No. 13-1379

IN THE
Supreme Court of the United States

ATHENA COSMETICS, INC.,

Petitioner,

v.

ALLERGAN, INC.,

Respondent.

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

BRIEF IN OPPOSITION

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QUESTION PRESENTED

Whether both courts below correctly held that a state-law unfair competition claim predicated on violations of a state-law health and safety provision that parallels and does not conflict with federal law is not preempted by federal law.

RULE 29.6 STATEMENT

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

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BRIEF IN OPPOSITION

Respondent Allergan, Inc. respectfully submits that the petition for a writ of certiorari should be denied.

STATEMENT

Petitioner Athena Cosmetics, Inc. sold an eyelash growth drug called RevitaLash in violation of the California Health and Safety Code. Allergan markets a competing product called Latisse, a prescription drug that is the only approved eyelash-growth product on the market. Allergan sued Athena under California law for engaging in unfair competition. The district court held that Allergan's state-law claim was not preempted by federal law, and the court of appeals unanimously affirmed.

1. Allergan develops and commercializes innovative pharmaceuticals, biologics, and medical devices. Among its significant discoveries in recent years are methods of using the prostaglandin analog Bimatoprost to grow hair, including eyelashes, and Allergan claimed this invention in a patent formerly at issue in this case. C.A. App. 363–74.

In 2008, Allergan submitted an application to the federal Food and Drug Administration (FDA) for approval of Bimatoprost for growing eyelashes. Such approval is required as a matter of federal law because the FDA has determined that *all* hair growth products for external use are "new drugs" requiring premarket approval. 21 C.F.R. § 310.527(b) ("Any OTC drug product that is labeled, represented, or promoted for external use as a hair grower ... is regarded as a new drug ... for which an approved new drug application ... is required"); 54 Fed. Reg. 28,772 (July 7, 1989). California has

adopted the same requirement under its separate drug-regulation regime (known as the Sherman Law), which generally parallels federal law. Cal. Health & Safety Code § 110110(a).

In support of its FDA application, Allergan submitted the results of robust safety and efficacy studies derived from years of clinical research involving thousands of subjects. Based on its excellent safety record and proof that Bimatoprost grows eyelashes, the FDA approved Allergan's application in December 2008. Allergan's Bimatoprost product, marketed as Latisse, remains the only prostaglandin drug product approved in the United States for growing eyelashes.

2. Petitioner Athena also markets and sells a line of prostaglandin hair-growth products, including its flagship product, RevitaLash, on which petitioner has made hundreds of millions of dollars in profits through over-the-counter and online sales. C.A. App. 1542–43. Petitioner has neither sought nor obtained regulatory approval to sell RevitaLash—from the California Department of Health Services, the FDA, or any other regulatory agency. *Id.* at 1525.

Petitioner's first version of RevitaLash contained the active ingredient Bimatoprost, which petitioner labeled "Formula LashGro (proprietary formulation)" on its packaging. C.A. App. 733. Petitioner has since reformulated RevitaLash—by swapping prostaglandin analogs—three times in an effort to avoid regulatory action or civil liability. Petitioner replaced Bimatoprost with a different prostaglandin analog in November 2007, in response to the FDA's seizure of a competing eyelash growth product sold by a former defendant in this case. *Id*. at 680–81, 1033 ("The FDA considers Age Intervention Eyelash

to be an unapproved and misbranded drug because [it] has [been] promoted ... to increase eyelash growth .... The agency takes seriously its responsibility to protect Americans from unapproved drugs."). Petitioner adopted yet another reformulation following the district court's claim construction ruling, under which petitioner's then-existing formulation fell within the scope of Allergan's patent. *Id*. at 3554–602. Petitioner reformulated RevitaLash *yet again* in 2011, following an FDA warning letter to another former defendant regarding a similar product, "RapidLash," which, the FDA stated, was an illegal unapproved new drug. *Id*. at 1036–38 ("Based on the labeling and promotional materials described above ... [these products] are drugs ... because they are articles intended to ... induc[e] eyelash and eyebrow growth").

