product.[37] According to the complaint, Coca-Cola's deceptive conduct generated "confusion . . . in the pomegranate blueberry juice market," "injure[d] [POM Wonderful's] relationships with existing and prospective customers," and denied the plaintiff both "business and goodwill."[38] For its remedy, the company sought damages, an injunction barring Coca-Cola from making additional "false statements," and an order for the removal of all juices with the allegedly misleading label.[39]

In response, Coca-Cola insisted that the Lanham Act challenges were precluded because its product labels were already in compliance with the FDCA and FDA's juice labeling requirements.[40] The defendant promptly filed motions seeking dismissal and

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30 *See id.* at 105 (describing the Coca-Cola product and its labeling).

31 *See id.*; *see also* Complaint for False Advertising Under Lanham Act 43(A) at 5, *Pom Wonderful LLC*, 727 F. Supp. 2d 849 (No. 2:08-cv-06237).

32 Complaint for False Advertising Under Lanham Act 43(A) at 7, *Pom Wonderful LLC*, 727 F. Supp. 2d 849 (No. 2:08-cv-06237).

33 *Id.* at 7.

34 *Id.* at 6.

35 *Id.* at 9–11. In addition to invoking the Lanham Act, POM Wonderful also brought several claims under California law. *See id.* at 9–11. These claims included allegations of "unfair competition," *see* CAL. BUS. & PROF. CODE § 17200 (West 2019), as well as asserted violations of California's own false advertising law, *see* CAL. BUS. & PROF. CODE § 17500. This Article limits its analysis to the Lanham Act claims.

36 Complaint for False Advertising Under Lanham Act 43(A) at 6, *Pom Wonderful LLC*, 727 F. Supp. 2d 849 (No. 2:08-cv-06237). The Lanham Act portion of POM Wonderful's complaint focused not only on the naming and labeling of the juice itself, but also on Coca-Cola's broader marketing campaign for the product. *See id.* at 5–6. POM Wonderful asserted that its competitor similarly relied on "false and misleading representations" to portray the juice as a "pomegranate blueberry" blend in its online, print, and television advertisements. *See id.*

37 *Id.* at 6–7.

38 *Id.* at 7.

39 *Id.* at 8–9.

40 Pom Wonderful LLC v. Coca Cola Co., No. CV 08-06237, 2009 WL 7050005, at *1–3 (C.D. Cal. Feb. 10, 2009) (summarizing the defendant's arguments on its initial motion to dismiss); *see, e.g.*, 21 U.S.C. §§ 331, 343 (2018); 21 C.F.R. § 102.33 (2019); *see also supra* notes 19–20 and accompanying text.

summary judgment, which were granted in part and denied in part.[41] The district court considered the components of the Lanham Act claim separately: POM Wonderful could proceed with its allegations regarding Coca-Cola's print and online advertising,[42] but the company was precluded from doing so with respect to the juice's name and label.[43] This preclusion, the court explained, was a result of the "interplay" between the Lanham Act and the FDCA;[44] the naming and labeling of juice bottles fell squarely within FDA's jurisdiction, and private Lanham Act claims could not be used to "indirectly attack" labels that passed muster under the agency's "considered judgments."[45] Pointing to the regulations for juice-blend labels, the court argued that FDA had already "spoken on the issues that form[ed] the basis of POM's Lanham Act claim" and had "reached a conclusion as to what [was] permissible."[46] The labels on Coca-Cola's pomegranate-blueberry blend satisfied the agency's various requirements, and accordingly, the plaintiff's naming and labeling challenges were foreclosed.[47]

The Ninth Circuit affirmed in relevant part, similarly concluding that "the FDCA and its regulations bar[red] pursuit of both the name and labeling aspects" of POM Wonderful's complaint.[48] The panel echoed the district court in its reasoning: "Congress and the FDA [had] . . . considered and spoken to what content a label must bear," and for a court to intervene "when the FDA has not — despite regulating extensively in [the] area — would risk undercutting the FDA's expert judgments and authority."[49] Put differently, barring the plaintiff's Lanham Act claim was necessary "[o]ut of respect for the statutory and regulatory scheme" established under the FDCA.[50]

### *C. The Supreme Court Opinion: Tackling the Preclusion Question*

The case eventually made its way to the Supreme Court, where the Justices seized the opportunity to address the confusion regarding whether or not a "private party [could] bring a Lanham Act claim challenging a food label . . . regulated by the FDCA."[51] The decision was unanimous: the lower courts had been "incorrect" in

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41 *See Pom Wonderful LLC*, 727 F. Supp. 2d at 849. The plaintiff's state law claims were rejected in their entirety. *See id.*

42 *Id.* at 876. With respect to the advertising and marketing claims, *see supra* note 35, the court found that "triable issues of material fact" remained as to whether Coca-Cola had "intentionally misled consumers," *id.* at 876, and whether POM Wonderful's proffered evidence of consumer deception was sufficiently reliable, *see id.* at 875–76.

43 *Id.* at 873.

44 *Id.* at 866.

45 *Id.* at 872.

46 *Id.* at 871.

47 *Id.* at 873 ("[B]ecause Coca-Cola's naming and labeling of the juice comports with the relevant FDCA and FDA regulations . . . POM is precluded from pursuing its Lanham Act claim against the naming and labeling on the juice's bottle.").

48 POM Wonderful LLC v. Coca-Cola Co., 679 F.3d 1170, 1176 (9th Cir. 2012).

49 *Id.* at 1177.

50 *Id.* at 1178.

51 POM Wonderful LLC v. Coca-Cola Co., 573 U.S. 102, 111 (2014).

concluding that "the FDCA precludes Lanham Act suits like the one brought by POM in this case," as "[n]othing in the text, history, or structure" of either federal statute suggested a "congressional purpose" to "forbid" such claims.[52] To the contrary, Justice Kennedy explained, the Lanham Act and the FDCA "complement each other in the federal regulation" of false and misleading labeling,[53] and the resulting scheme permits private competitors to "challenge food and beverage labels" subject to the FDCA and related FDA requirements.[54]

Justice Kennedy prefaced his reasoning with a clarification of two key premises. First, he noted that the alleged conflict between the two federal statutes raised a question of "preclusion," rather than a question of "pre-emption," though the latter principle could be "instructive."[55] Second, he explained that the dispute was fundamentally a "statutory interpretation case," and an "[a]nalysis of the statutory text, aided by established principles of interpretation," would dictate the outcome.[56]

The Court began with the language of the statutes themselves. Justice Kennedy observed that neither the Lanham Act nor the FDCA explicitly prohibited or limited false advertising claims challenging labels subject to FDA regulation, making clear that such claims were not "off limits" to private competitors under the text of the statutes.[57] Focusing first on the Lanham Act, he explained that the statute's "comprehensive imposition of liability" on parties who "misrepresent[] the nature" of their products "extends, by its own terms, to misrepresentations on labels, including food and beverage labels."[58] No other provision, he added, purported to "limit[] that understanding" or to "govern the relevant interaction" between the FDCA and the Lanham Act.[59] The Court reached the same conclusion with respect to the FDCA; nowhere in that federal statute did Congress expressly preclude or restrict Lanham Act claims.[60] Accordingly, "[n]o textual provision in either statute" revealed an intent to foreclose the sort of challenges that POM Wonderful had brought against Coca-Cola in this case.[61]

The Court went on to explain that the absence of an express prohibition on Lanham Act claims was particularly significant in light of the longstanding coexistence of the

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[52] *Id.* at 106. Eight of the nine Justices signed onto the judgment; Justice Breyer did not take part in the consideration of the case. *Id.* at 120.

[53] *Id.* at 121.

[54] *Id.* at 106.

[55] *Id.* at 111, 112. Justice Kennedy framed his analysis as a "preclusion" inquiry because the central issue in the case concerned whether a "cause of action under one federal statute" was foreclosed "by the provisions of another federal statute." *Id.* at 111. Thus, the case did not implicate the usual state-federal conflict that gives rise to a "preemption" dispute. *See id.* (explaining that the relevant question in a "preemption" case is "whether state law is preempted by a federal statute, or in some instances, federal agency action").

[56] *Id.* at 112.

[57] *Id.* at 113 ("[I]t must be observed that neither [statute], in express terms, forbids or limits Lanham Act claims challenging labels that are regulated by the FDCA.").

[58] *Id.* (quoting 15 U.S.C. § 1125(a) (2018)).

[59] *Id.*

[60] *See id.*

[61] *Id.*

two statutes.[62] The FDCA and the Lanham Act had operated alongside one another since the passage of the latter in 1946, giving Congress ample opportunity to "enact[] a provision addressing the issue" had it "concluded, in light of experience, that Lanham Act suits could interfere with the FDCA."[63] Congress had previously added to the FDCA an "express pre-emption provision [for] . . . *state* laws addressing food and beverage misbranding,"[64] and the omission of a federal law analog constituted "powerful evidence" that legislators never viewed "FDA oversight" as the "exclusive means" of label regulation.[65] In other words, "[b]y taking care to mandate express pre-emption of some state laws, Congress . . . indicated it did *not* intend the FDCA to preclude requirements arising from other sources"—including § 43 of the Lanham Act.[66]

Turning to the "structures" of the federal statutes, Justice Kennedy found that the frameworks under both the Lanham Act and the FDCA "reinforce[d] the conclusion drawn from the text."[67] He reiterated his earlier assertion that the two laws were complementary.[68] Though both statutes "touch[ed] on food and beverage labeling" to some extent, each was distinct in its "scope and purpose": the Lanham Act protects private "commercial interests" from the unfair practices of competitors, while the FDCA safeguards "public health and safety."[69] Moreover, the simultaneous operation of the two statutes produces "synergies" that allow for more effective policing of food and beverage mislabeling through "multiple methods" of regulation.[70] As the Court explained, private Lanham Act claims often target labels that fall beyond FDA's reach; the agency does not "preapprove" food or beverage labeling and cannot "pursue enforcement measures [against] all objectionable labels," leaving the Lanham Act as the only tool for challenging many misrepresentations.[71] Justice Kennedy added that FDA lacks the same insight into "unfair competition" and "market dynamics" that "day-to-day-competitors possess," and the Lanham Act capitalizes on this expertise by "empowering private parties to . . . protect their interests on a case-by-case basis."[72] If such claims were barred, then both private competitors and "the public at large" would be left with less meaningful protection against false and misleading labels.[73] In light of this complementarity, the Court declined to "hold that Congress nonetheless intended one federal statute to preclude the operation of the other."[74]

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62 *See id.*

63 *Id.*

64 *Id.* at 113–14 (emphasis added); *see* 21 U.S.C. § 343-1(a) (2018) (barring any "State or political subdivision of a State" from "directly or indirectly establish[ing]" labeling requirements for food and beverages that deviate from the FDCA and related FDA regulations).

