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No. 13-

Supreme Court, U.S.
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IN THE
Supreme Court of the United States

ATHENA COSMETICS, INC.,

Petitioner,

v.

ALLERGAN, INC.,

Respondent.

**On Petition for Writ of Certiorari to the United
States Court of Appeals for the Federal Circuit**

PETITION FOR A WRIT OF CERTIORARI

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QUESTION PRESENTED

In *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001), this Court unanimously held that the Federal Food, Drug, and Cosmetic Act ("FDCA") impliedly preempted a state-law tort claim that was predicated on an alleged violation of Food and Drug Administration ("FDA") rules governing the approval of an FDA-regulated product. More generally, *Buckman* explained, a state-law claim is preempted *whenever* "the existence" of the federal regulatory scheme "is a critical element" of the plaintiff's claim, because the FDCA's text "leaves no doubt" that Congress wanted that scheme administered "exclusively by the Federal Government." *Id.* at 349 n.4, 352-53.

Here, respondent alleged that petitioner violated one state's unfair competition law by selling a product without FDA pre-approval. FDA itself had declined to find such approval necessary, despite a protracted lobbying campaign by respondent. The lower courts nevertheless entertained respondent's private suit; stepped into FDA's shoes; made the regulatory determination that FDA had refused to make; and enjoined the sale of petitioner's product in California, unless petitioner seeks and obtains the very approval that FDA itself found unnecessary.

The question presented is whether, under *Buckman*, the FDCA impliedly preempts a private state-law claim for unfair competition premised on a party's purported failure to obtain FDA approval, where FDA itself has not imposed any such requirement.

**PARTIES TO THE PROCEEDING
AND RULE 29.6 STATEMENT**

In addition to the parties named in the caption, Murray A. Johnstone, M.D. and Duke University were nominal plaintiffs in the district court and nominal appellees in the Court of Appeals, and Pharma Tech International, Inc., Product Innovations, LLC, Northwest Cosmetic Laboratories, LLC, and R & G Business LLC were defendants in the district court.

Pursuant to this Court's Rule 29.6, undersigned counsel state that Athena Cosmetics, Inc. is a privately held company. It has no parent corporation, and no publicly held company owns 10% or more of its stock.

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PETITION FOR A WRIT OF CERTIORARI

Petitioner Athena Cosmetics, Inc. respectfully submits this petition for a writ of certiorari to review the judgment of the United States Court of Appeals for the Federal Circuit.

OPINIONS BELOW

The opinion of the court of appeals (Pet. App. 1a-19a) is reported at 738 F.3d 1350. Two of the four relevant district-court orders are unofficially reported at 2012 U.S. Dist. LEXIS 189655 (Pet. App. 46a-52a) and 2013 U.S. Dist. LEXIS 181933 (Pet. App. 20a-45a).

JURISDICTION

The court of appeals filed its opinion and entered its judgment on December 30, 2013. Pet. App. 1a-19a. On March 6, 2014, Chief Justice Roberts granted an extension of time for filing a petition for a writ of certiorari until May 15, 2014. No. 13A906. This Court has jurisdiction under 28 U.S.C. 1254(1).

CONSTITUTIONAL PROVISIONS, STATUTES, AND REGULATIONS INVOLVED

All pertinent constitutional provisions, statutes, and regulations are reproduced in the Petition Appendix at 98a-114a.

STATEMENT

Respondent Allergan, Inc. ("Allergan") sells a prescription drug called Latisse that treats

hypotrichosis, a medical condition characterized by abnormally inadequate eyelash growth. Petitioner Athena Cosmetics, Inc. (“Athena”) sells a cosmetic eyelash conditioner called RevitaLash. Allergan sued Athena under California’s “unfair competition” statute, and ultimately obtained an injunction that bans the sale of RevitaLash in California (but not in other states).

Crucially, Allergan did not argue below—much less prove—that RevitaLash was defective or unsafe, *cf. Wyeth v. Levine*, 555 U.S. 555 (2009); that Athena promoted RevitaLash deceptively, *cf. POM Wonderful LLC v. Coca-Cola Co.*, No. 12-761 (argued Apr. 21, 2014); or that Athena had unfairly tarnished Allergan’s goodwill or reputation, *cf. Lexmark Int’l, Inc. v. Static Control Components, Inc.*, 134 S. Ct. 1377 (2014). Rather, in Allergan’s words, its “unfair competition” claim arose “*purely as a result of [Athena’s] failure to obtain an approved new drug application from FDA before selling RevitaLash.*” C.A. App. 500.

The district court determined that RevitaLash is a “drug” whose sale requires pre-approval under the FDCA and parallel provisions of California law. That conclusion, however, was directly contrary to FDA’s position on the regulatory classification of cosmetic eyelash conditioners. Indeed, FDA has repeatedly stated that, in its view, products like RevitaLash are *not* drugs. C.A. App. 2879. But more fundamentally, how RevitaLash should be classified, and how Athena should be sanctioned (if at all) for failure to obtain “drug” approval, *are decisions Congress entrusted to*

FDA alone. Thus, Allergan’s “lack-of-FDA-approval” claim did not belong in court.

The text of the FDCA is “clear . . . that Congress intended” the statute’s requirements to “be enforced exclusively by the Federal Government.” *Buckman Co. v. Plaintiffs’ Legal Comm.*, 531 U.S. 341, 352 (2001); see 21 U.S.C. 337(a) (“all . . . proceedings for the enforcement, or to restrain violations, of this Act shall be by and in the name of the United States”). As *Buckman* held, § 337(a) does more than just bar *direct* private actions under the FDCA itself—it also “impliedly pre-empt[s]” claims “under state tort law” that are *functionally equivalent* to direct FDCA enforcement, as such claims pose the same threat to the statutory scheme. *Id.* at 343, 348; see generally *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941) (state law is impliedly preempted when it “stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress”).

The Federal Circuit concluded that Allergan’s state-law claim did not subvert Congress’s intent because the California rule that Allergan sought to enforce—*i.e.*, that new drugs require FDA approval—“parallel[ed]” that of the FDCA. Pet. App. 9a. In so ruling, the Federal Circuit misconstrued this Court’s holdings that “parallel” claims under state law are not *expressly* preempted to mean that such claims cannot be preempted *at all*—a position that *Buckman* plainly disavowed.

The Federal Circuit’s decision creates a direct circuit split regarding the preemption of state-law

“lack-of-FDA-approval” claims. More generally, it reflects the lower courts’ entrenched confusion over the scope of implied preemption under § 337(a)—an issue of paramount importance to all FDA-regulated industries. And, in permitting a private plaintiff to obtain a single-state ban on a product’s sale, the decision below poses an unprecedented threat to the national uniformity of the FDCA regime, and invites a tidal wave of novel private-enforcement claims.