Throughout all of these reformulations, petitioner has always marketed RevitaLash as a product that will *grow* eyelashes longer, thicker, and fuller, after a few weeks of nightly application. *See*, *e.g.*, C.A. App. 820–21, 862–63, 875. Indeed, petitioner sought to patent the growth of eyelashes using its latest RevitaLash formulation. The application disclosed the synthesis of the RevitaLash formulation, and stated that "[r]epeated application" "will ... stimulate or promote the growth of eyelashes" when "applied at the base of an eyelid adjacent to or where hair grows from the follicles (*e.g.*, along the lashline)" or to "the eyelashes themselves." *Id*. at 998. When asked during oral argument in the court of appeals whether RevitaLash "grows eyelashes," counsel for petitioner admitted that "it has that property, that's true."

http://www.cafc.uscourts.gov/oral-argument-recordings/2013-1245/all, at 16:11–30.

3. Allergan brought a California-law unfair competition claim against petitioner for promoting its eyelash growth products as a non-prescription alternative to Latisse. *See* C.A. App. 887 ("RevitaLash ... [is] The *Cosmetic* Alternative to Latisse" and "can be purchased by consumers whenever they want—*without seeing a physician or getting a prescription*").

California's Unfair Competition Law (UCL) prohibits "any unlawful, unfair or fraudulent business act or practice and unfair, deceptive, untrue or misleading advertising." Cal. Bus. & Prof. Code § 17200. By proscribing any unlawful business practice, the UCL "'borrows' violations of other laws and treats them as unlawful practices" that are "independently actionable." *Cel-Tech Commc'ns, Inc. v. L.A. Cellular Tel. Co.*, 20 Cal. 4th 163, 180 (1999) (citations omitted).

The predicate "unlawful" acts for Allergan's UCL claim were petitioner's many violations of the California Health and Safety Code, which prohibits the promotion, manufacturing, and sale of "drugs" that are "new" and "misbranded," if they have not been approved by either the California State Department of Health Services or the FDA. Cal. Health & Safety Code §§ 111550, 110398, 111440. Despite petitioner's repeated insinuations to the contrary, Allergan did not assert the Federal Food, Drug, and Cosmetic Act (FDCA) as an independent cause of action *or* as a predicate "unlawful" act for its UCL claim. C.A. App. 375–77.

Under California law, a product is a "drug" if it is intended to "affect" "any function" of the "human

body," including hair growth. Cal. Health & Safety Code § 109925(c). Federal law is identical. 21 U.S.C. § 321(g)(1)(C). Moreover, under both California and federal law, *all* hair growth drugs applied externally—including Latisse and RevitaLash—are automatically considered "new drugs" requiring premarket approval, because they are *by definition* not generally recognized as safe and effective. Cal. Health & Safety Code § 110110; 21 C.F.R. § 310.527; *see also United States v. Kasz Enters., Inc.*, 855 F. Supp. 534, 541–42 (D.R.I. 1994) (describing in detail regulatory history that led to blanket rule regarding hair growth drugs). As the FDA has explained, "[a]lthough many of these eyelash growth promoter products are marketed as cosmetics, they also may be drugs." C.A. App. 2837.

4. The district court granted summary judgment to Allergan.

a. The court first determined that RevitaLash is intended to "grow" eyelashes and "affect" a "function" of the "human body," and is therefore a "drug" under California law. Pet. App. 53a–75a. The district court made this determination based on hundreds of pages of uncontroverted evidence, including petitioner's marketing campaigns, internal emails, petitioner's CEO's deposition admissions, and petitioner's own patent application.

Because RevitaLash is a drug, petitioner was required to obtain regulatory approval—from the California Department of Health Services or the FDA—before selling it to the public in California. Petitioner did not do so, and its sales of RevitaLash therefore violated the California Health and Safety Code. Cal. Health & Safety Code § 111550. The district court held that Allergan, as a competitor,

could enforce that state-law violation through the UCL. Pet. App. 65a–67a.

b. Petitioner argued (for the first time) in a motion for reconsideration that Allergan's claim was preempted by the federal FDCA because the district court cited FDA regulations in its lengthy order granting Allergan's summary judgment motion. Pet. App. 54a–76a. In denying petitioner's motion for reconsideration, the district court stated that any references to federal law were merely "referential" to determine whether California's "Sherman [Law] is violated," and "nothing more." *Id.* at 51a.

The court also rejected the preemption argument as untimely. The court held that petitioner "could have ... made" the preemption argument earlier, but failed to do so. Pet. App. 50a. As the court noted, "[p]reemption was pled as an affirmative defense and no materials presented in the motions were not previously unavailable during the pendency of these motions." *Ibid.*

c. The district court entered an injunction prohibiting petitioner from selling RevitaLash anywhere in the United States. Pet. App. 20a–45a.