65 *POM Wonderful*, 573 U.S. at 114 (quoting Wyeth v. Levine, 555 U.S. 555, 574 (2009)).

66 *Id.* at 114 (emphasis added).

67 *Id.* at 115.

68 *Id.*; *see supra* notes 51–52 and accompanying text.

69 *POM Wonderful*, 573 U.S. at 115.

70 *Id.* at 115–16.

71 *Id.* at 116.

72 *Id.* at 115, 116.

73 *Id.* at 116.

74 *Id.* at 115.

The Court reversed the Ninth Circuit's judgment and remanded the case for further proceedings.[75] The litigation came to an anticlimactic end nearly two years later, when a jury found for Coca-Cola on POM Wonderful's Lanham Act claims.[76] The plaintiff recovered none of the $ 78 million that it had sought in damages,[77] though perhaps it did secure a smaller victory: the company continues to market its own pomegranate-blueberry juice to this day, while Coca-Cola was forced to pull its own variety from grocery store shelves because of low sales.[78]

Though the ultimate outcome of the *POM Wonderful* litigation may have disappointed the juice company itself, the Court's opinion appeared to widen the window of opportunity for prospective plaintiffs seeking to protect their economic interests against deceptive competitors. However, as noted above, subsequent developments in the application of the opinion—and the implications of those developments for players in FDA-regulated industries—have not been evaluated in detail. This Article accordingly explores the trends that have emerged as lower courts interpret and apply *POM Wonderful*.

## II. POST-*POM WONDERFUL* LANHAM ACT LITIGATION

The *POM Wonderful* Court was careful to specify that its analysis applied to "food and beverage labels,"[79] leaving open the question of whether its principles extended to other FDA-regulated industries. Many commentators and scholars speculated that the decision would drive an increase in Lanham Act litigation across all markets subject to the FDCA, even if the Court seemed to cabin its reasoning to the food and beverage context.[80] These predictions appear to have been accurate: a survey of available court filings and case law reveals that *POM Wonderful* has emboldened many private litigants—both within and beyond the food and beverage realm—to

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[75] *Id.* at 121; *see also* Adam Liptak, *Coke Can Be Sued by Rival Over Juice Claim, Court Says*, N.Y. TIMES (June 12, 2014), https://www.nytimes.com/2014/06/13/business/supreme-court-says-coca-cola-can-be-sued-by-Pom-Wonderful.html [https://perma.cc/P4Y6-7LR7].

[76] *See* Final Judgment at 1, POM Wonderful LLC v. Coca-Cola Co., 166 F. Supp. 3d 1085 (C.D. Cal. Mar. 29, 2016) (No. 2:08-CV-06237) ("[T]he jury found in favor of Coca-Cola against Pom, finding that Pom had not proved by a preponderance of the evidence that the label or packaging of Coca-Cola's juice product, even if literally true, nevertheless misled a substantial portion of consumers . . . . Pom Wonderful LLC shall take nothing and . . . judgment is hereby entered in favor of Defendant The Coca-Cola Company . . . .").

[77] *See* Mike Esterl, *Jury Sides with Coca-Cola in False-Advertising Suit by Pom*, WALL STREET J. (Mar. 21, 2016, 8:03 PM), https://www.wsj.com/articles/jury-sides-with-coca-cola-in-false-advertising-suit-by-pom-1458605039 [https://perma.cc/S9AE-XS2V].

[78] *See* Matt Reynolds, *POM Wonderful & Coca-Cola Duke It Out*, COURTHOUSE NEWS SERV. (Jan. 20, 2016), https://www.courthousenews.com/pom-wonderful-coca-cola-duke-it-out/ [https://perma.cc/AF5U-35FN] (noting that Coca-Cola discontinued its Minute Maid pomegranate-blueberry product in 2014 due to disappointing sales).

[79] *POM Wonderful*, 573 U.S. at 116.

[80] *See, e.g.*, Busch, *supra* note 8, at 534; Radis, *supra* note 8, at 428–29 (noting that "*POM* may generate a significant increase in litigation for deceptive labeling" and that the "decision . . . has the potential to be used strategically against competitors"). *But see* Eric Goldman, *Are We Going to See an Explosion of Food Labeling Lawsuits?*, FORBES (June 18, 2014, 1:45 PM), https://www.forbes.com/sites/ericgoldman/2014/06/18/are-we-going-to-see-an-explosion-of-food-labeling-lawsuits/#6f781e2e32fa [https://perma.cc/UA9L-34TE] (predicting that any increase in Lanham Act litigation would be "minor" because "industry competitors [who] adopt similar practices" to market their products would be disinclined "to challenge each other in court").

pursue Lanham Act claims against their competitors. In fact, while the opinion did lay the groundwork for several high-profile disputes between household names in the food and beverage markets,[81] a substantial portion of the uptick in post-*POM Wonderful* Lanham Act lawsuits can be attributed to actors in other FDA-regulated industries. Manufacturers and sellers of items ranging from eye drops to dog treats have invoked the decision to bring Lanham Act claims in federal court,[82] arguing that the logic of *POM Wonderful* applies with equal force to FDA-monitored products besides foods and beverages.[83]

A brief overview of recent litigation highlights the array of products that have been targeted under the Lanham Act in the years since *POM Wonderful*.[84] In the medical devices context, companies have pursued claims against competitors for falsely advertising or mislabeling blood centrifuges,[85] nervous system stimulation equipment,[86] components of intravenous lines,[87] and over-the-counter pregnancy

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[81] *See, e.g.*, Danone, U.S., LLC v. Chobani, LLC, 362 F. Supp. 3d 109, 118–26 (S.D.N.Y. 2019). In the clever words of Chief Judge McMahon of the U.S. District Court for the Southern District of New York, the *Danone* litigation was "the latest in a series of culture wars between two of the biggest players in the market for yogurt." *Id.* at 112. Dannon, the American subsidiary of a French multinational food corporation and a leading producer of yogurt products for children, sought a preliminary injunction barring Chobani from claiming that its drinkable yogurt product contained "33% less sugar than the leading kids' drinkable yogurt"—a phrase that "both parties agree[d] [was] a reference to Dannon's 'Danimals Smoothies' product." *Id.* Relying on *POM Wonderful*, the district court explained that Dannon was likely to succeed in reaching the merits of its false advertising claims because Chobani's compliance with FDA's sugar-labeling requirements did "not automatically negate Lanham Act liability." *Id.* at 121 (citing *POM Wonderful*, 573 U.S. at 120–21). The court nevertheless declined to issue the preliminary injunction, as Chobani had already "taken steps to address Dannon's objections to its packaging" in response to the litigation. *Id.* at 117. As a result, "no exigency" existed that "require[d] the court to take the extraordinary step" of granting Dannon's requested relief. *Id*. at 126. Regardless of the actual outcome, the trial court's reasoning in the *Danone* litigation indicates that competitors in the food and beverage industries face a greater risk of Lanham Act liability (or at least increased litigation expenses) in the aftermath of *POM Wonderful*.

[82] *See* Complaint & Demand for Jury Trial at 29, Allergan USA, Inc. v. Imprimis Pharm., Inc., 2017 WL 11113468 (C.D. Cal. Nov. 14, 2017) (No. 17-cv-01551) (asserting that a pharmaceutical industry competitor had advertised its glaucoma eyedrops in a "materially misleading" manner); Complaint and Notice of Removal at 9, Blue Buffalo Co. v. Nestle Purina Petcare Co., 2015 WL 3645262 (E.D. Mo. June 10, 2015) (No. 15-cv-00384) (bringing Lanham Act claims against another pet food company for allegedly employing a "nationwide false and deceptive advertising campaign" to market its products).

[83] *See, e.g.*, Brief for Plaintiff-Appellee at 14–15, 48–57, Church & Dwight Co. v. SPD Swiss Precision Diagnostics, GmBH, 843 F.3d 48 (2d Cir. 2016) (No. 15-2411-cv), 2015 WL 6693792 (arguing that the "Supreme Court's reasoning [in *POM Wonderful*] was not limited to a specific area of the FDCA," and that the opinion served as the "controlling precedent" in a medical device labeling dispute); *see also* Par Sterile Products, LLC's Memorandum in Opposition to Defendants' Motion to Dismiss at 12, JHP Pharm., LLC v. Hospira, Inc., 52 F. Supp. 3d 992 (C.D. Cal. 2014) (No. 13-cv-07460), 2014 WL 4552262 (insisting that the "Supreme Court's holding [in *POM Wonderful*] is not limited to food labels" and asserting that, just as the Court reasoned in the food and beverage context, Congress "never intended to leave less protection for competitors in the pharmaceutical industries than other industries").

