No. 13-1379

# In the Supreme Court of the United States

ATHENA COSMETICS, INC., PETITIONER

*v.*

ALLERGAN, INC., ET AL.

*ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT*

**BRIEF FOR THE UNITED STATES AS AMICUS CURIAE**

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## QUESTION PRESENTED

Whether the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 301 *et seq.*, impliedly preempts a private suit under California law to enjoin the intrastate distribution of a new drug that has not been approved by the Food and Drug Administration or by the California Department of Health Services.

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## INTEREST OF THE UNITED STATES

This brief is submitted in response to the Court's order inviting the Solicitor General to express the views of the United States. In the view of the United States, the petition for a writ of certiorari should be denied.

## STATEMENT

1. a. The Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. 301 *et seq.*, authorizes the Food and Drug Administration (FDA) to regulate, *inter alia*, drugs and cosmetics. See, *e.g.*, 21 U.S.C. 351-360b (drugs), 361-363 (cosmetics). Whether a product is a "drug" or "cosmetic" turns on the product's intended use. A product is a drug if, *inter alia*, it is "intended to affect the structure or any function of the body of man or other animals," or if it is "intended for use in the diagnosis, cure, mitigation, treatment, or

prevention of disease in man or other animals." 21 U.S.C. 321(g)(1)(B) and (C). A product is a cosmetic if, *inter alia*, it is "intended to be * * * applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance." 21 U.S.C. 321(i). A product may be both a drug and a cosmetic (*e.g.*, anti-dandruff shampoo and antiperspirant deodorants).

The FDCA prohibits introducing an unapproved new drug into interstate commerce. 21 U.S.C. 331(d), 355. A drug is a "new drug" if, *inter alia*, it is "not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested" in its labeling. 21 U.S.C. 321(p)(1). In contrast to drugs, cosmetics may be marketed without FDA approval.

The modern federal regime for pre-market approval of new drugs dates from the Drug Amendments of 1962 (1962 Amendments) to the FDCA. Pub. L. No. 87-781, 76 Stat. 780. The manufacturer has the burden of proving that a new drug is safe and effective for its intended use, in order to obtain approval. See *Wyeth* v. *Levine*, 555 U.S. 555, 567 (2009). A manufacturer that fails to comply with the new-drug approval requirement may be subject to criminal penalties and injunctive relief. 21 U.S.C. 331(d), 332, 333. The 1962 Amendments also provide that "[n]othing 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." 1962 Amendments, § 202, 76 Stat. 793.

FDA has determined by regulation that "[d]rug products containing active ingredients offered over-the-counter (OTC) for external use as hair growers or for hair loss prevention" are "new drug[s]" requiring pre-market approval under the FDCA. 21 C.F.R. 310.527(b); see 21 C.F.R. 310.527(a) ("Based on evidence currently available, all labeling claims for OTC hair grower and hair loss prevention drug products for external use are * * * false, misleading, or unsupported by scientific data," and such products "cannot be considered generally recognized as safe and effective for [their] intended use.").

b. California regulates drugs and cosmetics under the Sherman Food, Drug, and Cosmetic Law (Sherman Law), Cal. Health & Safety Code §§ 109875 *et seq.* (West 2012). The Sherman Law provides that "[n]o person shall sell, deliver, or give away any new drug" that has not been approved by FDA or by the State of California. *Id.* § 111550(a)-(b). The Sherman Law incorporates "[a]ll regulations relating to * * * new drug applications * * * adopted pursuant to Section 505" of the FDCA, 21 U.S.C. 355, Sherman Law § 110110(a) (West 2012), and its definitions of "cosmetic," "drug," and "new drug" parallel those in the FDCA. Cf. Sherman Law §§ 109900 (cosmetic), 109925(c) (drug), 109980 (new drug). California's new-drug pre-market approval requirements are, therefore, substantively identical to the requirements of the FDCA.

c. California's Unfair Competition Law (UCL) provides a private right of action against any person who engages in "unfair competition." Cal. Bus. &

Prof. Code § 17203 (West 2008). "Unfair competition" includes "any unlawful, unfair or fraudulent business act or practice." *Id.* § 17200. Any "person who has suffered injury in fact and has lost money or property as a result of the unfair competition" may sue under the UCL. *Id.* § 17204 (West 2008 & Supp. 2015). Only an injunction and restitution are available as relief. *Cel-Tech Commc'ns, Inc.* v. *Los Angeles Cellular Tel. Co.*, 973 P.2d 527, 539-540 (Cal. 1999).