Already this Term, this Court has called for the Solicitor General’s views on a petition concerning the implied preemption of a state-law tort claim under § 337(a). *See* Petition for Certiorari, *Medtronic, Inc. v. Stengel*, No. 12-1351, 134 S. Ct. 375 (Oct. 7, 2013). Even more starkly than *Stengel*—which involved an injured consumer seeking money damages for failure to warn of a product defect—this petition presents the question of how far a private plaintiff may go without colliding with § 337(a). This Court should grant certiorari (perhaps as an illustrative companion case to *Stengel*) and reverse.¹

A. The Parties And Their Products

Respondent Allergan is a multi-billion-dollar pharmaceutical company that sells, *inter alia*, a prescription drug called Latisse. The active ingredient in

¹ At minimum, this petition should be held pending resolution of the petitions in *Stengel* and in *Bank of America, N.A. v. Rose*, No. 13-662, which also concerns private enforcement of public statutes via California’s unfair-competition law.

Latisse is bimatoprost, a prostaglandin analog that has been shown to grow eyelashes. Latisse is marketed as a drug that “treats” a medical condition—“hypotrichosis [*i.e.*, insufficient growth] of the eyelashes”—by “promoting [eyelash] *growth*.” C.A. App. 364-65 (emphasis added).

Petitioner Athena is a small private cosmetics company founded in 2006. Its flagship product is an eyelash conditioner sold under the “RevitaLash” brand.² Eyelash conditioners are products used to beautify and enhance the *appearance* of eyelashes, which makes them cosmetics and not “drugs.” Accordingly, Athena did not seek FDA approval before introducing RevitaLash for sale.

RevitaLash contains a compound called 3D. Like the bimatoprost found in Latisse, 3D is a prostaglandin analog; however, as explained below, this fact—in FDA’s view—does not render RevitaLash a “drug.” *Post* at 7-10. Since at least 2007, Athena has consistently labeled and promoted RevitaLash as a cosmetic product that, like mascara, “improve[s] the *appearance* and enhance[s] the *beauty*” of eyelashes, much the way traditional shampoos and conditioners improve the appearance and enhance the beauty of a person’s hair.

² Athena has sold a range of products under the RevitaLash brand. This case only concerns the RevitaLash eyelash conditioner, and the term “RevitaLash” as used herein refers solely to that product.

B. Regulatory Background

1. The Federal Regime

a. Drugs And Cosmetics

The FDCA, Pub. L. No. 75-717, 52 Stat. 1040 (1938) (codified as amended at 21 U.S.C. 301 *et seq.*), comprehensively regulates the sale of, *inter alia*, drugs and cosmetics. In some respects, the FDCA treats drugs and cosmetics alike. Both are subject to prohibitions against adulteration and misbranding. See 21 U.S.C. 351-52, 361-62; *Estée Lauder, Inc. v. FDA*, 727 F. Supp. 1, 2 (D.D.C. 1989). Thus, FDA may take action against either a drug or a cosmetic that it finds to be unsafe or deceptively promoted. In one crucial respect, however, drugs and cosmetics are treated very differently: since the enactment of the FDCA in 1938, drugs, but not cosmetics, have been subject to a premarket approval requirement. See 21 U.S.C. 355; *Estée Lauder*, 727 F. Supp. at 2.

The FDCA's drug-approval regime was a sharp break from prior law, both state and federal. See *Weinberger v. Hynson, Westcott & Dunning, Inc.*, 412 U.S. 609, 623 (1973) ("Prior to 1938 there was no machinery for the premarketing approval of drugs sold in commerce."); *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 341-42 (2008) (Ginsburg, J., dissenting) (before FDCA's enactment, "no state regulations required premarket approval of . . . drugs"). Before 1938, scattered state statutes imposed *ex post* penalties for the sale of drugs that were unsafe or fraudu-

lently promoted,³ and the common law provided *ex post* monetary relief to consumers who were physically injured by defective drugs. See *Levine*, 555 U.S. at 566. But the notion of liability for the sale of a *safe* and *truthfully advertised* article, based solely on lack of preclearance, was unknown.

The new drug application (“NDA”) process is expensive and time-consuming, both for applicants and for FDA itself. NDAs “typically run to hundreds of thousands of pages,” and the process “takes an average of 15 years and costs in the range of 500 million dollars.” Food and Drug Administration Modernization Act of 1997, S. Rep. 105-43, 1997 WL 394244, at *6. “FDA must conduct a robust scientific analysis” of every NDA, requiring a “review team” of “medical doctors, chemists, statisticians, microbiologists, pharmacologists, and other experts.” Br. of the United States as *Amicus Curiae* in *Mutual Pharm. Co. v. Bartlett*, 2013 U.S. S. Ct. Briefs LEXIS 450, at *44 (Jan. 22, 2013).

b. The “Intended Use” Test

Whether an article is a “drug” or a “cosmetic” is thus a question of great consequence. The statutory test for classification, however, is murkier than one might expect.

³ See generally Wallace F. Janssen, *Outline of the History of U.S. Drug Regulation and Labeling*, 36 Food Drug Cosm. L.J. 420 (1981); Wallace F. Janssen, *America’s First Food and Drug Laws*, 30 Food Drug Cosm. L.J. 665 (1975).

The FDCA defines “drugs” and “cosmetics” not by their ingredients or physical effects, but by their so-called “intended use.” See *Estée Lauder*, 727 F. Supp. at 2; Peter Barton Hutt, *Reconciling the Legal, Medical and Cosmetic Chemist Approach to the Definition of a Cosmetic*, 3 CFTA Cosm. J., No. 3 (1971) (“the intended use of the product, rather than its inherent properties, control[s] its classification”). Specifically, a cosmetic is “[an] article[] *intended* to be . . . introduced into, or otherwise applied to the human body” for “cleansing, beautifying, promoting attractiveness, or altering the appearance.” 21 U.S.C. 321(i)(1) (emphasis added). A drug, in contrast, is an “article[] *intended* for use in the diagnosis, cure, mitigation, treatment, or prevention of disease” and/or an “article[] (other than food) *intended* to affect the structure or any function of the body.” *Id.* § 321(g)(1)(B)-(C) (emphasis added).⁴

The FDCA itself does not define “intended use,” but legislative history suggests that Congress viewed the manufacturer’s promotional claims as determinative. See S. Rep. No. 361, 74th Cong., 1st Sess. 4 (1935) (“The manufacturer of the article, through his representations in connection with its sale, can de-

⁴ “Intended use” governs many other classifications under the FDCA. See Respondents’ Br. on the Merits in *Buckman*, 2000 U.S. S. Ct. Briefs LEXIS 540, at *17 (Oct. 23, 2000) (“‘Intended use’ is at the heart of the FDCA regulatory scheme. It determines whether a product is a drug or device, the character of the product, the regulatory requirements to which it is subject, and the extent of those requirements.” (citations omitted)).

termine the use to which the article is to be put.”). An FDA regulation, 21 C.F.R. 201.128, defines “intended use” as the manufacturer’s so-called “objective intent,” as “determined by [its] expressions” or “the circumstances surrounding the distribution of the article.”

Historically, in determining “intended use,” FDA “looked solely at the actual statements made by [the] manufacturer in the marketplace about its product.” Gregory Gentry, *Criminalizing Knowledge: The Perverse Implications of the Intended Use Regulations for Off-Label Promotion Prosecutions*, 64 Food & Drug L.J. 441, 445 (2009). In recent years, FDA has occasionally invoked other factors. *Id.* at 449-58; see, e.g., 60 Fed. Reg. 41453, 41464 (Aug. 11, 1995). However, FDA continues to perceive that “[a] product’s intended use is usually primarily a function of the manner in which a company characterizes its product in the marketplace.” 59 Fed. Reg. 59820, 59822 (Nov. 18, 1994); see, e.g., *Sigma-Tau Pharms. v. Schwetz*, 288 F.3d 141, 146-47 (4th Cir. 2002) (affirming FDA’s decision to “rely[] primarily upon the [article’s] labeling” and to disregard other “surrounding circumstances”).