5. The Federal Circuit unanimously affirmed in part and reversed in part.

a. The court of appeals affirmed the district court's determination that RevitaLash is a "drug" under California law. Pet. App. 10a–14a. As the court explained, "there is no genuine dispute that Athena objectively intends for the products at issue to be used to affect the structure of eyelashes—*i.e.*, as drugs." *Id.* at 12a. Athena's marketing "consistently discusses physical changes to eyelashes" and its training "similarly references eyelash structure." *Id.* at 13a.

b. The court of appeals also held that "the FDCA does not impliedly preempt [Allergan's] UCL claim." Pet. App. 8a. As the court explained:

> We do not find a clear purpose by Congress to preempt the state law claim at issue. Congress expressed its intent to preempt state-law causes of action regarding, for example, non-prescription drugs and medical devices. Allergan's contention, however, is that the products at issue must ultimately be regulated as prescription drugs—about which Congress "declined to enact such a provision." *Wyeth* [*v. Levine*, 555 U.S. 555, 567 (2009)]; *see also Farm Raised Salmon Cases*, 42 Cal. 4th 1077, 72 Cal Rptr. 3d 112, 175 P.3d 1170, 1179 (Cal. 2008) ("[D]eference should be paid to Congress's detailed attempt to clearly define the scope of preemption under the FDCA."). Moreover, the California Health Code is not an obstacle to realizing federal objectives. To the contrary, it contains provisions that parallel the FDCA, such that the statutes have consistent goals.

Id. at 9a.

c. The court of appeals vacated the injunction as overly expansive. Pet. App. 14a–19a. "Neither the California courts nor the California legislature are permitted to regulate commerce entirely outside of the state's borders." *Id.* at 16a. Because Allergan's claim was predicated entirely on California law, "the district court should limit the scope of the injunction to regulate conduct occurring within California." *Id.* at 19a. In this respect, the court below pointed out that "California does not have the authority to stand in the shoes of the FDA to determine whether

Athena's sale of the products at issue amounts to the sale of an unapproved drug under the FDCA." *Id.* at 17a. "The FDA—and the FDA alone—has the power and the discretion to enforce the FDCA." *Ibid.* (citing 21 U.S.C. § 337(a)).

REASONS FOR DENYING THE PETITION

In this Court, petitioner does not dispute that its RevitaLash product is a "drug" under California law, or that California law prohibits the sale of that drug because petitioner failed to obtain approval from either California or federal regulators. Petitioner also does not dispute that its sales were in violation of the California Health and Safety Code, and actionable by Allergan under the California Unfair Competition Law. And petitioner does not dispute that California law authorizes a California-only injunction to prevent future unlawful sales of RevitaLash.

Petitioner's *only* contention in this Court is that Allergan's state-law unfair competition claim is preempted by federal law. Its argument, in brief, is that a state-law claim premised on the lack of FDA approval is preempted. Pet. 19–32 (arguing that the FDCA "squarely preempts 'lack-of-FDA-approval' claims").

But the fatal problem with petitioner's argument is that Allergan's claim does not depend on petitioner's failure to secure FDA approval, nor does it implicate FDA action or inaction. Allergan's state-law claim parallels federal law, and therefore does not conflict with or invade the province of a federal statute or federal regulatory agency. No court has held that a claim like Allergan's is preempted, and there is therefore no conflict or confusion in the lower

courts, and no reason for this Court's review. The petition should be denied.

I. ALLERGAN'S STATE-LAW CLAIM IS NOT PREEMPTED

Allergan sued under state law (California's Unfair Competition Law) to remedy violations of state law (the California Health and Safety Code). Allergan's claim—as pleaded in the complaint and established on summary judgment—is that Athena violated California Health and Safety Code sections 111550, 110398, and 111440 by "marketing, selling, and distributing [its] hair and/or eyelash growth products without [a new drug] application approved by the FDA *or* the California State Department of Health Services." C.A. App. 375–77 (emphasis added). Allergan did not allege any violation of the FDCA.