2. Respondent holds an approved new-drug application for Latisse, a prescription drug used for the treatment of hypotrichosis (a condition affecting hair growth) of the eyelashes. Latisse contains bimatoprost, an analog of prostaglandin.

Petitioner manufactures and sells RevitaLash Advanced, which the certiorari petition describes as an eyelash "conditioner." Pet. 2. RevitaLash Advanced contains a prostaglandin analog. Pet. App. 64a. Petitioner previously sold similar products under the names RevitaLashMD, RevitaLash, and RevitaLash Enhanced. *Id.* at 61a-63a. Petitioner sold its products over-the-counter in stores and via the Internet.

Different generations of petitioner's product contained different prostaglandin analogs. Pet. App. 62a-64a. Like Latisse, RevitaLashMD and an early version of RevitaLash, contained bimatoprost. *Id.* at 61a. In November 2007, the United States seized an eyelash product containing bimatoprost manufactured by a different company. *Id.* at 62a; see Compl. in Rem for Forfeiture, *United States* v. *An Undetermined Quantity of * * * Age Intervention[] Eyelash*, Civ. No. 7-5388 JL (N.D. Cal. Oct. 22, 2007). In response to that enforcement action, petitioner removed bima-

toprost from its product. Pet. App. 62a; see also Compl. ¶ 45.

RevitaLash Enhanced, the immediate predecessor to petitioner's current product, contained isopropyl cloprostenate, another prostaglandin analog. Pet. App. 62a-63a. In April 2011, FDA issued a warning letter to another manufacturer of a product containing isopropyl cloprostenate that was promoted for eyelash growth, stating that the agency considered the product misbranded and an unapproved new drug. See Warning Letter from FDA to Lifetech Resources LLC (Apr. 18, 2011), http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2011/ucm251951.htm. Petitioner then discontinued RevitaLash Enhanced and introduced RevitaLash Advanced. Pet. App. 64a.

3. a. Respondent brought this action against petitioner and other manufacturers of similar products. As relevant here, respondent alleges that petitioner violated the Sherman Law by selling an unapproved new drug and thereby engaged in "unfair competition" in violation of the UCL.[1] Compl. ¶¶ 73-85. Respondent asserts that petitioner marketed RevitaLash[2] to consumers as a product that would grow eyelashes, making it a "drug" under the Sherman Law. *Id.* ¶¶ 75-84. Respondent alleges that, by selling a competing drug without requiring a prescription and without an approved new-drug application, petitioner caused

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[1] Respondent also asserted several patent claims, which were dismissed and are not at issue here. Pet. App. 4a-5a.

[2] The lower courts referred to the various iterations of petitioner's products collectively as "RevitaLash," and we adopt that convention.

respondent to lose sales and suffer other financial injuries. *Id.* ¶ 85.

b. Petitioner asked the district court to defer to FDA by staying or dismissing the suit under the doctrine of primary jurisdiction. See Pet. App. 77a-97a. The court rejected that request. *Id.* at 86a-95a. It reasoned that the proper classification of petitioner's product under state law required no scientific expertise because California law, incorporating FDA regulations, classified all hair growth drug products as "new drugs" requiring approval. *Id.* at 89a; see Sherman Law § 110110(a) (West 2012) (incorporating, *inter alia*, 21 C.F.R. 310.527(b)). The court also reasoned that its ultimate ruling would be fact-bound and limited to RevitaLash, and thus "unlikely to create uniformity in administration problems." Pet. App. 93a. And the court concluded that its adjudication of respondent's claims did not risk interference with any identifiable ongoing FDA administrative action. *Id.* at 92a-94a.

On the merits, the district court granted summary judgment for respondent on its UCL claim. Pet. App. 53a-76a. Noting that petitioner had not disputed that it intended prior versions of its product to grow eyelashes, the court concluded that RevitaLash Advanced was a new drug that required approval under California law based on, among other facts, petitioner's marketing claims about eyelash growth and petitioner's strategy of promoting its various formulations of RevitaLash through comparison of the product to Latisse. *Id.* at 71a-74a. The court entered a permanent injunction prohibiting the sale of RevitaLash products nationwide. *Id.* at 20a-45a.