Courts recognize that the determination of “intended use” “entail[s] the exercise of judgment grounded in policy concerns,” and often requires FDA to “balance” competing policy objectives. *Sigma-Tau*, 288 F.3d at 146, 148. Determining “intended use” is therefore quintessentially within FDA’s primary jurisdiction. See 61 Fed. Reg. 44396, 44519 (Aug. 28, 1996) (“[I]t is within FDA’s primary jurisdiction and

expertise to determine [an article's] intended use."); *Biotics Research Corp. v. Heckler*, 710 F.2d 1375, 1377 (9th Cir. 1983). Indeed, to Athena's knowledge, until this case, the "intended use" of an FDA-regulated article has *never* been determined in a private proceeding without FDA's participation.

Moreover, an article's "intended use" is not graven in stone. Rather, if the manufacturer's promotional claims change, an article's "intended use" can also shift. See 21 C.F.R. 201.128 ("[t]he intended uses of an article may change"); *United States v. Articles of Drug . . . Neptone*, Food Drug Cosm. L. Rep. ¶ 38,240 (N.D. Cal. 1983) (classification of product as a drug based on manufacturer's recent promotion did not "establish[] for all time that [the product] is a drug").

c. FDA's Consideration Of Eyelash Conditioners

FDA is well aware of the "eyelash conditioner" product category, and of RevitaLash in particular. The record strongly indicates that FDA *does not* consider products such as RevitaLash that do not make "eyelash growth" claims to be "drugs."

Starting in early 2007, Allergan complained to FDA that Athena's original RevitaLash product was an unapproved "drug" because it contained the same "active ingredient" as Allergan's drug Latisse, and purportedly was being marketed for eyelash "growth." Athena provided FDA with detailed information regarding its products and advertising, and represented to the Agency that it would refrain

from making further “growth” claims. FDA thereafter abstained from taking any enforcement action.

One particular exchange is especially telling. In May 2007, Allergan complained to FDA about RevitaLash and another eyelash conditioner manufactured by a co-defendant in the district court. Allergan asserted that both products required FDA “drug” approval because they contained prostaglandin analogs, and asked FDA to find that the products’ lack of such approval rendered them illegal. The Agency’s response rejected Allergan’s interpretation of the “intended use” regulation, and specifically stated that the presence of a particular ingredient does not cause an eyelash conditioner to be a “drug.” Moreover, FDA pointed out, even if an eyelash conditioner *was once* a drug based on the manufacturer’s claims of eyelash growth, that product is *no longer* a drug if the manufacturer discontinues such claims. C.A. App. 2879.

Thereafter, Allergan recruited a member of Congress to lobby FDA to take action against cosmetic eyelash conditioners. In a 2010 response letter, FDA explained to the Congresswoman that it was “currently exploring its options for addressing products in this category.” FDA stressed that “[a]s violative products are identified, FDA interacts with the [manufacturers] to protect public health.” C.A. App. 2837-38. In a follow-up letter in 2011, FDA disagreed with the blanket assertion that eyelash conditioners “are unapproved new drugs” and reiterated that the Agency was “assessing” on a “product by product basis” whether “any such eyelash products are drugs as

defined by the [FDCA].” C.A. App. 2834.

d. FDA’s Sole Enforcement Authority

When FDA perceives a statutory violation, the FDCA provides it with a “variety of enforcement options to make a measured response.” *Id.* at 349; *see, e.g.*, 21 U.S.C. 332(a) (injunctions); *id.* § 333(a) (criminal penalties); *id.* § 333(b), (f) (civil fines); § 334(a) (seizures and forfeitures); § 334(g) (detention); § 336 (warning letters). Often, FDA will negotiate a settlement requiring corrective actions (*e.g.*, label changes) without a finding of liability. *Br. of the United States as Amicus Curiae in Warner-Lambert Co. v. Kent*, 2007 U.S. S. Ct. Briefs LEXIS 1867, at *42 (Nov. 28, 2007); *see, e.g., Estée Lauder*, 727 F. Supp. at 5. Congress also authorized FDA to *forgo* enforcement—even in the face of an undisputed violation—where the Agency “believes that the public interest will be adequately served” thereby. 21 U.S.C. 336; *United States v. Sullivan*, 332 U.S. 689, 694 (1948).⁵ This Court has recognized that the FDCA “commit[s] complete discretion to [FDA] to decide how and when” the statute’s enforcement tools “should be exercised,” *Heckler v. Chaney*, 470 U.S. 821, 835 (1985), and that these decisions are unreviewable, *id.* at 837-38.

⁵ *See, e.g.*, 78 Fed. Reg. 57397, 57398 (Sept. 18, 2013) (“FDA may exercise enforcement discretion to permit” certain ophthalmic drugs “that [are] not the subject of an approved NDA to be marketed,” provided that they “do[] not constitute a hazard to health” or “bear claims for serious disease conditions”).

From the beginning, the FDCA has provided that “all . . . proceedings for the enforcement, or to restrain violations, of this Act shall be by and in the name of the United States.” 21 U.S.C. 337(a). Thus, the FDCA “leaves no doubt that it is the Federal Government rather than private litigants who are authorized to file suit for noncompliance.” *Buckman*, 531 U.S. at 349 n.4 (citing § 337(a)). The entrustment of enforcement authority to FDA was the very “heart of” the FDCA regime. *Hynson, Westcott & Dunning*, 412 U.S. at 627.

It is not difficult to see why. Only FDA has the “expertise” and “specialization” required to administer the statute’s often-technical provisions. *Weinberger v. Bentex Pharms., Inc.*, 412 U.S. 645, 652-54 (1973). Only FDA has the broad perspective needed to ensure “[u]niformity and consistency” in the statute’s application. *Ibid.* Only FDA has the ability to “to decide which of the [many] statutorily prescribed remedies, *if any*,” best “fit [a given] violation and the overall purposes of the Act.” Br. of the United States as *Amicus Curiae* on the Merits in *Buckman*, 2000 U.S. S. Ct. Briefs LEXIS 504, at *41-42 (Sept. 13, 2000) (citing *Chaney*, 470 U.S. at 831) (emphasis added). And only FDA can ensure that the statute is applied in the broad public interest, rather than to advance the private interests of litigants in a particular action. See *ibid.* (citing *Pennsylvania v. Nelson*, 350 U.S. 497, 507-08 (1956)).

2. The California Regime

a. The Sherman Law

After the FDCA's enactment, many states moved to "assimilat[e] and adopt[]" its provisions. J. Albert Hutchinson, *Enforcement of California Food and Drug Acts*, 5 Food Drug Cosm. L.J. 387, 387 (1950). California did so in 1939. *Ibid.*; see also Wayne D. Hudson, *California's Part in Food and Drug Law*, 9 Food Drug Cosm. L.J. 579, 579 (1954) (noting that California's food-and-drug laws were "modeled after the [FDCA] of 1938").