[84] The examples cited here cover cases in which the plaintiffs themselves invoked *POM Wonderful* in their filings, or alternatively, in which judges discussed the Court's opinion while evaluating pretrial motions.

[85] Intra-Lock Int'l, Inc. v. Choukroun, No. 14-cv-80930, 2015 WL 11422285, at *1–2 (S.D. Fla. May 4, 2015).

[86] Innovative Health Sols., Inc. v. DyAnsys, Inc., No. 14-cv-05207, 2015 WL 2398931, at *1 (N.D. Cal. May 19, 2015).

[87] Catheter Connections, Inc. v. Ivera Med. Corp., No. 2:14-CV-70, 2014 WL 3536573, at *1 (D. Utah July 17, 2014).

tests.[88] Players in the dietary supplements market have also turned to the Lanham Act, initiating disputes in federal court over the mislabeling of protein-powder mixes,[89] muscle-building aids,[90] and "testosterone boosters."[91] The pharmaceutical industry has similarly witnessed a raft of post-*POM Wonderful* Lanham Act claims: recent examples include litigation over the marketing of injectable epinephrine,[92] thyroid medications,[93] nasal sprays,[94] and antibiotics.[95] The competitors caught up in these disputes include industry mainstays, such as Allergan and Novartis,[96] as well as more recent market entrants and specialty manufacturers guarding their commercial interests.[97] Given the difficulty in accessing court filings and unpublished opinions, the disputes listed here likely represent a subset of all recent Lanham Act litigation in the pharmaceutical industry.[98]

This uptick in Lanham Act claims, though perhaps modest, suggests that *POM Wonderful* has provided some clarity and reassurance for litigants who might otherwise hesitate to pursue their challenges under the statute. In the post-*POM Wonderful* landscape, the Lanham Act provides a more effective tool for protecting commercial interests against the unfair and deceptive practices of competitors—at least in the eyes of industry actors. However, an increase in the filing of Lanham Act

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[88] *See* Church & Dwight Co. v. SPD Swiss Precision Diagnostics, GmBH, 843 F.3d 48, 53–54 (2d Cir. 2016).

[89] *See* Hi-Tech Pharm. v. HBS Int'l Corp., 910 F.3d 1186, 1189–93 (11th Cir. 2018).

[90] *See* Hi-Tech Pharm. v. Hodges Consulting, Inc., 230 F. Supp. 3d 1323, 1326–37 (N.D. Ga. 2016).

[91] *See* ThermoLife Int'l, LLC v. Gaspari Nutrition Inc., 648 F. App'x 609, 611 (9th Cir. 2016).

[92] *See* JHP Pharm., LLC v. Hospira, Inc., 52 F. Supp. 3d 992, 996–97 (C.D. Cal. 2014).

[93] *See* Acella Pharm. v. Westminster Pharm., LLC, No. 1:18-CV-247, 2018 WL 6588520, at *2 (N.D. Ga. Apr. 24, 2018).

[94] *See* Genus Lifesciences Inc. v. Lannett Co., 378 F. Supp. 3d 823, 827 (N.D. Cal. 2019).

[95] *See* Arbor Pharm., LLC v. ANI Pharm., Inc., No. 17-4910, 2018 WL 3677923, at *1 (D. Minn. Aug. 2, 2018).

[96] *See*, *e.g.*, Complaint & Demand for Jury Trial at 2–10, 29, Allergan USA, Inc. v. Imprimis Pharm., Inc., No. 17-cv-01551 (C.D. Cal. Nov. 14, 2017); *see also* Second Amended Complaint for Injunctive and Other Relief at 1–5, 6–7, Novartis Pharm. Corp. v. Janssen Pharm. Co., No. 19-cv-00576 (D.D.C. Mar. 1, 2019). Allergan's lawsuit against Imprimis, which concerned the latter company's marketing of its ophthalmic drugs, recently concluded with a jury verdict awarding Allergan $48,500 in damages (only a fraction of its requested $7.2 million). *See* Allergan USA, Inc. v. Imprimis Pharm., Inc., No. SA CV 17-1551, 2019 WL 4546897, at *2 (describing the outcomes of the trial). Meanwhile, the Novartis lawsuit against Janssen, which alleged that the Johnson & Johnson subsidiary had falsely advertised its plaque psoriasis treatments, was resolved in a recent settlement. *See* Stipulation of Dismissal at 1, Novartis Pharm. Corp. v. Janssen Biotech, Inc., 19-cv-00576 (D.D.C. Apr. 25, 2019).

[97] *See, e.g.*, *Genus Lifesciences*, 378 F. Supp. 3d at 827 (addressing a specialty manufacturer's Lanham Act claim against a competitor in the market for hydrochloride nasal sprays); *Arbor Pharm.*, 2018 WL 3677923, at *1 (describing a five-year-old company's Lanham Act lawsuit against a drug producer claiming to market a generic version of the plaintiff's oral antibiotic).

[98] Among the unpublished opinions addressing Lanham Act disputes that *are* publicly available, several decisions further illustrate the wide variation in post-*POM Wonderful* drug-company litigation. *See, e.g.*, G&W Labs. v. Laser Pharm., No. 3:17–cv–3974, 2018 WL 3031943, at *1–5 (D.N.J. June 19, 2018) (summarizing a false advertising complaint against a manufacturer of hemorrhoid treatments); Belcher Pharm., LLC v. Hospira, Inc., No. 8:17-cv-2353, 2018 WL 4643292, at *1–2 (M.D. Fla. Apr. 9, 2018) (describing a defendant's motion to dismiss a claim challenging the marketing of its epinephrine injections); Concordia Pharm., Inc. v. Winder Labs., LLC, No. 2:16-CV-00004, 2017 WL 1001533, at *1–2 (N.D. Ga. Mar. 15, 2017) (outlining a Lanham Act dispute between two producers of enterocolitis medication).

challenges does not necessarily translate into greater judicial acceptance of such claims. That issue is addressed in Part III, which examines the judicial treatment of Lanham Act challenges to identify patterns in *POM Wonderful*'s application.

## III. *POM WONDERFUL* IN THE LOWER FEDERAL COURTS: A SURVEY OF DOCTRINAL DEVELOPMENTS

In spite of *POM Wonderful*'s repeated emphasis on its application to "food and beverage labels,"[99] the available case law suggests that lower courts have been more receptive to Lanham Act claims across *all* FDA-regulated industries in the wake of the decision. The case has been construed to establish a "general presumption in favor of Lanham Act claims and against preclusion,"[100] and several opinions have offered explicit rationales for extending that presumption beyond the domain of food and beverages.[101] While some courts have identified circumstances that warrant a departure from this presumption,[102] *POM Wonderful* has generally curtailed the ability of competitors to defend against Lanham Act claims at the early stages of litigation. The upshot, then, is that plaintiffs across all sectors subject to FDA oversight are more likely to succeed in bringing the merits of their Lanham Act allegations before the courts. These conclusions are discussed in further detail below.

### *A. Applying and Extending a General Presumption Against Preclusion*

In the years since *POM Wonderful*, lower courts have consistently treated the opinion as the basis for a "'general presumption'" that the "FDCA does not preclude Lanham Act claims based on false labeling."[103] Put differently, defendants can no longer assert that "regulatory compliance . . . automatically negate[s] Lanham Act liability,"[104] or that "one [statute] . . . precludes actions pursued under the other" when the two laws "touch on the same subject matter."[105] Building on the reasoning in *POM Wonderful*, the Second Circuit has offered its own articulation of the presumption against preclusion: the FDCA and associated FDA regulations establish a "floor," rather than a "ceiling," with respect to protections against false and misleading labeling.[106] Consequently, "FDA approval is no substitute for the intervention of . . . competitor[s]," who by virtue of their "'market expertise'" may be better positioned

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[99] *See, e.g.*, POM Wonderful LLC v. Coca-Cola Co., 573 U.S. 102, 113–14, 116 (2014).

[100] JHP Pharm., LLC v. Hospira, Inc., 52 F. Supp. 3d 992, 1000 (C.D. Cal. 2014).

[101] *See, e.g.*, Church & Dwight Co. v. SPD Swiss Precision Diagnostics, GmBH, 843 F.3d 48, 63–65 (2d Cir. 2016); ThermoLife Int'l, LLC v. Gaspari Nutrition Inc., 648 F. App'x 609, 612 (9th Cir. 2016); *JHP*, 52 F. Supp. 3d at 999–1000.

[102] *See infra* Part IV, pp. 31–36 (discussing limitations on the *POM Wonderful* presumption).

[103] Hi-Tech Pharm., Inc. v. Hodges Consulting, Inc., 230 F. Supp. 3d 1323, 1330 (N.D. Ga. 2016); *see also ThermoLife*, 648 Fed. App'x at 612 ("*POM Wonderful* established that the FDCA generally does not preclude Lanham Act claims for false labeling . . . ."); Frompovicz v. Niagara Bottling, LLC, 313 F. Supp. 3d 603, 616 (E.D. Pa. 2018) (explaining that "the FDCA generally does not preclude Lanham Act claims based on false labeling" (citing *POM Wonderful*, 573 U.S. at 114–15)).

[104] Danone, U.S., LLC v. Chobani, LLC, 362 F. Supp. 3d 109, 121 (S.D.N.Y. 2019).

[105] Intra-Lock Int'l, Inc. v. Choukroun, No. 14-cv-80930, 2015 WL 11422285, at *9 (S.D. Fla. May 4, 2015).