Petitioner filed a post-judgment motion to dismiss respondent's claims as preempted. See Pet. App. 46a-52a; see also Answer ¶ 29. Petitioner contended that respondent was impermissibly seeking to enforce the FDCA itself, in contravention of 21 U.S.C. 337(a), which provides (with specified exceptions) that proceedings to enforce the FDCA or restrain violations of the Act "shall be by and in the name of the United States." Petitioner further argued that the district court's decision created an actual conflict with federal law.

The district court denied the motion. See Pet. App. 46a-52a. It concluded that petitioner's preemption argument "shadows or is identical to" its primary jurisdiction argument and that petitioner's motion "does not demonstrate clear error" as "no court has found [that] a UCL claim based on [the] California Health and Safety Code is preempted." *Id.* at 50a.

c. The court of appeals affirmed, holding that respondent's claim is not preempted. Pet. App. 1a-19a. The court rejected petitioner's argument that *Buckman Co.* v. *Plaintiff's Legal Committee*, 531 U.S. 341 (2001), governs this case, concluding that respondent's claim does not intrude upon FDA's discretionary authority to enforce the FDCA. Pet. App. 6a-10a. The court explained that the California Health and Safety Code "is not an obstacle to realizing federal objectives," but rather "parallel[s] the FDCA, such that the statutes have consistent goals." *Id.* at 9a. Moreover, *Buckman* involved "a claim based on fraud before the FDA" that arose "solely by virtue of the FDCA disclosure requirements," *id.* at 10a (quoting *Buckman*, 531 U.S. at 352-353), and fraud on the FDA, the court noted, is "hardly a field which the States have tradi-

tionally occupied," *ibid.* (quoting *Buckman*, 531 U.S. at 347). The claim in *Buckman* was thus "unlike [respondent's] claim," which involved state regulation of health and safety, areas of state "historic primacy." Pet App. 9a (quoting *Buckman*, 531 U.S. at 348).

The court of appeals also agreed with the district court that RevitaLash qualified as a "drug" under California law. Pet. App. 10a-14a. Petitioner's marketing claims, the court noted, "invariably link eyelash appearance to physical changes caused by the products at issue." *Id.* at 13a.

The court of appeals concluded, however, that to subject petitioner to a nationwide injunction would be tantamount to permitting California "to stand in the shoes of the FDA to determine whether [petitioner's] sale of the products at issue amounts to the sale of an unapproved drug under the FDCA." Pet. App. 17a. The court therefore narrowed the injunction to regulate conduct occurring only in California. *Id.* at 14a-19a.

**DISCUSSION**

The court of appeals correctly held that the FDCA does not impliedly preempt this private civil action under California law to enforce state drug pre-market approval requirements that are substantively identical to those imposed by the FDCA. Respondent's claim creates no actual conflict with federal law, and *Buckman Co.* v. *Plaintiff's Legal Committee*, 531 U.S. 341 (2001), does not otherwise require preemption of the claim.

There is no split of authority on whether suits under state law to restrain the sale of unapproved drugs are preempted by the FDCA, and the results reached by lower courts in this general area are consistent

with one another and with this Court's precedents. Further review is therefore unwarranted.

**I. Respondent's Unfair Competition Claim Under State Law Is Not Impliedly Preempted By The FDCA**

This Court's FDCA preemption decisions, including *Buckman*, 531 U.S. at 353, establish that parallel state-law claims are not impliedly preempted unless they conflict with the FDA's administration of the FDCA. Petitioner concedes (Pet. 29-30, 33-38) that the FDCA leaves room for many private actions to enforce parallel requirements of state law, but it contends that the claims here are preempted for two principal reasons: first, because the FDA allegedly "regards RevitaLash as a lawful 'cosmetic,'" not a drug, in conflict with the decisions below, see Pet. 34; and second, because the claims here are akin to the fraud-on-the-FDA claim that *Buckman* held to be preempted, see Pet. 24-27, 32-34. Petitioner is wrong on both counts.

A. Respondent's UCL claim rests on the Sherman Law, which parallels the FDCA's prohibitions on marketing unapproved new drugs. The requirements under California law and the FDCA are substantively identical: both use the same definitions of "drug" and "new drug," see pp. 1-2, *supra*, and California directly incorporates the federal new-drug application regulations. Sherman Law § 110110(a) (West 2012).