One example is California's Sherman Food, Drug, and Cosmetic Law ("Sherman Law"), 1970 Cal. Stat. 1573. The Sherman Law contains definitions of "drug" and "cosmetic" substantially identical to the FDCA's. Cal. Health & Saf. Code 109925, 109900. Like the FDCA, the Sherman Law prohibits the sale of a "new drug" unless "a new drug application has been approved for it . . . under Section 505 of the federal act [*i.e.*, the FDCA]." *Id.* § 111550.⁶ And as with

⁶ Alternatively, § 111550 purports to allow the sale of a "new drug" if "the [California State] [D]epartment [of Health] has approved a new drug . . . application" for it. However, the state-level NDA process described in § 111550 is a dead letter: it was undisputed in both the district court and the Federal Circuit that California has never approved an NDA; that it has no mechanism for doing so; and that it uniformly relies on the FDA approval process. C.A. App. 2208. See *Jones v. Rath Packing Co.*, 430 U.S. 519, 526 (1977) (in preemption cases, courts must "consider the relationship between state and federal

the FDCA, the Sherman Law provides only for governmental enforcement. *Id.* § 111840.

b. The Unfair Competition Law

Under California's Unfair Competition Law ("UCL"), Cal. Bus. & Prof. Code 17200, any act by a business entity that violates any other law—federal, state or local—is deemed "unfair competition" and made privately actionable. *Cel-Tech Commc'ns, Inc. v. L.A. Cellular Tel. Co.*, 973 P.2d 527, 539-40 (Cal. 1999) ("[The UCL] 'borrows' violations of other laws and . . . [makes them] independently actionable."); accord *Webb v. Smart Document Solutions, LLC*, 499 F.3d 1078, 1082 (9th Cir. 2007). Thus, the UCL purports to provide a universal private right of action under California law for violation of any statute.

C. Proceedings Below

1. In The District Court

After unsuccessfully lobbying FDA to deem RevitaLash a "drug," Allergan turned its efforts to federal court. In July 2009, Allergan amended its complaint in a preexisting patent action against Athena (and several other eyelash-conditioner manufacturers) to add a claim under California's UCL. The conduct that allegedly constituted "unfair competition" was Athena's sale of RevitaLash without "new drug" approval. Allergan explicitly affirmed that its "UCL claim [was] *not* based on misrepresen-

laws as they are . . . applied, not merely as they are written").

tation or deception,” or on a purported lack of safety. C.A. App. 498 (emphasis in original). Rather, Allergan explained, its claim “ar[ose] purely as a result of Athena’s failure to obtain an approved new drug application.” C.A. App. 500.

Athena moved for judgment on the pleadings, arguing that Allergan’s “lack-of-FDA-approval” claim was an impermissible, back-door attempt to enforce the FDCA. In its opposition, Allergan emphasized the roundabout way in which its claim was pleaded: Allergan used (1) California’s UCL to “borrow” Athena’s alleged violation of (2) Section 111550 of California’s Sherman Law, which incorporates by reference (3) Section 505 of the FDCA, the requirement that all “new drugs” be approved by FDA. Allergan did not dispute that its UCL claim would be impliedly preempted if it had omitted step (2) of this sequence. But in Allergan’s view, the Sherman Law detour somehow dispelled any preemptive conflict.

The district court agreed with Allergan. It further held that no deference to FDA was appropriate, concluding that “[a]ny level of expertise required” to apply FDA’s “intended use” standard “is not the type that is beyond the Court or more likely found in an administrative agency.” Pet. App. 92a.

The district court granted summary judgment to Allergan, holding that all RevitaLash eyelash conditioners (past, present, and future) are “drugs” under FDA’s “intended use” regulation. In reaching this determination, the district court cited (1) the fact that RevitaLash contains a prostaglandin analog; (2)

long-discontinued marketing claims by Athena; (3) the “pricing” of RevitaLash (apparently under the impression that cosmetics are never expensive); and (4) the fact that RevitaLash is “applied . . . at night . . . over a period of weeks” (apparently believing that cosmetics are never so applied). Pet. App. 71a-74a. The court disregarded both (1) FDA’s statements about the Agency’s view of RevitaLash’s “intended use,” and (2) the fact that FDA had refused to take any action against Athena.

In light of its conclusion that Athena’s products are “drugs” under the FDCA’s “intended use” standard, the district court held that Athena had violated § 505 of the FDCA; that Athena had therefore also violated § 111550 of the Sherman Law, which incorporates § 505 by reference; and that *this Sherman Law violation* was actionable under California’s UCL. Pet. App. 75a-76a. To remedy this “unfair competition,” the district court permanently enjoined the sale of RevitaLash (or any similar Athena product) *anywhere in the United States*, unless and until Athena submits an NDA and receives “new drug” approval from FDA. Pet. App. 43a.

2. In The Federal Circuit

The Federal Circuit affirmed in part and reversed in part.⁷

⁷ Jurisdiction was proper in the Federal Circuit—as that court held—because Allergan’s original complaint contained patent claims, such that the district court’s jurisdiction arose under 28 U.S.C. 1338. Pet. App. 4a-6a; *see*

Athena argued that Allergan's invocation of the Sherman Law was a red herring: whether Athena's liability was premised on its obligation to seek FDA approval under the FDCA, or the very same obligation incorporated into state law, the claim involved Athena's "dealings with the FDA," *Buckman*, 531 U.S. at 347, and "[c]ould not exist absent the federal regulatory scheme established by the FDCA," *Riley v. Cordis Corp.*, 625 F. Supp. 2d 769, 777 (D. Minn. 2009) (citing *Buckman*, 531 U.S. at 352-53).

The Federal Circuit was unmoved. It began by invoking a "[pre]sumption" against preemption, Pet. App. 9a, even though *Buckman* unanimously held that "no presumption against pre-emption obtains" where a claim concerns the "inherently federal" FDA-approval process. 531 U.S. at 347-48.

The Federal Circuit then concluded that Allergan's claim could "not [be] an obstacle to realizing federal objectives" because the Sherman Law "parallel[s] . . . the FDCA." Pet. App. 9a. Because Allergan was ostensibly raising a "parallel" claim, the Federal Circuit did not analyze how such claims under state law impact FDA's administration of the federal scheme "[a]s a practical matter," as the *Buckman* Court had done. 531 U.S. at 350.

Holmes Grp., Inc. v. Vornado Air Circulation Sys., 535 U.S. 826, 829, 834 (2002) ("[T]he Federal Circuit's jurisdiction is fixed with reference to that of the district court, and turns on . . . whether a patent-law claim appear[ed] on the face of the plaintiff's well pleaded complaint.").

After rejecting Athena's preemption defense and affirming the district court's grant of summary judgment, the Federal Circuit nevertheless held that a *nationwide* injunction was an overbroad remedy, and narrowed the injunction to California. It reasoned that (1) the UCL does not apply extraterritorially; (2) under the Commerce Clause of the U.S. Constitution, the UCL *could not* so apply; and (3) a nationwide injunction would "usurp the discretionary enforcement authority of the FDA." Pet. App. 15a-18a. The Federal Circuit did not explain why a statewide injunction—or a patchwork of 50 such injunctions—would *not* "usurp" FDA's authority.