California's Health and Safety Code mirrors the FDCA, and therefore does not in any way conflict with federal law. California has adopted FDA regulations pertaining to "new drugs" as regulations of the state, so that conduct permitted by the FDA regulations is conduct permitted under California law. Cal. Health & Safety Code § 110110; Cal. Code Regs. tit. 17, § 10862. Petitioner therefore does not assert preemption based on any conflict between the state-law standard and the FDCA. Pet. 24–26.[1]

Indeed, California is one of *forty-five* states to have adopted, in whole or in part, the Uniform Food, Drug and Cosmetic Act, which is modeled after the

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[1] Nor does petitioner claim that it would be impossible to comply with both federal and state law, which renders *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567 (2011) (cited at Pet. 25–26), inapposite here.

federal statute. These and other parallel state regimes have consistently been recognized—by Congress, this Court, and the FDA—as important complements to, and *not* preempted by, the FDCA.

In the absence of an express preemption provision, this Court has repeatedly permitted state-law claims that parallel, and therefore do not conflict with, the FDCA. For example, the Court in *Wyeth v. Levine*, 555 U.S. 555 (2009), rejected the argument that "the FDCA establishes both a floor and a ceiling for drug regulation," holding instead that "the FDA [has] traditionally regarded state law as a complementary form of drug regulation." *Id.* at 573, 575–76. Petitioner's argument that any state enforcement of claims that parallel the FDCA are preempted also runs right into this Court's decisions in *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008), and *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996), both of which allowed enforcement of state-law claims that paralleled the FDCA. *See also Wyeth*, 555 U.S. at 575 ("if Congress thought state-law suits posed an obstacle to its objectives, it surely would have enacted an express pre-emption provision at some point during the FDCA's 70-year history").

When Congress amended the FDCA in 1962 to require the FDA to ensure that "new drugs" are safe and effective before approval, it expressly saved state-law claims from preemption: "Nothing in the amendments ... shall be construed as invalidating any provision of State law which would be valid in the absence of such amendments unless there is a direct and positive conflict between such amendments and such provision of State law." Drug Efficacy Amendment of 1962, Pub. L. No. 87-781, § 202, 76 Stat. 780, 793; C.A. App. 3845. Before the 1962 amendments, states had enacted statutes

parallel to the FDCA. *See McDermott v. Wisconsin*, 228 U.S. 115, 133 (1913) (recognizing that state legislatures have the "authority to make regulations consistent with the Federal law for the further protection of [their] citizens against impure and misbranded food and drugs"). And the savings clause in the 1962 amendments expressly preserved state authority to regulate health and safety of "new drugs." *Compare* Drug Efficacy Amendment of 1962, Pub. L. No. 87-781, § 202, 76 Stat. at 793 (no preemption absent "direct and positive conflict"), *with Cal. Fed. Sav. & Loan Ass'n v. Guerra*, 479 U.S. 272, 283 n.12 (1987) (explaining anti-preemption thrust of phrase "direct and positive conflict").

Petitioner asks the Court to treat Allergan's state-law claim as an attempt to enforce the FDCA. Pet. 23 n.9. And because 21 U.S.C. § 337(a) precludes private plaintiffs from directly enforcing the FDCA, petitioner claims that Allergan's state-law claim is effectively preempted by section 337. Petitioner is wrong.

The California Supreme Court in *Farm Raised Salmon Cases*, 42 Cal. 4th 1077 (2008), rejected the identical argument, which improperly conflates "efforts to enforce federal law with efforts based on state law." *Id*. at 1098. "That the Sherman Law imposes obligations identical to those imposed by the FDCA … does not substantively transform [the] action into one seeking to enforce federal law." *Id.* at 1095. Indeed, "the [FDCA], by its very terms, only implicates efforts to enforce *federal* law. What [it] does *not* do is limit, prohibit, or affect private claims predicated on *state* laws." *Id.* at 1095–96.

Petitioner gives *Farm Raised Salmon* the back of the hand, arguing only that the California Supreme

Court "effectively denied the existence of § 337(a) preemption." Pet. 28. But petitioner fails to recognize the fundamental and meaningful difference between a claim based on the FDCA and a claim based on a parallel state law.