Petitioner contends (Pet. 2), however, that, by treating RevitaLash as a drug under the Sherman Law, the court of appeals' decision is "directly contrary to FDA's position on the regulatory classification of cosmetic eyelash conditioners." To the contrary, the court of appeals' determination that RevitaLash is a

"drug" under the Sherman Law poses no conflict with federal law or with any decision of FDA.

Petitioner contends (Pet. 10-11) principally that the absence of FDA enforcement action in reaction to complaints about eyelash conditioners "strongly indicates" that FDA considers "products like RevitaLash" to be cosmetics, not drugs. No conflict with a supposed FDA position on RevitaLash can be inferred from the absence of FDA enforcement or other regulatory action against petitioner or its products. Such inaction does not equate to an affirmative FDA decision that RevitaLash is not a new drug. See pp. 4-5, *supra* (discussing measures taken by FDA against similar products).

Whether RevitaLash qualifies as a "drug" depends on its intended use. See Sherman Law § 109925(c). Here, the courts below found "no genuine dispute that [petitioner] objectively intends for the products at issue to be used to affect the structure of eyelashes," and that therefore RevitaLash is properly classified as a drug under the Sherman Law. Pet. App. 12a-14a; see also *id.* at 67a-76a. That conclusion is not in conflict with the FDCA, which, like the Sherman Law, classifies an article as a "drug" if it is intended to affect the structure or any function of the body. 21 U.S.C. 321(g)(1)(C); Sherman Law § 109925(c).

As respondent notes (Br. in Op. 20-21) and petitioner essentially concedes (Pet. 10-11), FDA has never approved RevitaLash to be marketed as a drug, nor has the agency taken any other affirmative step to authorize (or forbid) the sale of the product as a matter of federal law. Yet, unless a drug is generally recognized by qualified experts to be "safe and effective for use under the conditions prescribed,

recommended, or suggested in the labeling or advertising"—a standard that petitioner has never claimed it could satisfy—pre-market approval is required.[3] Sherman Law §§ 109980, 111550(a) (West 2012 & Supp. 2015).

Respondent's claim thus does not supplant any regulatory determination by FDA regarding the product's status as a cosmetic or a new drug. No conflict is presented between the federal and state standards in this regard or in the application of those standards to petitioner and RevitaLash.

B. In the absence of any direct conflict between federal and state law, petitioner invokes this Court's decision in *Buckman* to argue (Pet. 23-26, 35-37) that respondent's claim nonetheless is impliedly preempted. But unlike the fraud-on-the-FDA claim in *Buckman*, respondent's claim of unfair competition poses no "obstacle to the accomplishment and execution" of federal objectives under the FDCA. *PLIVA, Inc.* v. *Mensing,* 131 S. Ct. 2567, 2587 (2011). California may authorize courts to restrain the distribution, sale, and marketing of unapproved new drugs in California through respondent's private UCL suit.

1. In *Buckman*, the plaintiffs alleged injuries from medical devices that had been cleared for sale by FDA

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[3] The parties disagree (compare Br. in Opp. 9, 19-20, with Reply Br. 2-7) about whether, as a practical matter, petitioner could have satisfied its obligations under the Sherman Law by seeking approval for RevitaLash from the California Department of Health Services, rather than from FDA. See Sherman Law § 111550(b) (West 2012 & Supp. 2015) (permitting the manufacturer of a new drug to satisfy its duty to obtain approval through a state-run process). As the following discussion indicates, *infra* Part I.B., respondent's claim is not preempted even assuming that the California approval process is not practically available to petitioner.

through the efforts of the defendant, a consultant that assisted the device manufacturer in navigating the federal regulatory process. 531 U.S. at 343, 346. The defendant's efforts, the plaintiffs claimed, involved a fraud on FDA, and "[h]ad [those fraudulent] representations not been made, the FDA would not have [cleared] the devices, and plaintiffs would not have been injured." *Id.* at 343.

This Court held that plaintiffs' fraud-on-the-FDA claim was preempted, relying on several considerations. First, the putative state-law claims sought to police fraud on a federal agency by entities the agency itself regulated, a matter of an exclusively federal character over which the federal agency at issue—the FDA—possessed ample direct authority. *Buckman*, 531 U.S. at 347-350. Such state-law claims, the Court reasoned, "would exert an extraneous pull" (*id.* at 353) on the relationship between FDA and those it regulates. *Id.* at 350-351.