REASONS FOR GRANTING THE PETITION

This case merits review for three reasons. *First*, by allowing a state-law tort claim premised on a party's alleged failure to obtain FDA approval, the Federal Circuit created a direct split with decisions of the Second, Sixth, and Ninth Circuits (and many district courts) that have held such claims impliedly preempted under FDCA § 337(a). *Second*, the decision below epitomizes the deep and longstanding confusion concerning the proper scope of § 337(a) preemption—an issue relevant to all litigation concerning FDA-regulated articles. *Third*, by allowing a private suit to ban a product in one state, the decision below poses an unprecedented threat to the uniformity of the federal regulatory scheme and invites a tidal wave of disruptive "parallel" litigation.

I. THE DECISION BELOW CREATES A DIRECT CIRCUIT SPLIT REGARDING THE VIABILITY OF STATE-LAW “LACK-OF-FDA-APPROVAL” CLAIMS.

Unlike the Federal Circuit, at least three circuit courts of appeal, and numerous district courts, have concluded that § 337(a) *does* bar private suits under state unfair-trade-practices statutes based on alleged failure to obtain FDA approval.⁸

In *PDK Labs, Inc. v. Friedlander*, 103 F.3d 1105 (2d Cir. 1997), the defendant sold products it claimed were “dietary supplements” under the FDCA. The plaintiff argued—as Allergan does here—that the products “contain[ed] ingredients which render[ed] them ‘new drugs’ for which FDA approval is required.” *Id.* at 1111-12 & n.6. Just as here, FDA “ha[d] never objected to [defendant’s] products or advertising, despite access to both.” *Ibid.* The plaintiff sued under (*inter alia*) Georgia’s Deceptive Trade Practices Act. *Id.* at 1107. The Second Circuit concluded that, notwithstanding the claims’ state-law framing, the plaintiffs’ “insistence that [the] products [were] sold without proper FDA approval” was an “impermissible” attempt “to privately enforce alleged violations of the FDCA.” *Id.* at 1113 (citing § 337(a)).

⁸ The Federal Circuit purported to apply Ninth Circuit law. Pet. App. 6a. However, the Federal Circuit cited no Ninth Circuit precedent in support of its preemption holding, which it purported to derive directly from decisions of this Court. Pet. App. 9a-11a.

Loreto v. P&G, 515 F. App'x 576 (6th Cir. 2013), involved a similar claim. There, the plaintiff alleged that “[i]n order . . . to properly sell [its] Products in interstate commerce, [defendant] was . . . required to submit a ‘new drug’ application and have it approved by the FDA.” *Loreto v. P&G*, 737 F. Supp. 2d 909, 915 (S.D. Ohio 2010), *rev'd in part*, 515 F. App'x 576. The lack of such approval, the plaintiffs alleged, caused the products’ sale to violate several state unfair-trade-practices statutes. *Id.* at 909, 916-18; 515 F. App'x at 579. Relying on *Buckman*, the Sixth Circuit held this claim “clearly preempted.” *Id.* at 579. The teaching of *Buckman*, the court observed, is that a state-law claim—however pleaded—is barred if, “were it not for the federal regulatory scheme the FDCA created, there would have been no [valid] claim.” *Id.* at 579.

PhotoMedex, Inc. v. Irwin, 601 F.3d 919 (9th Cir. 2010), presented an analogous claim involving a medical device. Under the FDCA, new devices need not be pre-cleared for sale if FDA has cleared a previous version, and the device has not “significantly changed.” *Id.* at 925-26. The plaintiff alleged that the defendant’s device “varied enough from [the] cleared [version] to require a separate [FDA] filing,” *id.* at 927-28. As in this case, FDA “ha[d] not itself concluded that there was [any] violation,” even though the plaintiff had lobbied for such a result. *Id.* at 924, 926-27. The Ninth Circuit held that just as “Section 337(a) of the FDCA bars private enforcement of th[at] statute,” it “also limits the ability of a private plaintiff to pursue claims under state law theories

where such claims collide with the exclusive enforcement power of the federal government.” *Id.* at 924 (quoting *Buckman*). A private plaintiff, the court concluded, “is not permitted to circumvent the FDA’s exclusive enforcement authority by seeking to prove” that a device required FDA clearance “when the FDA did not reach that conclusion.” *Id.* at 928; *accord Perez v. Nidek Co.*, 711 F.3d 1109, 1120 (9th Cir. 2013) (“whether [approval] of [a] device [is] required” is a determination that “rest[s] within the enforcement authority of the FDA, not this Court”).

Many district courts have similarly held “lack-of-FDA-approval” claims preempted, as “the FDA, not [a] district court, must determine whether a drug is legally on the market.” *Autin v. Solvay Pharms., Inc.*, 2006 U.S. Dist LEXIS 19507, at *2-3, *10-11 (W.D. Tenn. Mar. 31, 2006) (barring state unfair-trade-practices claim that product “cannot be sold legally because it is a new drug without FDA approval”); *accord Sadler v. Advanced Bionics, Inc.*, 929 F. Supp. 2d 670, 685 n.20 (W.D. Ky. 2013); *Reeves v. PharmaJet, Inc.*, 846 F. Supp. 2d 791, 794-98 (N.D. Ohio 2012); *Purchase v. Advanced Bionics, LLC*, 896 F. Supp. 2d 694, 696 (W.D. Tenn. 2011); *Braintree Labs, Inc. v. Nephro-Tech, Inc.*, 1997 U.S. Dist. LEXIS 2372, at *4, *22-24 (D. Kan. Feb. 26, 1997).

The decision below created a direct split with this unbroken line of authority. This Court should grant certiorari and restore that prior consensus.⁹

II. THE DECISION BELOW ILLUSTRATES THE DEEP CONFUSION REGARDING THE SCOPE OF IMPLIED PREEMPTION UNDER SECTION 337(a).

Although the lower courts were unanimous until now that “lack-of-FDA-approval” claims are impliedly preempted, there is a deep and longstanding division about the proper test for implied preemption under § 337(a).

That provision, again, states that “[a]ll . . . proceedings for the enforcement, or to restrain violations, of [the FDCA] shall be by and in the name of the United States.” It goes without saying that § 337(a) precludes private claims under the FDCA itself. In *Buckman*, however, this Court held unanimously that § 337(a) does more than just that: it also “impliedly pre-empt[s]” at least *some* claims “under

⁹ Allergan argued below that some of these cases are distinguishable because Allergan’s claim arose under a *state statute* that incorporates the FDCA by reference, rather than the FDCA itself. This is a distinction without a difference: *any* claim premised on lack of FDA approval, whatever the statutory hook, implicates the federal approval process, and could not exist “were it not for the federal regulatory scheme the FDCA created.” *Loreto*, 515 F. App’x at 579. Indeed, *Buckman* itself involved a *state-law* claim of alleged misconduct during the FDA-approval process—not a direct claim for violation of the FDCA. *Post* at 24.

state tort law.” *Id.* at 343, 348. Which claims fall within § 337(a)’s preemptive ambit remains an unsettled question.