Section 337 provides that, in general, "proceedings for the enforcement, or to restrain violations, of [the FDCA] shall be by and in the name of the United States." 21 U.S.C. § 337(a). As the FDA recognized when it promulgated regulations to implement a later amendment to this provision, section 337 "applies only to proceedings to enforce the [FDCA]." State Enforcement Provisions of the NLEA of 1990, 58 Fed. Reg. 2457, 2458 (Jan. 6, 1993). It "does not prohibit a State from enforcing an identical State law." *Ibid.*

At this Court's invitation, the Solicitor General confirmed the government's agreement with the preemption analysis in *Farm Raised Salmon*: "Although [the FDCA] precludes private actions to enforce the FDCA itself, [it] does not prohibit private actions to enforce parallel state requirements." Brief for the United States as *Amicus Curiae* in Opposition to Certiorari, *Albertson's, Inc. v. Kanter*, 555 U.S. 1097 (2009) (No. 07-1327), 2008 WL 5151069, at *8. This is because "[a]ctions to enforce state laws that impose requirements identical to those under the FDCA are not actions to enforce the FDCA itself." *Ibid.* And, as here, "[a]lthough [the] requirement" in the California Health and Safety Code "mirrors the FDCA's requirement," "respondents can prove that petitioners violated [California law] without even referring to the FDCA." *Ibid.*

Accordingly, because Allergan does not attempt to enforce federal law, and the state law Allergan

invokes in no way conflicts with federal law, the courts below correctly held that Allergan's claim is not preempted.

II. THERE IS NO CONFLICT OF DECISION

Athena does not cite a single appellate decision that conflicts with the Federal Circuit's determination that Allergan's state-law claims are not preempted.

1. The three opinions cited by Athena as supposedly conflicting (Pet. 20–22) each involve an attempt to privately enforce *federal* law, and two of them do not even involve preemption. There is no conflict in the lower courts warranting this Court's review.

Athena's first case, *PDK Labs, Inc. v. Friedlander*, 103 F.3d 1105 (2d Cir. 1997), is not even a preemption case. In fact, the word "preemption" does not appear in the opinion at all. Rather, *PDK* held that the plaintiff lacked standing to sue under the Lanham Act without "a commercial interest to be protected" because he did not sell the same product as the defendant. *Id.* at 1111–12. In dictum, the court opined that the plaintiff's "true goal" was to "use the Lanham Act as a vehicle by which to enforce the FDCA." *Id.* at 1113 (quotation omitted). *PDK* is therefore inapposite. *See* Brief for the United States as *Amicus Curiae* in Opposition to Certiorari, *Albertson's, Inc. v. Kanter*, 555 U.S. 1097 (2009) (No. 07-1327), 2008 WL 5151069, at *20 (*PDK* held that "the *FDCA* does not create a *federal* private right of action" but did not address "the distinct question at issue here—whether the FDCA preempts private actions under *state law* to enforce state requirements that are identical to federal requirements").

Athena's second case, *PhotoMedex, Inc. v. Irwin*, 601 F.3d 919 (9th Cir. 2010), fares no better. Like *PDK*, *PhotoMedex* concerns the Lanham Act, not federal preemption. The case addressed whether a medical device manufacturer barred from bringing a claim under the FDCA (21 U.S.C. § 337(a)), may nevertheless maintain a suit under the Lanham Act based on a claim that its competitor violated the FDCA by misrepresenting that a product had FDA approval. 601 F.3d. at 922. It is therefore a case about the interplay of two federal statutes, not preemption of a state-law claim, "[s]o the state-federal balance does not frame the inquiry." *POM Wonderful LLC v. Coca-Cola Co.*, 134 S. Ct. 2228, 2236 (2014) (recognizing the distinction between preemption and preclusion cases, including that in preclusion cases like *PhotoMedex* and *PDK*, the "'presumption against pre-emption' has no force") (citation omitted). Moreover, *PhotoMedex* is no longer good law after this Court's decision last Term in *POM Wonderful*, 134 S. Ct. at 2241.

Athena's third and final case is an unpublished disposition from the Sixth Circuit, *Loreto v. Proctor & Gamble Co.*, 515 F. App'x 576 (6th Cir. 2013), which involved a claim under the New Jersey Consumer Fraud Act predicated expressly on the FDCA's labeling requirements. The court held that this claim was preempted because the "theory of liability depend[ed] entirely upon an FDCA violation." *Id.* at 579. Indeed, "the *only* reason [defendant's] products were allegedly 'illegal' was because they failed to comply with FDCA labeling requirements." *Ibid.* In contrast, Allergan's claim depends entirely on state law. Athena's products are illegal because they fail to comply with various provisions of the California Health and Safety Code.

Several courts have distinguished *Loreto* on these grounds. *See*, *e.g.*, *Bruton v. Gerber Prods. Co.*, 961 F. Supp. 2d 1062, 1084 n.11 (N.D. Cal. 2013); *Gustavson v. Wrigley Sales Co.*, 961 F. Supp. 2d 1100, 1119 n.3 (N.D. Cal. 2013).[2]

In short, petitioner has not identified a single case holding that state-law causes of action like Allergan's are federally preempted. There is no division of authority.