Additionally, the claims in *Buckman*, which were directed at a defendant that was not the manufacturer of the devices and therefore did not have a manufacturer's duty to warn purchasers of safety risks, did not "rely[] on traditional state tort law." 531 U.S. at 353. Rather, the plaintiffs relied on a theory that "exist[ed] solely by virtue of the FDCA," *ibid.*, based on duties that were wholly "dictated by [the FDCA's] provisions" and turned on "dealings with the FDA," *id.* at 347-348. And enforcement of the FDCA is vested exclusively in the United States. *Id.* at 349 n.4, 352 (citing 21 U.S.C. 337(a)).

The Court in *Buckman* further reasoned that allowing plaintiffs to pursue a "fraud-on-the-FDA" claim under state law could compromise FDA's "flexi-

bility" to pursue "difficult (and often competing) objectives" under the FDCA's medical device provisions. 531 U.S. at 349. In the Court's view, such claims would interfere with FDA's prerogative to decide for itself whether it had been defrauded and what sanction to impose; would make the abbreviated clearance process the defendant had invoked less attractive and efficient for applicants and the agency; and could deter off-label uses of devices. *Id.* at 348-351.

2. Petitioner argues (Pet. 12-13, 32-38) that implied preemption is appropriate here as it was in *Buckman* because FDA has exclusive authority to determine a product's regulatory classification and to enforce the FDCA. See also Pet. i (asserting that California's UCL and the Sherman Law allow courts to "step[] into FDA's shoes" to make "the regulatory determination [*i.e.*, that RevitaLash is a drug] that FDA had refused to make"). Petitioner maintains (Pet. 13) that implied preemption would promote "uniformity and consistency," and would ensure proper administration of the FDCA's "often-technical provisions." (brackets omitted).

This Court has concluded, however, that "Congress did not intend FDA oversight to be the exclusive means of ensuring drug safety and effectiveness," *Wyeth* v. *Levine*, 555 U.S. 555, 575 (2009), and that FDA has "traditionally regarded state law as a complementary form of drug regulation," *id.* at 578-579. Indeed, Congress specified, when enacting the modern drug pre-approval regime, that the FDCA does not "invalidat[e] 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."

1962 Amendments, § 202, 76 Stat. 793. As explained above, *supra* Part I.A, there is no such conflict here.

Respondent's state-law suit to enjoin the sale of an unapproved drug does not compromise FDA's objectives. While FDA is well-equipped to decide the adequacy of pre-market submissions actually filed with the agency, cf. *Buckman*, 531 U.S. at 349, 351, this Court has noted FDA's "limited resources to monitor" the thousands of drugs on the market after they have been approved, *Wyeth*, 555 U.S. at 578-579. The agency's capacity to police the vast marketplace of consumer products that have never been submitted to FDA for pre-market review is even more constrained. See FDA, *Guidance for FDA Staff and Industry: Marketed Unapproved Drugs—Compliance Policy Guide*, 3 (Sept. 19, 2011), http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM070290.pdf (estimating that thousands of unapproved drugs are marketed in the United States). Moreover, both the FDCA and California's Sherman Law make it the *manufacturer's* burden, not FDA's, to establish through a rigorous vetting process that any new drug is safe and effective for its intended use. See *Weinberger* v. *Hynson, Westcott & Dunning, Inc.*, 412 U.S. 609, 630 (1973).[4] Petitioner further fails to articulate why California's restraint on the distribution of unapproved drugs poses a "vastly greater threat to national uniformity," Pet. 34, than failure-to-warn litigation and other tradi-

[4] As RevitaLash has not received FDA approval for *any* purpose, there is no basis for petitioner's concern (Pet. 35-37) that respondent's UCL claim could raise policy questions regarding "off-label" use. Cf. *Buckman*, 531 U.S. at 350-351 & n.5.

tional state tort suits, which this Court has permitted to proceed. See, *e.g.*, *Wyeth*, 555 U.S. at 563-581.