[106] *Church & Dwight Co.*, 843 F.3d at 63–64.

to expose "misleading messaging . . . [that] the federal agency either overlooked or failed to appreciate as important."[107] The presumption against preclusion, the appellate panel explained, preserves an additional layer of protection "against the capacity of . . . representations to mislead."[108]

A close look at the case law applying this general presumption reveals another significant trend: almost uniformly, courts adjudicating Lanham Act disputes outside of the food and beverage realm have construed *POM Wonderful* to cover products in other FDA-regulated industries. Some courts have explicitly announced their intention to extend *POM Wonderful* to other industry contexts, with thorough explanations describing the applicability of the Court's reasoning to different product categories subject to FDA oversight.[109] Others have applied the presumption beyond food and beverage labeling without any express justification for doing so, usually relying on other case law or simply assuming that *POM Wonderful*'s logic would control the dispute.[110] Regardless of these differences in reasoning, an apparent consensus has emerged that the "logical building blocks" of *POM Wonderful*'s "specific holding" are "equally applicable" to "drug marketing, medical device labeling, cosmetics branding, or any other kind of marking or representation which would fall under both the Lanham Act and the FDCA."[111] Thus, as one federal judge explained shortly after the release of Justice Kennedy's opinion, the "general presumption following *POM Wonderful* . . . is that Lanham Act claims . . . are permissible, and, indeed, desirable" with respect to all "FDCA-regulated products."[112]

To illustrate *POM Wonderful*'s application outside of the food and beverage domain, this Article highlights several noteworthy opinions addressing Lanham Act disputes over medical devices, drugs, dietary supplements, and pet food. These cases shed light on the underlying rationales for extending *POM Wonderful* to other industries, and they make clear that the opinion has increased exposure to Lanham Act liability across a variety of FDA-supervised product markets.

### *1. Medical Devices*

Among the many cases that have extended *POM Wonderful* beyond food and beverage labels, the Second Circuit's decision in *Church & Dwight Co. v. SPD Swiss*

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[107] *Id.* at 63.

[108] *Id.*

[109] *See, e.g.*, *id.* at 63–64; *ThermoLife*, 648 Fed. App'x at 612; JHP Pharm., LLC v. Hospira, Inc., 52 F. Supp. 3d 992, 999–1000 (C.D. Cal. 2014).

[110] *See, e.g.*, Arbor Pharm., LLC v. ANI Pharm., Inc., No. 17-4910, 2018 WL 3677923, at *3 (D. Minn. Aug. 2, 2018) (acknowledging a general presumption against FDCA preclusion of Lanham Act claims in the context of drug labeling); Allergan USA, Inc. v. Imprimis Pharm., Inc., No. SA CV 17-1551, 2017 WL 10526121, at *6 (C.D. Cal. Nov. 14, 2017) (same in another drug-labeling claim); Nutrition Dist., LLC v. New Health Ventures, LLC, No. 16-cv-02338, 2017 WL 2547307, at *6 (S.D. Cal. June 13, 2017) (same in a Lanham Act dispute over dietary supplements); *see also* Genus Lifesciences Inc. v. Lannett Co., 378 F. Supp. 3d 823, 833–34 (N.D. Cal. May 3, 2019) (collecting cases in support of the proposition that "[c]ourts can evaluate Lanham Act claims that do not require . . . interpretation of the FDCA's requirements"); Par Sterile Prod., LLC v. Fresenius Kabi USA, LLC, No. 14 C 3349, 2015 WL 1263041, at *4 (N.D. Ill. Mar. 17, 2015) (relying on post-*POM Wonderful* case law in other jurisdictions to conclude that "the FDCA does not preclude Lanham Act claims like the one [the plaintiff pharmaceutical company] asserts here" (citing *JHP*, 52 F. Supp. 3d at 999)).

[111] *JHP*, 52 F. Supp. 3d at 1000.

[112] *Id.*

*Precision Diagnostics*[113] stands out as particularly significant. The underlying dispute began when the plaintiff, a leading manufacturer of over-the-counter pregnancy tests, filed a Lanham Act claim alleging that a competitor had been misleading consumers with the advertising and labeling of its product.[114] According to the plaintiff, the competing device—which included a feature for estimating the duration of a woman's pregnancy—had been marketed in a manner conveying "the false impression" that the product used the "same metric" as medical professionals.[115] The defendant pointed to a lengthy back-and-forth with FDA as proof that its device already complied with the labeling requirements for Class II medical devices,[116] and it insisted that this "intensive regulation" under the FDCA precluded the plaintiff's Lanham Act claims.[117]

The trial court invoked *POM Wonderful* to reject the defendant's preclusion argument, and the Second Circuit affirmed that conclusion on appeal.[118] In the course of doing so, the unanimous panel articulated an explicit rationale for extending *POM Wonderful*'s general presumption into the medical devices context. The court acknowledged that competitors in the market for medical devices are subject to a specific set of regulations governing premarket clearances and approvals, but it declined to distinguish *POM Wonderful* on that basis.[119] In fact, the panel saw "no reason why the subjugation of [the] Defendant's product labeling to FDA regulation through the § 510(k) [preclearance] process should categorically immunize it from Lanham Act claims by competitors regarding the regulated labeling."[120] Even if FDA's role in the regulation of medical devices is "more proactive, extensive, and focused" than its oversight of juice labels, the underlying justifications for *POM Wonderful*'s presumption still apply; the FDCA and the Lanham Act similarly serve

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[113] 843 F.3d 48 (2d Cir. 2016).

[114] *See id.* at 53–54.

[115] *Id.* at 53. Briefly, the "weeks estimator" on the competitor's pregnancy test communicated the length of a woman's pregnancy based on "the number of weeks [that had] passed since the woman's ovulation." *Id.* Within the medical profession, however, the conventional method for determining the duration of a pregnancy involves measuring the number of weeks since the woman's "last menstrual period"—an event that typically occurs two weeks before ovulation. *Id.* at 53. As a result of this difference, the defendant's product "announce[d] a number of weeks [of pregnancy duration] that [was] about two weeks lower than what the doctor would say." *Id.*

[116] *See, e.g.*, 21 U.S.C. § 360, 360c (2018); *Church & Dwight Co.*, 843 F.3d at 57–60. The defendant's communications with FDA regarding its pregnancy tests first began in 2008, when the company submitted a premarket notification pursuant to § 510(k) of the FDCA. *See id.* at 57; *see also* 21 U.S.C. § 360. FDA reviewed the product's labeling and issued a "hold letter" in 2012, which expressed concerns that the "weeks indicator feature may provide misleading information" to consumers. *Church & Dwight Co.*, 843 F.3d at 57. FDA soon followed up with a "clearance letter," but the agency invoked its authority under § 513(i)(1)(E) of the FDCA to impose additional labeling requirements "notwithstanding a substantial equivalence determination" for the device. *Id.* at 56–57; *see* 21 U.S.C. § 360c. FDA mandated, for instance, that the company explicitly state on the product's label that its test "provide[d] a different estimate that [could] not be substituted for a doctor's determination of gestational age." *Church & Dwight Co.*, 843 F.3d at 57. When the defendant failed to comply, FDA issued a warning letter that ultimately spurred the company to implement the revised packaging. *See id.* at 58–60.

[117] *Church & Dwight Co.*, 843 F.3d at 62.

[118] *See id.* at 54 (holding that the district court had been correct to conclude that the plaintiff's "Lanham Act claim [was] not precluded by the Food, Drug and Cosmetic Act").

[119] *See id.* at 63.

[120] *Id.*

complementary purposes in the medical devices realm,[121] and Congress would not have intended for "the FDCA's precautions [to] undermine[] . . . still greater protection against consumer miscomprehension" beyond what had been "mandated by the FDA."[122] The panel therefore concluded that challenges to the marketing and labeling of medical devices "must be governed by *POM Wonderful*, which establishe[d] that a Lanham Act claim is not precluded by FDA regulation under the FDCA."[123]

The Second Circuit is certainly not an outlier in applying the *POM Wonderful* presumption to Lanham Act disputes over medical devices. Several district courts have taken the same step, relying on *POM Wonderful*'s core holding to address the assertion that FDA regulation should foreclose a plaintiff's claims.[124] Coupled with the reasoning in *Church & Dwight Co.*, this trend in the case law suggests that competitors in the medical devices market can no longer rely on FDCA preclusion as a general defense against challenges brought under the Lanham Act.

### *2. Pharmaceuticals*

Courts adjudicating Lanham Act disputes over pharmaceutical products have similarly broadened *POM Wonderful*'s reach beyond its initial application. Judges have consistently extended the presumption against FDCA preclusion to cover drug-marketing claims, though many have taken care to note that this presumption is not absolute.

Several district court opinions stand out as particularly useful in exploring *POM Wonderful*'s extension into the pharmaceutical context. One such case is *JHP Pharmaceuticals, LLC v. Hospira, Inc.*,[125] where the district court considered whether the FDCA precluded a drug manufacturer's Lanham Act claims alleging that a competitor had falsely advertised an injectable epinephrine product.[126] The federal judge rejected the defendant's effort to "limit the reach" of *POM Wonderful* to food and beverage labels, explaining that the "broad language of the opinion [did] not support that view."[127] Rather, the Court's "arguments, logic, and holding [in] *POM Wonderful* . . . strongly suggest[ed] a more wide-ranging application."[128] The court

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[121] *Id.* ("As the *POM Wonderful* opinion noted, regardless of the fact that the FDCA and Lanham Act sometimes overlap in scope and effect, each statute nonetheless has a distinct purpose, and in carrying out its FDCA duties, the FDA is not charged with protecting the interests of its subject's competitors."); *see also id.* at 65 (reiterating that the "two statutes serve distinct and complementary purposes" in preventing the use of misrepresentations in the medical devices industry).

[122] *Id.* at 64.

[123] *Id.* at 65.