Petitioner argues that its Lanham Act cases are nevertheless relevant because the state versus federal nature of the predicate violation is a "distinction without a difference." Pet. 23 n.9. Petitioner thus argues, in effect, that section 337 occupies the field and that only the United States can bring any claim regarding drug safety. But there is no support for that argument. Section 337 does not preempt state-law claims in the abstract, just

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[2] Like *Loreto*, *Goldsmith v. Allergan, Inc.*, 2011 WL 147714 (C.D. Cal. Jan. 13, 2011), involved a UCL claim undisputedly predicated on an FDCA violation, not on a violation of the California Health and Safety Code, and which was therefore held preempted by 21 U.S.C. § 337(a). The other district court cases Athena cites are also inapplicable. *Sadler v. Advanced Bionics, Inc.*, 929 F. Supp. 2d 670 (W.D. Ky. 2013) (addressing express preemption under the Medical Device Amendments, and not addressing a state law parallel to FDCA); *Purchase v. Advanced Bionics, LLC*, 896 F. Supp. 2d 694 (W.D. Tenn. 2011) (same); *Reeves v. PharmaJet, Inc.*, 846 F. Supp. 2d 791 (N.D. Ohio 2012) (addressing preemption of a state law claim undisputedly predicated on an FDCA violation, not on a violation of a state parallel statute); *Autin v. Solvay Pharm., Inc.*, 2006 WL 889423 (W.D. Tenn. Mar. 31, 2006) (same); *Braintree Labs., Inc. v. Nephro-Tech, Inc.*, 1997 WL 94237 (D. Kan. Feb. 26, 1997) (addressing preclusion of claim to enforce FDCA, not preemption, and not a state law parallel to FDCA).

because they parallel, complement, or incorporate by reference the FDCA. *Wyeth*, 555 U.S. at 578–79; *cf. Riegel*, 552 U.S. at 330; *Lohr*, 518 U.S. at 496–97.

In our federal system, state laws have independent existence and force unless they have been displaced, expressly or impliedly, by federal law. *Lohr*, 518 U.S. at 485 ("because the States are independent sovereigns in our federal system, we have long presumed that Congress does not cavalierly pre-empt state-law causes of action"). This Court's precedents confirm that there is no field preemption in this area, and the FDCA's prescription drug provisions (unlike the medical device provisions) include no express preemption provision. *Wyeth*, 555 U.S. at 574 ("despite its 1976 enactment of an express pre-emption provision for medical devices … Congress has not enacted such a provision for prescription drugs"). Thus, a parallel state-law claim is preempted only if it directly conflicts with the FDCA, but there is no such conflict here.

2. Contrary to petitioner's contention (Pet. 23–32), there is no tension between *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001), and the decision below. Indeed, *Buckman* is entirely inapposite, and thus any "confusion" that might exist in the lower courts regarding the outer reaches of *Buckman*-type preemption could not be resolved in this case.

a. The plaintiffs in *Buckman* alleged that the defendant defrauded the FDA in order to get bone screws on the market. "Had the representations not been made," the plaintiffs argued, "the FDA would not have approved the devices, and plaintiffs would not have been injured." 531 U.S. at 343. This Court held that the claim was preempted by 21 U.S.C.

§ 337(a), which, as described above, provides that *only* the FDA may enforce certain provisions of the FDCA.

The Court's reasoning was essentially two-fold. Unlike the regulation of "health and safety," policing fraud against a federal agency is "hardly a field which the States have traditionally occupied," and therefore the presumption against preemption did not apply. 531 U.S. at 347–48. And because the claim in *Buckman* was premised wholly on dealing with the federal agency, the claim directly conflicted with the FDA's duty to police fraud. *Id.* at 352–53.

The Court in *Buckman* expressly distinguished "fraud on the agency" from claims (like those presented here) involving matters of health and safety. 531 U.S. at 348 ("in contrast to situations implicating 'federalism concerns and the historic primacy of state regulation of matters of health and safety,' no presumption against pre-emption obtains in this case") (citation omitted). As this Court explained in *Wyeth*, *Buckman* "involved state-law fraud-on-the-agency claims, and the Court distinguished state regulation of health and safety as matters to which the presumption does apply." *Wyeth*, 555 U.S. at 565 n.3; *cf. Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 449 (2005) ("In areas of traditional state regulation, we assume that a federal statute has not supplanted state law unless Congress has made such an intention 'clear and manifest'") (citation omitted).