There is also nothing about the statewide injunction in this case that dictates preemption. Where "Congress specifically preserve[s] authority for the States, it stands to reason that Congress did not intend to prevent the States from using appropriate tools to exercise that authority." *Chamber of Commerce* v. *Whiting*, 131 S. Ct. 1968, 1981 (2011) (plurality opinion); see *Medtronic* v. *Lohr*, 518 U.S. 470, 495 (1996); 518 U.S. 513 (O'Connor, J., concurring in part and dissenting in part).[5] Those tools have traditionally included injunctive relief.[6]

3. Petitioner also argues (Pet. 35) that, under *Buckman*, respondent's UCL claim should be preempted because it is based "*entirely* on a party's alleged failure to procure FDA pre-approval." See Pet. 21-22. Petitioner further contends (Pet. 26) that *Buckman* stands for the "broad proposition that the FDCA preempts a state tort-law claim based on failure to properly communicate with the FDA" (brackets, emphasis, and internal quotation marks omitted). The court of appeals correctly concluded, however, that respondent's claim relies on law within the States' traditional authority to regulate health and safety. Pet. App. 9a ("The fact that [the Sherman

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[5] The imposition of criminal sanctions, as distinguished from civil remedies, might alter the preemption calculus, but the California UCL does not authorize criminal penalties. See *Cel-Tech Commc'ns, Inc.* v. *Los Angeles Cellular Tel. Co.*, 973 P.2d 527, 539-540 (Cal. 1999).

[6] The FDCA itself provides for an injunction to restrain violations of the FDCA, including failure to comply with new-drug approval requirements. 21 U.S.C. 331, 332, 355.

Law] parallels certain FDCA provisions does not mean that it does not implicate an historic state power that may be vindicated under state law tort principles.").

Although lack of FDA approval is one element of respondent's claim, its suit does not turn on petitioner's actual "dealings with the FDA," as in *Buckman*, 531 U.S. at 347. Petitioner never submitted a marketing application to FDA, and FDA never approved petitioner's product for marketing. Thus, unlike in *Buckman*, respondent's suit does not require a court to evaluate the propriety of submissions to FDA that formed the basis for action by the agency, nor does it present a case where "disclosures to the FDA, although deemed appropriate by the Administration, will later be judged insufficient in state court." *Id.* at 351.

Whether false statements have been made to a federal agency, and what sanction to impose if they were, are matters to be decided by the federal government, the sovereign that established that administrative forum. Cf. *In re Loney*, 134 U.S. 372, 375-376 (1890) (States may not punish perjury that occurs in federal court). By contrast, this Court has sustained state laws that barred certain conduct in the State without a permit or approval by a federal agency, where the state law served legitimate state purposes and the federal statute did not reflect a congressional intent to preempt such state measures. See *California* v. *Zook*, 336 U.S. 725, 726-738 & n.1 (1949) (sustaining California statute making it criminal for a motor carrier to sell transportation without a permit from the Interstate Commerce Commission or the California Public Utilities Commission); *Asbell* v. *Kansas*, 209 U.S. 251, 258 (1908). See also *Arizona* v. *United States*, 132 S.

Ct. 2492, 2502-2503 (2012) (discussing *Zook*, *Loney*, and *Buckman*); *Gilbert* v. *Minnesota*, 254 U.S. 325, 331 (1920); *Fox* v. *Ohio*, 46 U.S. (5 How.) 410, 433-434 (1847).

Here, California law, like the FDCA, is designed to protect the public from the health risks of drugs that are not safe and effective. See Sherman Law § 109980 (defining "new drug," *inter alia*, as a drug "*not generally recognized*, among experts * * * as safe and effective for use under the conditions prescribed, recommended, or suggested" in its labeling or advertising) (emphasis added). By authorizing private suits to enjoin the intrastate distribution, sale, and marketing of an unapproved drug, California is acting within the State's historic purview to regulate health and safety, see *Wyeth*, 555 U.S. at 565 n.3; *Buckman*, 531 U.S. at 348, as well as to protect against unfair competition. And, as explained above (see Part I.B.2 *supra*), the FDCA preserves that role for the States where, as here, there is no conflict with federal law.

## II. Any Divisions Among The Lower Courts Regarding Implied Preemption Of Parallel State-Law Claims And Section 337(a) Do Not Warrant Review In This Case

The courts of appeals are not meaningfully divided on the standard for when the FDCA impliedly preempts parallel state-law claims, and any divergence in the lower courts' approach to Section 337(a) does not merit this Court's review in this case.