A. This Court’s Decisions In *Buckman* And *Mensing*

In *Buckman*, the plaintiffs sought damages for personal injuries caused by a medical device. As in this case, their claim “d[id] not depend on any showing that the device was somehow defective, or falsely advertised.” Br. of the United States as *Amicus Curiae* in Support of Certiorari in *Buckman*, 1999 U.S. S. Ct. Briefs LEXIS 1003, at *26 (June 7, 1999). Instead, the plaintiffs asserted that the device was unlawfully on the market because the defendants misrepresented its “intended use” during the FDA-approval process. See *In re Orthopedic Bone Screw Prods. Liab. Litig.*, 159 F.3d 817 (3d Cir. 1998), *rev’d sub nom. Buckman v. Plaintiffs’ Legal Comm.*, 531 U.S. 341 (2001); *Buckman*, 531 U.S. at 346-47.

Importantly, although the FDCA imposes a duty of truthfulness on applicants, the plaintiffs’ so-called “fraud-on-the-FDA” claim *did not invoke* that federal statutory duty, directly or indirectly. *Bone Screw*, 159 F.3d at 821-22. Rather, the plaintiffs based their claim entirely on a *state common-law* duty not to make false statements to one party that foreseeably cause injury to another party. *Id.* at 822, 826-27 (citing RESTATEMENT (SECOND) TORTS § 310); see *Buckman*, 531 U.S. at 343 (“Plaintiffs s[seek] damages from petitioner under state tort law.”).

The Court held that this claim “conflict[ed] with, and [was] therefore impliedly pre-empted by,” the FDCA. *Buckman*, 531 U.S. at 348. The conflict was not one of *substantive* standards: both the FDCA and state law purportedly required truthful disclosures to FDA. Instead, the conflict was with FDA’s *singular enforcement role*—as underscored by the Court’s repeated citations to § 337(a). *See id.* at 349 n.4 (citing § 337(a)); *id.* at 352 (same). As this Court explained, “in practice,” state-law claims like the plaintiffs’ would have the same deleterious consequences that Congress desired to avoid when it expressly barred private plaintiffs from meddling with FDA’s enforcement choices. *Id.* at 347-51.¹⁰

More recently, in *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567 (2011), the Court made clear that implied preemption under § 337(a) goes beyond the specific facts of *Buckman*. *Mensing* was a classic state-law failure-to-warn case. However, under the federal scheme regulating generic drugs, the defendant manufacturers could not have changed their labels to include the warnings that state law required without FDA’s authorization. The ultimate question was whether this scenario resulted in implied “impossibil-

¹⁰ *Cf. Astra USA, Inc. v. Santa Clara Cnty.*, 131 S. Ct. 1342, 1348 (2011) (where Congress barred private actions under the Public Health Services Act, state-law claims that “incorporate [those federal] statutory obligations” are “in essence . . . suit[s] to enforce the statute,” and are “inconsistent with the legislative scheme to the same extent” as claims “directly under the statute”).

ity” preemption. But *Buckman* (and, thus, “purposes and objectives” preemption under § 337(a)) played a key role in the Court’s analysis.

In analyzing whether the manufacturers could simultaneously comply with both federal and state law, the Court deemed it irrelevant that FDA might have authorized a label change if the manufacturers had sought its permission. The Court cited *Buckman* for the broad proposition that the FDCA “preempt[s] a state tort-law claim based on *failure to properly communicate* with the FDA.” *Id.* at 2578 (emphasis added). Stated otherwise, a manufacturer’s decision whether to approach FDA and “ask[] for [its] help” is simply “not a matter of state-law concern.” *Id.* at 2581. Because the manufacturers could not meet their state-law duty without FDA authorization, and because *Buckman* places the decision whether to approach FDA beyond the states’ purview, a finding of impossibility was compelled. *Ibid.*

B. The Lower Courts’ Split Concerning Section 337(a)’s Preemptive Effect

In the view of Athena and others, § 337(a) squarely preempts “lack-of-FDA-approval” claims. See Steven Boranian, “Federal Circuit Bats an Eye at FDCA Preemption,” Drug and Device Law, Jan. 10, 2014, <http://druganddevicelaw.blogspot.com/2014/01/federal-circuit-bats-eye-at-fdca.html> (“[Athena] had a point. . . . Congress gave the FDA exclusive authority to determine whether a product should be regulated as a drug, and that prerogative cannot co-exist with . . .

thousands of courts applying state law[] undertaking the same task.”).

However, lower-court views of § 337(a) preemption “have diverged.” Matthew A. Reed, *What’s the Implication? Courts and the Scope of Implied Medical Device Preemption*, 27 Wash. Legal Found. Legal Backgrounder 22 at 3 (Nov. 16, 2012). Commenters have described “the extent of” § 337(a) preemption as an issue “fraught with controversy,” Catherine M. Sharkey, *The Fraud Caveat to Agency Preemption*, 102 Nw. U. L. Rev. 841, 856-57 (2008), and noted that the “judicial disarray” in this area “has caused confusion and a lack of predictability for both injured parties and . . . manufacturers,” Jean Macchiaroli Eggen, *Navigating Between Scylla and Charybdis: Preemption of Medical Device “Parallel Claims,”* 9 J. Health & Biomed. L. 159, 160-61, 208 (2013).

Some lower courts, viewing *Buckman* as a one-off decision, apply § 337(a) preemption “solely to fraud-on-the-FDA claims.” J. David Prince, *Medical Device Law: The Puzzle of Parallel Claims, Preemption, and Pleading the Particulars*, 39 Wm. Mitchell L. Rev. 1034, 1074-75 (2013). Here, for example, the Federal Circuit purported to distinguish *Buckman* on the grounds it “involved a claim based on fraud before the FDA.” Pet. App. 10a. The Ninth Circuit took a similarly narrow view of § 337(a) in *Stengel v. Medtronic, Inc.*, 704 F.3d 1224, 1230 (9th Cir. 2013) (en banc); see Prince, *supra*, 39 Wm. Mitchell L. Rev. at 1076-77 (“*Stengel* . . . clearly stands for the proposition that state-law claims are not impliedly preempt-

ed unless they are specifically a fraud-on-the-FDA claim.”).¹¹

Indeed, in a widely-cited decision that the Federal Circuit relied upon below, the California Supreme Court effectively denied the existence of § 337(a) preemption altogether:

The crux of defendants’ preemption argument is that plaintiffs’ private state claims [under California’s UCL] are precluded because they improperly seek to enforce the FDCA in violation of section 337(a). . . . [But § 337(a)], by its very terms, only implicates efforts to enforce *federal* law. What section 337 does *not* do is limit, prohibit, or affect private claims predicated on *state* laws.

Farm Raised Salmon Cases, 175 P.3d 1170, 1181-82 (Cal. 2008), *cert. denied sub nom. Albertson’s Inc. v. Kanter*, 555 U.S. 1097 (2009).

By and large, these courts’ cramped view of § 337(a) preemption stems from a misunderstanding of *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996) and *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008). *Lohr* addressed whether a traditional state-law product-liability claim was *expressly* preempted under 21 U.S.C. § 360k, a clause added to the FDCA by the

¹¹ *Accord Bausch v. Stryker Corp.*, 630 F.3d 546, 557 (7th Cir. 2010); *Howard v. Zimmer, Inc.*, 711 F.3d 1148, 1150-52 (10th Cir. 2012).