The Court further stated that although "any violation of the FDCA" will not "support a state-law claim," "certain state-law causes of action that parallel federal safety requirements" (like California's Health and Safety Code) are not

preempted. *Buckman*, 531 U.S. at 353; *see also Chamber of Commerce of the U.S. v. Whiting*, 131 S. Ct. 1968, 1981, 1983 (2011) (distinguishing state law in *Buckman* from state law that "closely track[ed]" federal law "in all material respects" and only required the court to "consider … the federal government's determination").

Allergan's California unfair competition claim is predicated expressly on a California Health and Safety Code violation (C.A. App. 375–77), which clearly implicates matters of health and safety. Under both California and federal law, unapproved externally applied hair growth drugs are *by definition* unsafe and ineffective. 54 Fed. Reg. 28,772 ("final rule establishing that any over-the-counter (OTC) hair grower … drug product for external use is not generally recognized as safe and effective and is misbranded"); Cal. Health & Safety Code § 110110(a) (adopting same rule). Because Athena was undisputedly selling such a product *without* regulatory approval—from the California Department of Health Services, the FDA, or any other agency—Allergan's claim necessarily involved a product that was unsafe.

The claim in *Buckman* was preempted because it existed "solely by virtue of the FDCA disclosure requirements," and any attempt to enforce those requirements would "exert an extraneous pull on" the FDA. *Buckman*, 531 U.S. at 353. The FDCA "empower[ed] the FDA to punish and deter fraud against the [FDA]," but the state-law claim would have necessarily resulted in "additional burdens" on the FDA because it would have caused applicants to "deluge" the FDA with additional information. *Id.* at 348, 351.

By contrast, this Court has upheld state-law claims that incorporate, parallel, or complement federal law. *See Wyeth*, 555 U.S. at 578; *cf. Riegel*, 552 U.S. at 312; *Bates*, 544 U.S. at 453–54; *Lohr*, 518 U.S. at 495. The FDA cannot monitor every unapproved and unlawful drug. *See Wyeth*, 555 U.S. at 578 ("The FDA has limited resources to monitor the 11,000 drugs on the market"). And claims enforcing parallel state laws like California's Health and Safety Code complement FDA enforcement and fill in the gaps where the FDA is unable to reach. *POM Wonderful*, 134 S. Ct. at 2238 ("The FDA … does not have the same perspective or expertise in assessing market dynamics that day-to-day competitors possess" such as an "awareness of unfair competition practices [that is] more immediate and accurate than that of agency rulemakers and regulators").

b. It is not true, as petitioner posits, that the federal regulatory scheme is "a critical element" of Allergan's claim, such that Allergan's claim "could not exist" without it. Pet. i, 23 n.9. This Court's preemption decisions teach that the FDCA does not preempt a state-law claim for violating a state-law duty that parallels a federal duty. Thus, even if petitioner's description of the holding in *Buckman* were accurate, it would not affect this case.

As described above, Allergan sued *only* under state law, and Allergan's unfair competition claim asserts that petitioner is liable for "marketing, selling, and distributing [its] hair and/or eyelash growth products without an approved … new drug application on file with the FDA *or* the California Department of Health Services." C.A. App. 375–77 (emphasis added). Indeed, although California makes it lawful to sell a new drug if a new drug

application has been approved under section 505 of the FDCA (*see* Cal. Health & Safety Code § 111550(a)), it *also* makes the sale of a new drug lawful if the California Department of Health Services has approved a new drug application (*id.* § 111550(b)). In other words, what makes petitioner's conduct illegal is its failure to obtain *any* regulatory approval, not simply that it did not obtain approval from the FDA.

Allergan's claim would therefore exist, and the outcome in this case would be the same, with or without the existence of the federal FDCA and its regulations.

c. Athena's assertion that there is no mechanism for filing a new drug application in California (Pet. 14 n.6) is incorrect. Sections 111550 and 111555 of the California Health and Safety Code describe in detail the process for submitting such applications. Cal. Health & Safety Code § 111550(b) ("Any person who files a new drug or device application with the department shall submit, as part of the application, all of the following information" and listing several criteria). Athena's own purported expert admitted that the California Department of Health Services has accepted new drug applications. C.A. App. 2208.