### A. The Cases Identified By Petitioner Do Not Conflict With The Federal Circuit's Decision In This Case

Petitioner contends that the decision below conflicts with decisions of other courts of appeals in *Loreto* v. *Procter & Gamble Co.*, 515 Fed. Appx. 576 (6th

Cir. 2013); *PDK Labs, Inc.* v. *Friedlander*, 103 F.3d 1105 (2d Cir. 1997) (*PDK Labs*); *PhotoMedex, Inc.* v. *Irwin*, 601 F.3d 919 (9th Cir. 2010); and *Perez* v. *Nidek Co.*, 711 F.3d 1109 (9th Cir. 2013). Those decisions do not present a clear split of authority warranting review.

Respondent's California UCL claim in this case is distinguishable from the claims in *PDK Labs* and *Loreto*, which were essentially efforts to enforce the FDCA itself, rather than parallel state law. In *PDK Labs*, the Second Circuit observed in passing, in what appears to be dictum, that the FDCA impliedly preempts a claim that a competitor had falsely represented that its products had "proper FDA approval." 103 F.3d at 1113. But the court affirmed the dismissal of the plaintiff's suit under the Lanham Act and Georgia fair trade practices law for lack of standing, not on the merits. *Id.* at 1111-1113.

In *Loreto*—an unpublished decision that would not in any event give rise to the sort of circuit conflict warranting this Court's review—the Sixth Circuit held that the FDCA impliedly preempted a state consumer protection claim based on the defendant's alleged failure to tell consumers that its products were "illegal." 515 Fed. Appx. at 579. The court held that that claim, while "formally asserted under state law," was "in substance one seeking to enforce the FDCA" because "the *only* reason [the] products were allegedly 'illegal' was because they failed to comply with FDCA labeling requirements." *Ibid.* The Sixth Circuit found no preemption of a second claim alleging false and misleading advertising regarding the effect of Vitamin C, which constituted the "type of conduct that would traditionally give rise to liability under state law." *Id.*

at 579-580 (quoting *Riley* v. *Cordis Corp.*, 625 F. Supp. 2d 769, 777 (D. Minn. 2009)).

In contrast to those cases, the court of appeals in this case found that the Sherman Law constitutes a parallel state-law basis for respondent's claim and fits "precisely" within the "historic primacy of state regulation of matters of health and safety." Pet. App. 9a (quoting *Buckman*, 531 U.S. at 348).

*PhotoMedex* and *Perez* are likewise inapt. In *PhotoMedex*, the Ninth Circuit held that a Lanham Act claim arising from a manufacturer's allegedly misleading statements about FDA's approval of its device was precluded. *PhotoMedex*, 601 F.3d at 927-931. But the court's decision in *PhotoMedex* was closely tied to its particular facts. The plaintiff sought "to prove that Defendants violated the FDCA" even though FDA "ultimately cleared" the product and "elected not to find any violation" of the FDCA, *id.* at 930. The Ninth Circuit concluded that "in the circumstances of this case," permitting a Lanham Act claim would implicate the same concerns about infringing upon FDA prerogatives that this Court had identified in *Buckman*. *Id.* at 924-928. Also, because *PhotoMedex* involved a claim under the Lanham Act, not state law, it would be premature for this Court to grant review on the basis of an asserted conflict with *PhotoMedex*. The Ninth Circuit should first have an opportunity to revisit that decision in light of this Court's decision in *POM Wonderful LLC* v. *Coca-Cola Co.*, 134 S. Ct. 2228 (2014), which addressed the relationship between the Lanham Act and the FDCA.

In *Perez*, the Ninth Circuit concluded that a state common-law claim alleging that the defendant manufacturers misled patients by failing to disclose that a

device was not FDA-approved for certain surgeries was impliedly preempted.[7] Nonetheless, as in *PhotoMedex*, it was important to the Ninth Circuit's decision that the FDA had affirmatively approved the device and ultimately approved the uses challenged by plaintiffs. The court in *Perez* found that FDA was aware of the defendant's off-label use, had actively taken "steps to halt abuses," and ultimately approved the device for the relevant procedures. 711 F.3d at 1112-1113, 1120. The court explained that while "some fraud and false advertising claims related to FDA status may go forward," Perez's suit impermissibly "rest[ed] solely on the non-disclosure to patients of facts tied to the scope of [pre-market] approval," under the FDCA. *Id.* at 1119. As explained above, petitioner has never sought or received FDA approval for RevitaLash.