[124] *See, e.g.*, Innovative Health Sols., Inc. v. DyAnsys, Inc., No. 14-cv-05207, 2015 WL 2398931, at *7 (N.D. Cal. May 19, 2015); Intra-Lock Int'l, Inc. v. Choukroun, No. 14-cv-80930, 2015 WL 11422285, at *9 (S.D. Fla. May 4, 2015) (acknowledging generally that the "FDCA and the Lanham Act . . . do[] not preclude actions pursued under the other" while adjudicating a dispute over the marketing of blood centrifuges); Catheter Connections, Inc. v. Ivera Medical Corp., No. 2:14-CV-70, 2014 WL 3536573, at *4 (D. Utah July 17, 2014) (noting that the "very recent" decision in *POM Wonderful* stood for the "proposition that the Lanham Act overlaps with the FDCA" and that "false advertising claims related to FDA approval may go forward").

[125] 52 F. Supp. 3d 992 (C.D. Cal. 2014).

[126] *Id.* at 996.

[127] *Id.* at 999.

[128] *Id.* at 999–1000.

then reviewed each of *POM Wonderful*'s core conclusions and found that the Court's rationales were equally relevant in the market for FDA-regulated drugs.[129] In light of this reasoning, the court explained, *POM Wonderful*'s "general presumption . . . against preclusion" must be extended to cover Lanham Act claims between competitors in the pharmaceutical industry.[130]

The *JHP* court, however, did note that drug-labeling claims could implicate uniquely complex and technical questions that warrant caution in applying the presumption. To support this argument, the opinion highlighted a specific passage in *POM Wonderful* where Justice Kennedy had noted the following: "Unlike other types of labels regulated by the FDA, such as drug labels . . . the FDA does not preapprove food and beverage labels . . . and instead relies on enforcement actions, warning letters, and other measures."[131] The district court construed this language to suggest that the Justices recognized some "difference" between the regulatory frameworks for "food labeling . . . and drug labeling," leaving open the possibility that "*some* claims *may* require expertise" beyond the capacity of the judiciary.[132] With this caveat in mind, the court concluded that "Lanham Act claims, . . . as a general matter, [are not] . . . barred by the FDCA,"[133] but judges should proceed on a case-by-case basis to determine whether preclusion is warranted for specific drug-labeling allegations.[134]

Other federal courts have adopted similar reasoning, first extending *POM Wonderful*'s general principle to cover drug-related claims and then suggesting that the presumption against preclusion might be overcome in certain circumstances. Like the *JHP* opinion, these decisions have repeatedly acknowledged that FDA regulation does not automatically bar private Lanham Act claims targeting pharmaceutical products.[135] Nevertheless, the "deference given to allow Lanham Act claims to

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[129] *Id.* at 1000. The following excerpt illustrates the court's view:

> [T]he Court's argument that the Lanham Act draws on the market expertise of competitors does not depend on anything peculiar to food and beverage labeling. Nor does its argument that "neither the Lanham Act nor the FDCA, in express terms, forbids or limits Lanham Act claims challenging labels that are regulated by the FDCA," nor does its point that "the Lanham Act and the FDCA have coexisted since the passage of the Lanham Act in 1946" and Congress has never sought to address preclusion by one or the other.

*Id.* (quoting POM Wonderful LLC v. Coca-Cola Co., 573 U.S. 102, 112 (2014)).

[130] *Id.*; *see also id.* at 999.

[131] *Id.* at 998 (citing *POM Wonderful*, 573 U.S. at 115) (emphasis omitted).

[132] *Id.* at 999 (emphasis added).

[133] *Id.*

[134] *See id.* at 998 (explaining that "at a minimum," a Lanham Act claim "might . . . [be] precluded by the FDCA where it turns on the content of a drug label, especially if that drug label were preapproved by the FDA").

[135] *See, e.g.*, Concordia Pharm., S.A.R.L. v. Winder Labs., No. 2:16-CV-00004, 2017 WL 1001533, at *3 (N.D. Ga. Mar. 15, 2017) ("Although both statutes touch on food and beverage labeling, the Lanham Act protects commercial interests against unfair competition, while the FDCA protects public health and safety . . . . The same holds true with drug labeling. Neither the Lanham Act nor the FDCA contain provisions expressly precluding the other from applying where the two overlap."); *see also* Genus Lifesciences Inc. v. Lannett Co., Inc., 378 F. Supp. 3d 823, 833 (N.D. Cal. 2019); Arbor Pharm., LLC v. ANI Pharm., Inc., No. 17-4910, 2018 WL 3677923, at *3 (D. Minn. Aug. 2, 2018); Acella Pharm., Inc. v. Westminster Pharm., LLC, No. 1:18-CV-247, 2018 WL 6588520, at *3 (N.D. Ga. Apr. 24, 2018); Belcher Pharm., LLC v. Hospira, Inc., No: 8:17-cv-2353, 2018 WL 4643292, at *4 (M.D. Fla. Apr. 9, 2018); Allergan USA, Inc. v. Imprimis Pharm., Inc., No. SA CV 17-1551, 2017 WL 10526121, at *6 (C.D. Cal.

proceed . . . is not unfettered": echoing the *JHP* court, other judges have noted that cases "involving 'drug labels' might require more scrutiny in determining whether preclusion is appropriate."[136] Put differently, *POM Wonderful* has been construed to "reserve the possibility that *some* Lanham Act cases might be precluded by the FDCA" where specific drug-labeling issues are ill-suited to judicial resolution.[137]

Notwithstanding these statements of caution, the overall trends in the case law suggest a meaningful departure from the pre-*POM Wonderful* treatment of Lanham Act claims between pharmaceutical competitors. Lower federal courts no longer accept the argument that the FDCA categorically precludes challenges to the labeling and marketing of drugs; instead, courts presume that a plaintiff's Lanham Act claims are permissible unless a fact-intensive inquiry into the nature of the allegations reveals grounds to conclude otherwise.[138]

### *3. Dietary Supplements*

Lower federal courts have also applied *POM Wonderful*'s presumption against FDCA preclusion in several decisions involving Lanham Act disputes over dietary supplements. One notable example was the Ninth Circuit's opinion in *ThermoLife International, LLC v. Gaspari Nutrition, Inc.*,[139] where an Arizona-based supplements manufacturer alleged that its competitor's "testosterone boosters" were falsely advertised as "compliant with the . . . FDCA [and] . . . the Dietary Supplement Health Education Act (DSHEA)."[140] The district court—adjudicating the dispute in the months before *POM Wonderful*—had granted the defendant's motion for summary judgment on the grounds that the FDCA precluded ThermoLife's Lanham Act claims.[141] The Ninth Circuit reversed that decision two years later, allowing the Lanham Act challenges to proceed because the Court's intervening opinion in *POM Wonderful* "squarely control[led]" the preclusion question.[142]

In reaching this conclusion, the Ninth Circuit provided an explicit justification for extending *POM Wonderful*'s presumption into the dietary supplements context. According to the panel, "[b]oth of the Court's rationales" for its *POM Wonderful* holding were equally applicable in disputes over the labeling of nutritional supplements[143]—neither the FDCA nor the Lanham Act "expressly bar[red]" the sort of claims that ThermoLife had filed, and the two federal statutes complemented one another to ensure protection against false and misleading information in the

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Nov. 14, 2017); Par Sterile Prods., LLC v. Fresenius Kabi USA LLC, No. 14 C 3349, 2015 WL 1263041, at *4 (N.D. Ill. Mar. 17, 2015).

136 *Acella*, 2018 WL 6588520, at *3.

137 G&W Labs. v. Laser Pharm., No. 3:17-cv-3974, 2018 WL 3031943, at *6 (D.N.J. June 19, 2018) (emphasis added).

138 *See, e.g.*, *JHP*, 52 F. Supp. 3d at 1000; *Acella*, 2018 WL 6588520, at *3.

139 648 F. App'x 609 (9th Cir. 2016).

140 *Id.* at 611; *see* Dietary Supplement Health and Education Act of 1994, Pub. L. No. 103-417, 108 Stat. 4325 (codified as amended at 21 U.S.C. §§ 321, 331, 342–343, 350 (2018)).

141 *See* ThermoLife Int'l, LLC v. Gaspari Nutrition, Inc., No. CV-11-01056, 2014 WL 99017, at *14–15 (D. Ariz. Jan. 10, 2014) (citing 21 U.S.C. § 342) (reasoning that ThermoLife could not bring Lanham Act claims implicating FDA's regulatory jurisdiction over the quality of supplements).

142 *ThermoLife*, 648 F. App'x at 612.

143 *Id.*

supplements market.[144] Other courts have similarly applied *POM Wonderful* to permit Lanham Act claims against supplements manufacturers,[145] signaling that industry competitors can no longer rely on compliance with the FDCA or its DSHEA amendments to shield themselves against false advertising litigation.

### *4. Pet Food*

As the parties in *POM Wonderful* awaited the release of Justice Kennedy's opinion, two major players in the pet food industry initiated what would ultimately become a two-and-a-half-year dispute over the labeling of their respective products.[146] Blue Buffalo, a rising star in the pet care market known for its "premium" products, filed a Lanham Act claim alleging that industry giant Purina had engaged in a "false and deceptive advertising campaign" that "deliberately mis[led] consumers" about the contents of ten different pet food brands.[147] Echoing Coca-Cola's attempted defense in *POM Wonderful*, Purina contended that, as a matter of law, it could not be held liable under the Lanham Act for advertisements and labels that were already in compliance with applicable FDA regulations.[148]

In an opinion issued almost exactly a year after *POM Wonderful*, the U.S. District Court for the Eastern District of Missouri invoked the Court's decision to reject Purina's defense.[149] Citing Justice Kennedy's argument, the federal judge explained that "compliance with labeling regulations does not preclude 'comprehensive imposition of liability' under the Lanham Act."[150] The district court relied on reasoning similar to that of the other cases highlighted above, arguing that "reasonable consumer[s]" could still be "misled by labeling that complies with FDA and [other relevant pet food] regulations."[151] While the court did not explicitly articulate a general rule that *POM Wonderful* applies in the pet food realm, its reliance on the opinion to reject Purina's defense represents yet another extension of the presumption against FDCA preclusion into an arena beyond food and beverage labeling.[152]

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[144] *Id.* ("[W]hereas the FDCA protects public health by relying on the FDA's expertise, Lanham Act claims like ThermoLife's protect commercial interests by relying on . . . market expertise.").