Medical Device Amendments of 1976. Because the terms of that clause bar only state-law device requirements “different from, or in addition to” federal requirements, the Court logically concluded that “[n]othing in § 360k denies [states] the right to provide a traditional damages remedy for violations of common-law duties [that] parallel federal requirements.” *Id.* at 495 (emphasis added). *Riegel* reiterated the same conclusion. 552 U.S. at 330.

Many lower courts—including the Federal Circuit below—have construed *Lohr* and *Riegel* as “an across-the-board holding that there [is] no preemption” of “parallel” claims “under any . . . categor[y]” of preemption. *Stengel*, 704 F.3d at 1228, 1230; *accord Bass v. Stryker Corp.*, 669 F.3d 501, 514 (5th Cir. 2012) (interpreting *Riegel* as “unequivocally” precluding even implied preemption of “parallel” claims); *Farm Raised Salmon*, 175 P.3d at 1181-82 (same). Under that interpretation of *Lohr* and *Riegel*, *Buckman*—a case where a “parallel” claim *was* deemed impliedly preempted—would indeed appear to be an aberration, limited to its specific facts.

But this reading of *Lohr* and *Riegel* is wrong. In *Buckman*, this Court cautioned that *Lohr* “did not . . . address . . . implied preemption.” 531 U.S. at 353 (emphasis added). Nor was implied preemption at issue in *Riegel*. 552 U.S. at 345 (Ginsburg, J., dissenting) (noting that respondent “relie[d] exclusively on § 360k[] and d[id] not argue [implied] preemption”). Thus, as this Court has unanimously recognized, *Lohr* and *Riegel* “do[] not and cannot stand for the proposition” that parallel claims always—or even

generally—escape *implied* preemption under § 337(a). *Buckman*, 531 U.S. at 353; cf. *Arizona v. United States*, 132 S. Ct. 2492, 2505 (2012) (“[T]he existence of an express pre-emption provision does not . . . impose a ‘special burden’ that would make it more difficult to establish [implied] preemption of laws falling outside the clause.”).

Other lower courts, unburdened by this misreading of *Lohr* and *Riegel*, have taken a diametrically opposite approach to § 337(a) preemption. These courts read *Buckman* “broadly” as preempting “any private [state-law] action that incorporates a violation of an FDA regulation.” Prince, *supra*, 39 Wm. Mitchell L. Rev. at 1072 (emphasis added). See, e.g., *Sprint Fidelis Leads Prods. Liab. Litig.*, 623 F.3d 1200, 1204 (8th Cir. 2010) (“[T]he plaintiff must not be suing *because* the [defendant’s] conduct violates the FDCA,” as “such a [state-law] claim would be impliedly preempted”). These cases reason that private plaintiffs “cannot make an end run around” § 337(a) “by recasting violations of the FDCA as violations” of “parallel” state laws. *McClelland v. Medtronic, Inc.*, 944 F. Supp. 2d 1193, 1200 (M.D. Fla. 2013).¹²

Still other courts have staked out intermediate positions. These courts do not limit § 337(a) preemp-

¹² Allergan itself successfully advanced this maximalist position when its own ox was being gored. See *Goldsmith v. Allergan, Inc.*, 2011 U.S. Dist. LEXIS 6233 (C.D. Cal. Jan. 13, 2011), *subsequent order* at 2011 U.S. Dist. LEXIS 80998 (C.D. Cal. May 25, 2011) (finding California UCL claim against Allergan impliedly preempted).

tion to “fraud-on-the-FDA” claims, but neither do they extend it to *all* state-law claims involving FDCA violations. The precise tests that these courts have adopted depend on which of several passages in *Buckman* they deem authoritative.

The Fifth Circuit, for example, has held that “the dispositive factor” for implied preemption under § 337(a) is whether a state-law claim “involve[s] the relationship between the federal regulator [*i.e.*, FDA] and the regulated entity.” *Lofton v. McNeil Consumer & Specialty Pharms.*, 672 F.3d 372, 377 (5th Cir. 2012). *Cf. Buckman*, 531 U.S. at 347 (“[T]he relationship between a federal agency and the entity it regulates is inherently federal in character”).

Pointing to different language in *Buckman*, the Ninth Circuit has articulated another test, where “[t]he key factor” is whether “the existence of . . . federal enactments is a critical element in [the plaintiff’s] case.” *Nathan Kimmel v. DowElanco*, 275 F.3d 1199, 1206 (9th Cir. 2002) (quoting *Buckman*, 531 U.S. at 353); *accord Perez*, 711 F.3d at 1119-20.

And relying on still other language in *Buckman*, the Sixth Circuit has framed a slightly different test:

[To avoid preemption, t]he conduct on which the claim is premised must be the type of conduct *that would traditionally give rise to liability under state law*—and that would give rise to liability under state law even if the FDCA had never been enacted.

Loreto, 515 F. App'x at 579 (emphasis added and internal quotation marks omitted); accord *Blankenship v. Medtronic, Inc.*, 2014 U.S. Dist. LEXIS 39063, at *10-11, *23-24 (E.D. Mo. Mar. 25, 2014); *Caplinger v. Medtronic, Inc.*, 921 F. Supp. 2d 1206, 1214-15 (W.D. Okla. 2013); cf. *Buckman*, 531 U.S. at 353 (“[P]laintiffs . . . [are] not . . . relying on traditional state tort law which had predated the federal enactments in question”).

Athena submits that the cramped, “fraud-on-the-FDA-only” view adopted by the Federal Circuit cannot be correct. Nothing in the text of § 337(a) or this Court’s precedents suggests such an arbitrary limitation to that provision’s preemptive effect. Whatever the proper test, this case provides an excellent vehicle to resolve this deep and troublesome division in the lower courts.

III. THIS CASE RAISES ISSUES OF NATIONAL IMPORTANCE WARRANTING THIS COURT’S IMMEDIATE ATTENTION.

The extent of implied preemption under § 337(a) is a question of profound national importance. It potentially bears on *every* state-law suit involving an FDA-regulated article—and such articles “account[] for 25 cents of every dollar spent by [U.S.] consumers.” John P. Swann, *FDA’s Origin*, <http://www.fda.gov/AboutFDA/WhatWeDo/History/Origin/ucm124403.htm>. But *this particular* § 337(a) preemption case raises especially critical concerns warranting immediate review and reversal.

A. The Decision Below Is An Unprecedented Threat To The Uniformity And Consistency Of The FDCA Regime.

In enacting the FDCA, Congress intended to replace the existing patchwork of state-by-state regulation with a nationwide approach. Without doubt, “[u]niformity and consistency” were key objectives of the new regime. *Bentex Pharms.*, 412 U.S. at 652-54; see *United States v. Regenerative Scis., LLC*, 741 F.3d 1314 (D.C. Cir. 2014) (“[t]he FDCA enact[ed] a comprehensive, uniform regulatory scheme”); H.R. Rep. No. 59-2118, at 5-6 (1906) (“One of the hoped for good results of a national [food and drug] law is . . . a uniformity of laws and regulations.”).