**B. Lower Court Decisions Considering Section 337(a) Are Consistent With Each Other And With This Court's Precedents**

Petitioner separately contends (Pet. 23-32) that the lower courts are divided on the preemptive scope of Section 337(a). But the outcomes in the cases cited by

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[7] *Perez* first held that the plaintiff's claim was expressly preempted by the Medical Device Amendments to the FDCA (MDA), 21 U.S.C. 360k(a). See 711 F.3d at 1117-1119. Implied preemption was an alternative holding. *Id.* at 1119-1120. While suits predicated on state-law duties that parallel federal requirements may be permitted, the MDA expressly preempts state-law duties that are "different from, or in addition to" those applicable under the MDA. See 21 U.S.C. 360k(a)(1); see also *Caplinger* v. *Medtronic, Inc.*, No. 13-6061, 2015 WL 1786742 (10th Cir. Apr. 21, 2015) (finding Section 360k(a) expressly preempted plaintiff's medical-device state tort claims that were not parallel to MDA requirements).

petitioner are consistent with one another and with this Court's precedents.

When presented with state-law claims that parallel federal requirements and do not conflict with federal law, courts have held that the FDCA does *not* bar plaintiffs' suits. See *Stengel* v. *Medtronic, Inc.*, 704 F.3d 1224, 1226, 1233-1234 (9th Cir. 2013) (en banc), cert. denied, 134 S. Ct. 2839 (2014); U.S. Amicus Br. at 19-20, *Stengel*, *supra*, (No. 12-1351) (explaining that the *Stengel* plaintiffs' claim was best understood as "mirror[ing] the failure-to-warn claim * * * that th[e] Court held was not impliedly preempted in *Wyeth*); *Loreto*, 515 Fed. Appx. at 579-580 (permitting state law claim that paralleled FDA regulations); *Bass* v. *Stryker Corp.*, 669 F.3d 501, 515 (5th Cir. 2012) (same); see also *Farm Raised Salmon Cases*, 175 P.3d 1170, 1196 (Cal. 2008) ("No court * * * has ever held that states may not provide a private remedy for the violation of state laws imposing requirements identical to those imposed by federal law."), cert. denied *sub nom. Albertson's, Inc.* v. *Kanter*, 555 U.S. 1097 (2009); U.S. Amicus Br. at 19-20, *Albertson*'s *Inc.*, *supra* (No. 07-1327) (explaining that the plaintiffs' claim involved "state requirements that are identical to federal requirements" and "do[] not pose the concerns about skewing the FDA's approval process on which th[e] Court relied in *Buckman*"). These results are consistent with this Court's decision in *Wyeth*.

In cases involving claims of fraud against a federal agency, courts of appeals have concluded that federal law *does* bar plaintiffs' suits. See *Lofton* v. *McNeil Consumer & Specialty Pharm.*, 672 F.3d 372, 381 (5th Cir. 2012) (state-law claim of fraud on FDA preempt-

ed by the FDCA); *Nathan Kimmel, Inc.* v. *DowElanco*, 275 F.3d 1199, 1208 (9th Cir. 2002) (state-law claim of fraud on Environmental Protection Agency preempted by the Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. 136-136y). These outcomes are faithful to this Court's decision in *Buckman*.

Finally, in cases involving claims that seek to enforce the FDCA itself, courts have concluded that the FDCA *does* bar plaintiffs' suits. See *Loreto*, 515 Fed. Appx. at 579 (FDCA preempted claim where "the *only* reason" a device manufacturer should be held liable was that it "failed to comply with FDCA labeling requirements"); *In re: Medtronic, Inc., Sprint Fidelis Leads Prods. Liab. Litig.*, 623 F.3d 1200, 1205 (8th Cir. 2010) (claims that defendant "failed to provide the FDA with sufficient information and did not timely file adverse event reports, as required by federal regulations," were "simply an attempt by private parties to enforce the [Medical Device Amendments to the FDCA]"); U.S. Amicus Br. at 23, *Stengel*, *supra* (No. 12-1351) (explaining that *Sprint Fidelis* plaintiff's theory "apparently was that they were entitled to recover based simply on the manufacturer's alleged violation of federal requirements"). These results are also in accord with this Court's decision in *Buckman*. In short, the differences in the outcomes of the cases cited by petitioner reflect differences in the underlying claims, not a concrete conflict regarding the appropriate preemption framework that would warrant review by this Court.

## CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted.

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