Petitioner also suggests throughout its petition that the FDA approved the sale of RevitaLash through inaction. *E.g.*, Pet. i, 5, 10, 17, 34 ("FDA regards RevitaLash as a lawful cosmetic"). That is completely false. The FDA has expressed no opinion on RevitaLash, though it has seized millions of dollars' worth of virtually identical eyelash growth drugs sold illegally over the counter. C.A. App. 1033–38. The FDA has also expressed its "concern regarding the potential safety risks" the "several

other eyelash products … on the market" "pose to the American public." *Id.* at 2833. The fact that petitioner has managed to stay one step ahead of the law as it has continued to change its formula cannot insulate it from unfair competition challenges.[3]

* * *

Petitioner contends throughout its petition that section 337 "squarely preempts 'lack-of-FDA-approval' claims." *E.g.*, Pet. 3, 20, 22–23, 26. But petitioner is attacking a case that Allergan did not bring. Allergan's claim is not predicated on alleged violations of the FDCA, or on petitioner's failure to obtain FDA approval. The claim exists entirely independently of federal law, and because Allergan's state-law claim is parallel to and does not in any way conflict with federal law, it is not preempted under *Buckman*. Thus, the question that petitioner asks this Court to decide is not actually presented in this case, and this Court should therefore deny review.

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[3] Petitioner also argues "there is a deep and longstanding division about the proper test for implied preemption under § 337(a)." Pet. 23. But not a single case cited in the petition holds that a claim like Allergan's is preempted. *See Lofton v. McNeil Consumer & Specialty Pharm.*, 672 F.3d 372, 376–77 (5th Cir. 2012) (holding state-law claim preempted because "[a]s in *Buckman*, the plaintiffs must show fraud-on-the-FDA for their claims to survive"); *Sprint Fidelis Leads Prods. Liab. Litig.*, 623 F.3d 1200, 1205–08 (8th Cir. 2010) (holding claim premised solely on Medical Device Amendments preempted, and not addressing a state-law claim based on a state statute that paralleled the FDCA); *Nathan Kimmel, Inc. v. DowElanco*, 275 F.3d 1199, 1208 (9th Cir. 2002) (finding state-mandated labeling requirement preempted by the Federal Insecticide, Fungicide, and Rodenticide Act, not the FDCA). These decisions are entirely consistent with the court of appeals' decision below.

III. THIS CASE PRESENTS NO ISSUES OF NATIONAL IMPORTANCE WARRANTING THIS COURT'S REVIEW

Petitioner claims that the decision below will threaten "the uniformity and consistency of the FDCA regime" by inviting a "wave" of "usurpative" "lawyer-driven class actions," which will "clog the courts, undermine FDA's policy judgments, and perhaps even endanger lives." Pet. 33–38. Petitioner is wrong.

At bottom, petitioner simply disagrees with this Court's preemption jurisprudence. The Court has made clear, time and again, that *some* state-law claims involving FDA-regulated products are not preempted. *Wyeth*, 555 U.S. at 578–79, 581; *Riegel*, 552 U.S. at 330; *Lohr*, 518 U.S. at 496–97. The necessary consequence is that such claims can be brought, and some will succeed. This is such a case.

Petitioner does not dispute in this Court that RevitaLash is a drug. Petitioner does not dispute in this Court that its sales of RevitaLash were in violation of California law. Petitioner does not dispute in this Court that this violation is redressable under the UCL. And petitioner does not dispute in this Court that a California-only injunction is an appropriate remedy for petitioner's violations of California law.

California had the authority to regulate snake oil peddlers before the FDCA was enacted, and it retains that authority to this day. Nothing in section 337 or this Court's preemption jurisprudence precludes California from forbidding the sale of unapproved drug products. Petitioner's rash invocation of hypothetical and inapposite lawsuits regarding "off-label" promotion of drugs (Pet. 36) and

"class actions against food manufacturers" (*id.* at 37)—situations not presented here—is simply an acknowledgment that this case itself is unremarkable, and unworthy of this Court's review.

Petitioner knows all this, just as it knows this case does not warrant plenary review. Petitioner was really playing for a "hold" in light of the CVSG order in *Medtronic, Inc. v. Stengel*, No. 12-1351. *See* Pet. 4 n.1. But the Court denied certiorari in that case on June 23, 2014; it should also deny certiorari here.

CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted.

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