All private quasi-enforcement suits hinder Congress’s desire for uniformity and consistency, but some suits pose much greater threats than others. In particular, before now, successful private “parallel” litigation was limited to claims for *money damages*. See *Levine*, 555 U.S. at 579 (parallel “[s]tate tort suits . . . serve a distinctly *compensatory* function” (emphasis added)); *Lohr*, 518 U.S. at 495 (“[n]othing in § 360k denies [states] the right to provide a *traditional damages remedy* for . . . parallel [claims]” (emphasis added)). Occasional state-law damages suits make it more burdensome for manufacturers to operate nationwide. See *Buckman*, 531 U.S. at 350. But they do not pose categorical obstacles to national uniformity.

Suits like this one do. The Federal Circuit permitted an unprecedented private claim *to determine an*

article's regulatory classification under FDA's "intended use" standard and, on that basis, *to ban an article's sale* in one state. As a result of the judgment below, RevitaLash (and any similar product Athena may introduce in the future) is an unlawful "drug" for purposes of FDA's intended-use regulation within the borders of California. But FDA regards RevitaLash as a lawful "cosmetic" under that same regulation, and permits it to be sold everywhere else. "Parallel" litigation of this sort is fundamentally different from a "parallel" claim for damages to redress personal injury, and it poses a vastly greater threat to national uniformity. *Cf. Mutual Pharm. Co. v. Bartlett*, 133 S. Ct. 2466, 2488, 2491 (2013) (Sotomayor, J., dissenting).

To make matters worse, several other companies who were co-defendants in the district court remain free to sell *their* eyelash conditioners—which Allergan had also alleged to be unapproved "drugs"—everywhere in the United States. This disparity is not attributable to any differences between their products and Athena's, but to Allergan's strategic decision to settle with some parties and not others. Thus, even within a single state, this sort of private litigation creates arbitrary, non-uniform outcomes repugnant to the FDCA's objectives. *Cf. Bentex Pharms.*, 412 U.S. at 653 (rejecting a construction of the FDCA that would "require[] compliance by one manufacturer while his competitors marketing similar [articles] remain free to violate the Act").

B. The Decision Below Invites A Wave Of Novel And Usurpative Private Lawsuits.

Before now, the scope of “parallel” litigation has been cabined in another important way: such claims have invariably required an allegation (and, ultimately, proof) that the challenged article was *actually defective, harmful, or misrepresented*. See, e.g., *Levine*, 555 U.S. at 555 (drug with inadequate warning caused loss of plaintiff’s arm); *Lohr*, 518 U.S. at 481 (defective pacemaker caused “heart block” requiring surgery); *Farm Raised Salmon*, 175 P.3d at 1173 (deceptive colorants “caused consumers to believe farmed salmon [was] wild salmon”).

No longer. The Federal Circuit has allowed an unprecedented private claim that is “wholly independent of” any consumer harm, and is based *entirely* on a party’s alleged failure to procure FDA pre-approval. C.A. App. 498. In so doing, the Federal Circuit has opened a Pandora’s box of “parallel” claims that, if not immediately closed, threatens to clog the courts, undermine FDA’s policy judgments, and perhaps even endanger lives.

Take, for example, “off-label” promotion of drugs and devices. As this Court has noted, “off-label” use of such articles—i.e., use for other than FDA-approved indications—is lawful, ubiquitous, and often medically necessary. *Buckman*, 531 U.S. at 350-51 & n.5. Yet *promoting* drugs and devices “off-label” changes their “intended use” under 21 C.F.R. 201.128 (the same regulation at issue here), and renders them “unapproved new drugs.” See FDA, *Guid-*

ance for Industry: Good Reprint Practices for the Distribution of Medical Journal Articles, <http://www.fda.gov/RegulatoryInformation/Guidances/ucm125126.htm> (“An approved . . . drug that is marketed for an unapproved use is an unapproved new drug with respect to that use.”). The “boundary between permissible and impermissible” promotion—*i.e.*, between conduct that changes an article’s “intended use” and conduct that does not—is a policy question that requires “difficult and subtle balancing.” *Bone Screw*, 159 F.3d at 831 (Cowen, J., dissenting); see FDA, *Guidance for Industry: Responding to Unsolicited Requests for Off-Label Information* at 3, <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM285145.pdf> (“FDA recognizes that,” under certain circumstances, “it can be in the best interest of public health for a firm to . . . [provide] information about off-label uses of [its] products”).

Before now, state-law claims based on “off-label” promotion have been held preempted, because “the very concept of ‘off-label’ use and promotion is derived from the regulatory system imposed by . . . the FDCA.” *Gavin v. Medtronic, Inc.*, 2013 U.S. Dist. LEXIS 101216, at *55 (E.D. La. July 19, 2013). But under the Federal Circuit’s ruling, a company who convinces a court that a competitor’s statements established a new “intended use” for its product can seek an injunction against such statements. Under the Federal Circuit’s rationale, it would make no difference whether the allegedly off-label statements were 100% true and beneficial—or even vital—to the

public health. Nor would it matter if FDA had made a considered decision to forbear enforcement for those very reasons.

There are countless other scenarios where a manufacturer may arguably be out of compliance with the FDCA without causing any tangible injury or deception to consumers. Under the Federal Circuit's ruling, any such scenario now supports a private claim under "parallel" state law. The ability to sue without true injury will launch a slew of unnecessary and opportunistic lawsuits, and FDA's role as the centralized, expert enforcer of the federal scheme will continue in name only.

This is not idle speculation. California's courts are already swamped by a tide of lawyer-driven class actions against food manufacturers based on picayune FDCA violations, all asserted—like Allergan's claim here—as "parallel" claims under the UCL and Sherman Law. See Anthony J. Anscombe & Mary Beth Buckley, *Jury Still Out on the 'Food Court': An Examination of Food Law Class Actions and the Popularity of the Northern District of California*, BNA Class Action Litig. Report (July 2012), <http://about.bloomberglaw.com/practitioner-contributions/jury-still-out-on-the-food-court/> (noting 170 such actions filed in California federal courts from April 2012 to April 2013 alone); Paul M. Barrett, *California's Food Court: Where Lawyers Never Go Hungry*, BusinessWeek, Aug. 22, 2013, <http://www.businessweek.com/articles/2013-08-22/californias-food-court-where-lawyers-never-go-hungry>. Because these cases' "parallelism" rationale has now been endorsed by a federal appeals

court, there is “nothing to prevent the craziness of California food litigation from . . . spilling over” into *all* FDA-related industries. Michelle Yeary, “A Tale of Two Decisions,” Drug and Device Law, Feb. 12, 2014, <http://druganddevicelaw.blogspot.com/2014/02/a-tale-of-two-decisions.html>.¹³

* * *

In sum, while the lower courts have long disagreed on the preemptive scope of § 337(a), this case poses that question in an especially urgent context. This Court need not—and should not—wait to resolve this question until the disruptive and dangerous consequences of the Federal Circuit’s decision have been realized.

¹³ Indeed, the decision below has already spawned a copy-cat consumer class action—ironically, against *Allergan*—alleging that certain of its skin-care products “qualify as drugs . . . under both [the FDCA] and parallel state laws,” but purportedly lack necessary “approv[al] . . . for sale.” See Complaint, *Ruhnke v. Allergan, Inc.*, No. 14-420, ¶ 6 (C.D. Cal. Mar. 19, 2014).

CONCLUSION

For the above reasons, the petition for a writ of certiorari should be granted.

Respectfully submitted.

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