[145] Nutrition Dist. LLC v. New Health Ventures, LLC, No. 16-cv-02338, 2017 WL 2547307, at *6 (S.D. Cal. June 13, 2017) (relying on *POM Wonderful* to explain that a supplement distributor's Lanham Act claims alleging false advertising of a competitor's "synthetic androgen receptor modulators," or "SARMs," were not precluded); Nutrition Dist. LLC v. Applied Anabolic Sci., No. 16-cv-2340, 2016 WL 9488702, at *1–3 (S.D. Cal. Dec. 16, 2016) (assuming without discussion that the same distributor's Lanham Act claims against a different competitor in the supplements industry were permitted).

[146] *See* Elizabeth G. Olson, *Pet Food Wars: David v. Goliath Edition*, FORTUNE (May 28, 2014), https://fortune.com/2014/05/28/pet-food-wars-david-v-goliath-edition/ [https://perma.cc/KR8E-CQ2Y] (describing the origins of the lawsuits between Purina and the "upstart" Blue Buffalo).

[147] Complaint and Notice of Removal at 9, Blue Buffalo Co. v. Nestle Purina Petcare Co., 2015 WL 3645262 (E.D. Mo. June 10, 2015) (No. 15-cv-00384); *see also Blue Buffalo Co.*, 2015 WL 3645262, at *1.

[148] *Blue Buffalo Co.*, 2015 WL 3645262, at *5.

[149] *See id.* at *4–5.

[150] *Id.* at *5.

[151] *Id.*

[152] After evaluating Purina's defenses, the district court partially denied the defendant's motion to dismiss and allowed the Lanham Act claims to proceed. *See id.* at *14. The litigation between the two pet food rivals came to an end in late 2016, when the companies agreed to a settlement and received the court's approval. *See* Lisa Brown, *Purina, Blue Buffalo Settle False Advertising Lawsuit*, ST. LOUIS

### *B. Emerging Limitations on the Presumption Against Preclusion*

Though federal judges have largely embraced the application of *POM Wonderful*'s presumption across all FDA-regulated industries, many courts have acknowledged that "some circumstances" exist where "the FDCA *does* preclude Lanham Act claims."[153] The *JHP* court, for instance, was careful to note that Lanham Act challenges should generally be permitted "unless preclusion is required for some specific reason."[154] In the years since *POM Wonderful*, lower federal courts have identified a handful of scenarios in which the presumption against preclusion ought not to apply. This area of the law is "still evolving,"[155] and the courts have yet to distill these limitations into a single coherent framework. Nevertheless, recent developments in the case law point to several emerging principles that could limit the application and effect of *POM Wonderful*'s general presumption going forward. This Part provides a preliminary evaluation of those limits.

The animating concerns behind the limits on *POM Wonderful* are primarily institutional: courts are reluctant to invade FDA's regulatory jurisdiction or to make determinations that require the agency's expertise. Thus, to ensure appropriate "deference to the FDA," federal judges have tread carefully when adjudicating Lanham Act disputes that implicate questions "more properly within the exclusive purview" of the agency.[156] The resulting opinions have articulated a range of possible restrictions on *POM Wonderful*, but two limits stand out with particular clarity: the presumption against preclusion does not apply where the grounds for a plaintiff's Lanham Act claim "conflict with an affirmative policy judgment of the FDA,"[157] or where agency expertise is needed to resolve an underlying issue in the dispute.[158]

The latter of these two limitations forms the basis of the "primary jurisdiction doctrine,"[159] which has emerged as the clearest constraint on *POM Wonderful*'s application. The doctrine has been defined as a "prudential" principle under which "courts may, [in] appropriate circumstances, determine that the initial decision[]" on a particular issue "should be [made] by the relevant agency" rather than a judge.[160]

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POST-DISPATCH (Nov. 3, 2016), https://www.stltoday.com/business/local/purina-blue-buffalo-settle-false-advertising-lawsuit/article [https://perma.cc/4QTJ-HBYG].

153 Hi-Tech Pharm., Inc. v. Hodges Consulting, Inc., 230 F. Supp. 3d 1323, 1330 (N.D. Ga. 2016) (emphasis added).

154 JHP Pharm., LLC v. Hospira, Inc., 52 F. Supp. 3d 992, 1000 (C.D. Cal. 2014).

155 Belcher Pharm., LLC v. Hospira, Inc., No. 8:17-cv-2353, 2018 WL 4643292, at *9 (M.D. Fla. Apr. 9, 2018).

156 *Hi-Tech Pharm.*, 230 F. Supp. 3d at 1330.

157 Frompovicz v. Niagara Bottling, LLC, 313 F. Supp. 3d 603, 616 (E.D. Pa. 2018) (citing *JHP*, 52 F. Supp. 3d at 998); *see also* Allergan USA, Inc. v. Imprimis Pharm., Inc., No. SA CV 17-1551, 2017 WL 10526121, at *7 (C.D. Cal. Nov. 14, 2017) (noting that "Lanham Act suits in direct conflict with the agency's policy choice may still be precluded post-*POM Wonderful*" (internal quotation marks omitted) (citation omitted)).

158 *JHP*, 52 F. Supp. 3d at 999 (explaining that while "Lanham Act claims . . . are not, as a general matter, precluded . . . some claims may require the expertise of the FDA to resolve").

159 *Id.* at 1001.

160 *Allergan*, 2017 WL 10526121, at *9 (internal quotation marks omitted) (citation omitted); *see also JHP*, 52 F. Supp. 3d at 1001 ("Under the primary jurisdiction doctrine, a court . . . may in some situations be required to 'refer' the matter to an administrative agency for resolution of a particular issue."); G&W Labs. v. Laser Pharm., No. 3:17-cv-3974, 2018 WL 3031943, at *5 (D.N.J. June 19, 2018) (explaining that

Elaborating on this definition, several courts have explained that the doctrine is properly invoked when a claim "implicates technical and policy questions that should be addressed in the first instance by the agency with [the necessary] regulatory authority."[161]

With this general understanding in mind, courts have identified various circumstances that might warrant application of the primary jurisdiction doctrine to Lanham Act challenges targeting FDA-regulated products. For example, judges have been "wary of permitting a claim" where "determining falsity of a representation requires interpretation and application of [FDA or FDCA] regulatory provisions,"[162] or where resolving the dispute would "require litigation of [an] alleged underlying FDCA violation" that FDA has not yet spoken to.[163]

Though no "fixed formula" exists for applying the primary jurisdiction doctrine, federal courts adjudicating Lanham Act disputes have relied on some variation of a four-factor test. According to one useful articulation, the doctrine forecloses otherwise permissible claims that implicate the following: "(1) the need to resolve an issue that (2) has been placed by Congress within the jurisdiction of an administrative body having regulatory authority (3) pursuant to a statute that subjects an industry or activity to a comprehensive regulatory scheme that (4) requires expertise or uniformity in administration."[164] In circumstances where these factors are satisfied, a defendant can overcome the usual presumption against the preclusion of Lanham Act challenges.

Notably, multiple courts have indicated that this limitation on the *POM Wonderful* presumption is narrow in its scope. Judges applying the primary jurisdiction doctrine have gone out of their way to reiterate *POM Wonderful*'s conclusions, suggesting that Lanham Act claims targeting FDA-regulated products should be assumed permissible unless a careful inquiry reveals core issues requiring agency expertise. For instance, after considering whether the doctrine applied to a claim alleging that a drug product had been falsely marketed as "legal"—an issue that may, in some cases, require an initial FDA judgment—the *JHP* court made clear that challenges raising questions of

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the primary jurisdiction doctrine applies where a claim "requires the resolution of issues which, under a regulatory scheme, have been placed within the special competence of an administrative body" (citation omitted)); Acella Pharm., Inc. v. Westminster Pharm., LLC, No. 1:18-CV-247, 2018 WL 6588520, at *2 (N.D. Ga. Apr. 24, 2018) (same definition).

[161] Nutrition Dist. LLC v. Applied Anabolic Sci. LLC, No. 16-cv-2340, 2016 WL 9488702, at *2 (S.D. Cal. Dec. 16, 2016) (citation omitted); *see also Allergan*, 2017 WL 10526121, at *9.

[162] Concordia Pharm., S.A.R.L. v. Winder Labs., No. 2:16-CV-00004, 2017 WL 1001533, at *3 (N.D. Ga. Mar. 15, 2017); *see also* Belcher Pharm., LLC v. Hospira, Inc., No. 8:17-cv-2353, 2018 WL 4643292, at *3 (M.D. Fla. Apr. 9, 2018) (noting that a "Lanham Act claim [that] requires direct application or interpretation of the FDCA" remains "within the FDA's jurisdiction" (citation omitted)).

[163] *Belcher*, 2018 WL 4643292, at *3 (citation omitted) (alteration in original).

[164] *JHP*, 52 F. Supp. 3d at 1001 (quoting United States v. Gen. Dynamics Corp., 828 F.2d 1356, 1362 (9th Cir. 1987)); Eclat Pharm., LLC v. West-Ward Pharm. Corp., No. LA CV13-06252, 2014 WL 12598861, at *2 (C.D. Cal. July 10, 2014) (quoting the same). For an alternative version of this test, see *G&W Laboratories, Inc. v. Laser Pharmaceuticals, LLC*, No. 3:17-cv-3974, 2018 WL 3031943 (D.N.J. June 19, 2018), where the court relied on the following factors to determine the applicability of the primary jurisdiction doctrine: "(1) whether the question at issue . . . involves . . . considerations within the agency's . . . expertise, (2) whether the question . . . is particularly within the agency's discretion, (3) whether there exists a substantial danger of inconsistent rulings, and (3) whether a prior application to the agency has been made." *Id.* at *6.

"legality" were "*not* precluded as a categorical matter."[165] Instead, such claims can be heard so long as courts are "not called upon to make determinations" on legality that exclusively require FDA's expertise.[166] Similarly, in *Acella Pharmaceuticals, Inc. v. Westminster Pharmaceuticals, LLC*,[167] a court considering the primary jurisdiction question in a Lanham Act drug-labeling dispute explained that "one should begin *not* with the position that favors preclusion, but rather with the baseline understanding that '[t]he FDCA generally *does not* preclude Lanham Act claims based on false labeling.'"[168] The implications of this sort of reasoning are explored further in Part IV, which considers the practical effects of *POM Wonderful* on Lanham Act litigants in FDA-regulated industries.

## IV. *POM WONDERFUL* IN PRACTICE: IMPLICATIONS FOR FDA-REGULATED LITIGANTS

More than five years after the release of the *POM Wonderful* opinion, lower federal courts continue to navigate "the tightrope between permitted and precluded Lanham Act claims."[169] The available case law makes clear, however, that the opinion has already affected the judicial treatment of Lanham Act disputes over products subject to the FDCA. This Part takes a closer look at those effects to shed light on *POM Wonderful*'s practical implications for Lanham Act litigants.

While courts have interpreted and applied *POM Wonderful* across a wide range of circumstances, their conclusions can be distilled into a single principle: Lanham Act claims targeting FDA-regulated products are permissible to the extent that they do not necessitate the resolution of issues requiring the agency's expertise.[170] As one court explained, the practical consequence of this general rule is that the "preclusion question [now] turns on the specific nature of the claim in question—only claims where the law is unclear and FDA's particular expertise or rulemaking authority is required are precluded by the FDCA."[171] This understanding marks a significant

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[165] *JHP*, 52 F. Supp. 3d at 1004 (emphasis added). In this particular case, the claim at issue alleged that the defendants were "falsely representing to consumers that their products 'compl[ied] with all applicable laws, including the FDCA,'" for "new" drugs. *Id.* at 1003 (citation omitted). The veracity of this claim turned on the threshold question of whether the product actually qualified as a "new" drug under the relevant FDA regulations—a question that, in the court's view, required agency expertise for resolution. *Id.*

[166] *Id.* at 1004.

[167] No. 1:18-CV-247, 2018 WL 6588520 (N.D. Ga. Apr. 24, 2018).

[168] *Id.* at *3 (emphasis added) (alteration in original) (quoting Hi-Tech Pharm., Inc. v. Hodges Consulting, Inc., 230 F. Supp. 3d 1323, 1330 (N.D. Ga. 2016)). Another federal judge echoed this point in *Concordia Pharmaceuticals, S.A.R.L. v. Winder Laboratories*, No. 2:16-CV-00004, 2017 WL 1001533 (N.D. Ga. Mar. 15, 2017), where the court explained that the primary jurisdiction doctrine would apply only to those allegations where "determining [the] falsity" of a defendant's representations "depends on an interpretation in the first instance of FDA regulations under the FDCA." *Id.* at *4. Otherwise, the court explained, "claims under the Lanham Act regarding drug labels are not precluded." *Id.*

[169] Frompovicz v. Niagara Bottling, LLC, 313 F. Supp. 3d 603, 616 (E.D. Pa. 2018) (quoting *Hi-Tech Pharm.*, 230 F. Supp. 3d at 1331).

[170] *See, e.g.*, *JHP*, 52 F. Supp. 3d at 999 ("[T]he Supreme Court [in *POM Wonderful*] . . . make[s] clear two things. First, Lanham Act claims . . . are not, as a general matter, precluded . . . . But second, some claims may require the expertise of the FDA to resolve.").

[171] Allergan USA, Inc. v. Imprimis Pharm., Inc., No. SA CV 17-1551, 2017 WL 10526121, at *7 (C.D. Cal. Nov. 14, 2017).

departure from the pre-*Pom Wonderful* landscape, in which courts were often receptive to the argument that compliance with applicable FDA requirements foreclosed Lanham Act challenges. Now, judges can no longer treat the FDCA as a categorical bar on such claims; courts must instead begin the analysis with a presumption that favors the plaintiff, leaving defendants across all FDA-regulated markets with fewer arguments to guard against Lanham Act litigation.

### *A. The Effects of the General Presumption Against Preclusion*

The implications of *POM Wonderful*'s presumption against preclusion are already apparent in the case law. One particularly noteworthy effect is that defendants have been far less successful in securing the rejection of Lanham Act claims during the pretrial stages of litigation—federal judges have repeatedly invoked *POM Wonderful* to dispose of defendants' preclusion arguments on motions to dismiss or requests for summary judgment.[172] To be sure, these early triumphs for plaintiffs do not necessarily translate into victories on their claims overall, but they certainly increase the likelihood that the actual merits of a Lanham challenge will reach a judge or jury. As a result, Lanham Act litigants now enjoy a meaningful opportunity to prevail on claims that may have been discarded entirely in the years before *POM Wonderful*.

For a useful illustration of this trend, consider the recent spate of Lanham Act challenges alleging that products were falsely marketed as FDA-approved. Since 2014, multiple litigants have filed claims insisting that their competitors were misleadingly communicating to consumers that their products had received the required approvals from the federal agency.[173] Before *POM Wonderful*, the question of whether the FDCA precluded such claims was a source of considerable judicial confusion.[174] But in recent years, judges applying *POM Wonderful*'s presumption appear to have reached a consensus that "courts can review a claim [alleging] . . . a competitor falsely represented its product as FDA approved."[175] The rationale behind this conclusion, one court explained, was that the judicial analysis required a "binary factual determination" that could be made without usurping the agency's regulatory

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[172] *See, e.g.*, Church & Dwight Co. v. SPD Swiss Precision Diagnostics, GmBH, 843 F.3d 48, 54 (2d Cir. 2016); ThermoLife Int'l, LLC v. Gaspari Nutrition, Inc., 648 F. App'x 609, 617 (9th Cir. 2016); *JHP*, 52 F. Supp. 3d at 1006; Arbor Pharm., LLC v. ANI Pharm., Inc., No. 17-4910, 2018 WL 3677923, at *3, *6 (D. Minn. Aug. 2, 2018); Belcher Pharm., LLC v. Hospira, Inc., No. 8:17-cv-2353, 2018 WL 4643292, at *9 (M.D. Fla. Apr. 9, 2018); *Allergan*, 2017 WL 10526121, at *14; Blue Buffalo Co. Ltd. v. Nestle Purina Petcare Co., No. 4:15 CV 384, 2015 WL 3645262, at *5, *14 (E.D. Mo. June 10, 2015); Innovative Health Sols., Inc. v. DyAnsys, Inc., No. 14-cv-05207, 2015 WL 2398931, at *8 (N.D. Cal. May 19, 2015); Par Sterile Prods., LLC v. Fresenius Kabi USA, LLC, No. 14 C 3349, 2015 WL 126304, at *1, *4 (N.D. Ill. Mar. 17, 2015); Eclat Pharm., LLC v. West-Ward Pharm. Corp., No. LA CV13-06252, 2014 WL 12598861, at *3, *7 (C.D. Cal. July 10, 2014).

[173] *See, e.g.*, Genus Lifesciences v. Lannett Co., Inc., 378 F. Supp. 3d 823, 827 (N.D. Cal. 2019); *JHP*, 52 F. Supp. 3d at 1000; *Belcher*, 2018 WL 4643292, at *4; *Par Sterile Prods.*, 2015 WL 126304, at *4.

[174] *Cf. Innovative Health Sols.*, 2015 WL 2398931, at *6–7 (discussing pre-*POM Wonderful* cases that contributed to the muddled state of the law on this question of preclusion).

[175] *Genus Lifesciences*, 378 F. Supp. 3d at 833 (quoting *Belcher*, 2018 WL 4643292, at *4); *see also Innovative Health Sols.*, 2015 WL 2398931, at *8 ("[T]o the extent plaintiff alleges that defendants have falsely represented that they obtain[ed] FDA approval for their products, those claims are not precluded."); *Par Sterile Prods.*, 2015 WL 126304, at *4 (explaining that the "Lanham Act is concerned" with approval-related claims "to the extent [those claims] involve[] deception of consumers as to the fact of whether a product carries the imprimatur of FDA approval," which is an entirely different question from "whether the product is safe and effective enough to be approved by the FDA").

responsibility.[176] In at least five cases, district courts have relied on this reasoning to permit claims alleging that defendants misleadingly represented the approvals for various drugs and dietary supplements[177]—a development that fits neatly within the broader trend of extending *POM Wonderful*'s plaintiff-friendly presumption.

### *B. The Early Implications of the Primary Jurisdiction Doctrine*

With the presumption against preclusion firmly established, defendants in FDA-regulated markets appear to be turning to the primary jurisdiction doctrine as an alternative defense against Lanham Act claims. The crux of the typical argument is as follows: even if the FDCA does not preclude Lanham Act challenges as a general matter, the plaintiff's specific claims should be barred because their resolution would implicate questions within FDA's exclusive purview. This defense has been raised with particular frequency in disputes between pharmaceutical competitors,[178] but other industry actors have turned to the primary jurisdiction doctrine as well.[179]

Across the small but growing body of cases discussing the primary jurisdiction question, parties relying on this defense have experienced varying degrees of success. On several occasions, courts have rejected defendants' efforts to invoke the doctrine in their entirety.[180] One notable opinion explicitly cautioned against broad applications of the primary jurisdiction principle, offering a reminder that "allowing a factfinder to determine the legitimacy" of many Lanham Act claims will "not invade the regulatory authority of the FDA."[181]

Several recent examples suggest that when courts do accept the primary jurisdiction defense, they tend to cabin its preclusive effect to only a subset of the plaintiff's Lanham Act challenges. In other words, these courts have applied the doctrine to bar specific allegations better left to FDA while allowing litigants to proceed with the remainder of their claims. A clear illustration of this approach appears in *Catheter*

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[176] *JHP*, 52 F. Supp. 3d at 1004; *see also Eclat Pharm.*, 2014 WL 12598861, at *6 (reasoning that the "allegation that defendants misrepresented that they were exempt from FDA approval can be readily verified" without "interfer[ing] with the regulatory oversight of the FDA").

[177] *See, e.g.*, *Genus Lifesciences*, 378 F. Supp. 3d at 833; *JHP*, 52 F. Supp. 3d at 1000–03; *Innovative Health Sols.*, 2015 WL 2398931, at *7–8; *Belcher*, 2018 WL 4643292, at *4, *9; *Par Sterile Prods.*, 2015 WL 126304, at *4.

[178] *See, e.g.*, *JHP*, 52 F. Supp. 3d at 1003; Acella Pharm., Inc. v. Westminster Pharm., LLC, No. 1:18-CV-247-CAP, 2018 WL 6588520, at *3 (N.D. Ga. Apr. 24, 2018); Allergan USA, Inc. v. Imprimis Pharm., Inc., No. SA CV 17-1551-DOC (JDEx), 2017 WL 10526121, at *9 (C.D. Cal. Nov. 14, 2017); Concordia Pharm., S.A.R.L. v. Winder Labs., No. 2:16-CV-00004-RWS, 2017 WL 1001533, at *3 (N.D. Ga. Mar. 15, 2017); *Belcher*, 2018 WL 4643292, at *1–2; *Eclat Pharm.*, 2014 WL 12598861, at *6.

[179] *See, e.g.*, Nutrition Dist., LLC v. Applied Anabolic Sci., LLC, No. 16cv2340, 2016 WL 9488702, at *2 (S.D. Cal. Dec. 16, 2016) (dietary supplements); Nutrition Dist., LLC v. New Health Ventures, LLC, No. 16-cv-02338, 2017 WL 2547307, at *3–6 (S.D. Cal. June 13, 2017) (same); Catheter Connections, Inc. v. Ivera Medical Corp., No. 2:14-CV-70, 2014 WL 3536573, at *5–7 (D. Utah July 17, 2014) (medical devices).

[180] *See, e.g.*, *Acella*, 2018 WL 6588520, at *2 (rejecting the defendant's argument that "resolution of the claims would impinge upon the exclusive enforcement domain" of FDA); *Belcher*, 2018 WL 4643292, at *9 (allowing the plaintiff to proceed with its Lanham Act claims regarding an injectable drug product even though "the progression of the lawsuit could reveal issues which are more appropriate for the FDA to determine instead of the court"); *Allergan*, 2017 WL 10526121, at *9, *14; *Nutrition Dist.*, 2017 WL 2547307, at *3, *6; *Nutrition Dist.*, 2016 WL 9488702, at *2–3 (permitting claims alleging false advertising of a dietary supplement because "FDA's technical and policy expertise [was] not necessary to determine whether [the] advertisements [were] false or misleading").

[181] *Acella*, 2018 WL 6588520, at *3.

*Connections, Inc. v. Ivera Medical Corp.*,[182] where a manufacturer of medical devices filed various Lanham Act claims against a competitor in the market for intravenous equipment. Those claims included an allegation that the defendant had falsely marketed an updated model of its product as "not need[ing] FDA clearance independent of the [§] 510(k) clearance letter" issued when the device was initially released.[183] The defendant responded that it had appropriately chosen to forego a second clearance in accordance with § 510(k) because the "modification in the device" did not "significantly affect [its] safety or effectiveness."[184] The court declined to wade into this dispute; in its view, the underlying question of whether the defendant had applied a "correct" understanding of § 510(k) fell "within the FDA's exclusive jurisdiction."[185] Accordingly, the clearance-related allegations were barred—but the court, citing *POM Wonderful*, allowed the plaintiff to pursue its remaining Lanham Act claims.[186]

Similar cases have emerged in the pharmaceuticals context. The *JHP* court, for example, applied the primary jurisdiction doctrine to preclude a Lanham Act claim alleging that another company had falsely represented its "new" drug as "lawfully marketed."[187] According to the *JHP* opinion, resolving that claim would have "arrogate[d] the authority of the FDA" to determine the "legality . . . of marketing a particular substance" in the "first instance."[188] The plaintiff's remaining Lanham Act claims, however, were allowed to proceed in light of the *POM Wonderful* presumption.[189] The district court in *Concordia Pharmaceuticals, S.A.R.L. v. Winder Laboratories*[190] relied on similar reasoning, finding that only a subset of a plaintiff's Lanham Act claims were barred under the primary jurisdiction doctrine.[191] The precluded allegations included an assertion that would have required the court to interpret the use of the word "drug" in an FDA notice, a task that falls within the exclusive domain of the agency itself.[192] But as in *Catheter Connections*, *JHP*, and several other cases invoking the primary jurisdiction doctrine,[193] the *Concordia* court deliberately narrowed the scope of this constraint on *POM Wonderful*'s general presumption.

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[182] No. 2:14-CV-70, 2014 WL 3536573 (D. Utah July 17, 2014).

[183] *Id.* at *5.

[184] *Id.* at *3 (quoting 21 C.F.R. § 807.81(a)(3) (2019)).

[185] *Id.* at *5.

[186] *See id.* at *5, *7.

[187] JHP Pharm., LLC v. Hospira, Inc., 52 F. Supp. 3d 992, 1004 (C.D. Cal. 2014).

[188] *Id.*

[189] *See id.* at 1003–04.

[190] No. 2:16-CV-00004, 2017 WL 1001533 (N.D. Ga. Mar. 15, 2017).

[191] *See id.* at *3, *9.

[192] *See id.* at *3–4. Specifically, the claim raised the question of whether the defendant had been falsely marketing its product as a "DESI drug" (a "drug covered by an ongoing Drug Efficacy Study Implementation program"), which could be addressed only with an interpretation of the meaning of "drug" in the agency's DESI notice. *Id.* at *3.

[193] *See JHP*, 52 F. Supp. 3d at 1004; Catheter Connections, Inc. v. Ivera Med. Corp., No. 2:14-CV-70, 2014 WL 3536573, at *5, *7 (D. Utah July 17, 2014); *see also* Nutrition Dist. LLC v. Custom Nutraceuticals LLC, 194 F. Supp. 3d 952, 956 (D. Ariz. 2016); G&W Labs., Inc. v. Laser Pharm., LLC, No.3:17-cv-3974, 2018 WL 3031943, at *6–7 (D.N.J. June 19, 2018).

Thus, while the primary jurisdiction doctrine has served as a meaningful limitation in a number of disputes, the general tenor of post-*POM Wonderful* case law has been decidedly plaintiff-friendly. Courts appear to be applying this prudential principle sparingly, even as defendants in Lanham Act litigation raise primary jurisdiction arguments with increasing frequency. Going forward, the doctrine will likely operate to filter out a small subset of claims raising highly technical questions without evolving into a major roadblock for prospective Lanham Act plaintiffs.

## CONCLUSION

A five-year period is an admittedly short timeframe for evaluating the implications of a Supreme Court opinion, but the sizable body of case law that has emerged since *POM Wonderful* points to several preliminary conclusions. First, lower federal courts have largely accepted the proposition that *POM Wonderful* establishes a presumption in favor of Lanham Act claims and against preclusion under the FDCA. Second, judges have consistently relied on this presumption in Lanham Act disputes outside of the food and beverage context, demonstrating that the Court's general principles are applicable across all FDA-regulated industries. Third, courts have suggested that certain circumstances will warrant a departure from *POM Wonderful*'s presumption, though the precise contours of these limits remain hazy. Perhaps the most notable limitation to materialize thus far is the notion that Lanham Act claims may be precluded when they implicate underlying issues best left to FDA, a prudential constraint that arises out of the primary jurisdiction doctrine. Finally, notwithstanding the emergence of these limitations, *POM Wonderful* has been invoked repeatedly to reject or narrow the preclusive effect of the FDCA—a sign that the opinion has restricted the ability of defendants to shield themselves from Lanham Act claims at the early stages of litigation.

Nevertheless, these post-*POM Wonderful* doctrinal developments are still in their infancy, and several important issues remain unresolved. For instance, the courts have yet to distill a coherent framework for limiting *POM Wonderful*'s presumption against preclusion, and they continue to grapple with the relationship between the primary jurisdiction doctrine and the Court's core holding. Another question that warrants exploration is whether the opinion has had any meaningful effect on the marketing and labeling practices of FDA-regulated competitors.

The practical implications of the Court's opinion will become clearer as the case law develops, but generally, the post-*POM Wonderful* landscape is a far more plaintiff-friendly environment. In a relatively short period of time, a case that began with a dispute over pomegranate-blueberry juice has increased exposure to Lanham Act litigation across the full range of FDA-regulated industries. Competitors in a variety of product markets have treated the opinion as a greenlight to bring false advertising and mislabeling challenges, and if the past five years' worth of case law is any indication, more claims of this sort are sure to come.