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September 2, 2015

The Honorable Tani Cantil-Sakauye, Chief Justice
and Associate Justices
Supreme Court of California
350 McAllister Street
San Francisco, CA 94102

Re: Amicus Letter in Support of Petition for Review
Eckler v. Neutrogena Corp.; *Engel v. Neutrogena Corporation*
Second Appellate District, Division Seven, Nos. B23691; B253899
Supreme Court of California Case No. S228429

Dear Chief Justice Cantil-Sakauye and Associate Justices:

Pursuant to Rule 8.500(g) of the California Rules of Court, Public Citizen submits this amicus letter urging the Court to grant Steve Engel's pending petition for review in the above-captioned case.

Public Citizen is a national non-profit organization that engages in research, education, lobbying, and litigation on a wide range of public-health and consumer-safety issues. Since its founding in 1971, Public Citizen has assessed the safety and efficacy of drugs, provided information on drug safety to the public, and petitioned the Food and Drug Administration (FDA) to act to reduce safety risks. Public Citizen has a longstanding interest in fighting exaggerated claims of federal preemption of state health, safety, and consumer laws, and its lawyers have represented parties in many cases presenting the question whether the Food, Drug, and Cosmetic Act (FDCA) preempts state-law claims, including *Warner-Lambert Co., LLC v. Kent*, 552 U.S. 440 (2008), *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008), and *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996).

Public Citizen urges the Court to accept review of this case because the court of appeal's decision, which misunderstands the scope of preemption under the FDCA, is inconsistent with a recent Ninth Circuit decision concerning FDCA preemption, and, if left in place, would have wide-ranging implications for Californians' ability to hold accountable drug manufacturers who place false or misleading information on the labels

of their over-the-counter drugs. Review is accordingly needed to secure uniformity and settle an important question of law. *See* Rule 8.500(a)(1).

I. The Decision Below Misunderstands the Scope of FDCA Preemption.

This case concerns claims that Neutrogena violated California consumer-protection laws by falsely labeling its sunscreen products "waterproof," "sweatproof," and "sunblock," when they were not impervious to water and sweat and did not block the sun's rays.[1] The court of appeal held that because the FDA did not promulgate a final rule declaring use of the terms "waterproof," "sweatproof," and "sunblock" on sunscreen false or misleading until June 2011, and because that rule did not require compliance with its provisions until December 2012, Mr. Engel's claims arising before December 2012 were preempted under 21 U.S.C. § 379r(a)(2), which preempts state requirements that are "different from or in addition to, or that [are] otherwise not identical with" federal law. According to the court of appeal, the product labels at issue were "in compliance with federal law" until the effective date of the final rule, and Mr. Engel's claims that the labels violated California law before that date therefore seek to enforce a state requirement that is different from the federal requirements. Petition Exhibit A (Pet. Ex.) 28.

The court of appeal's decision is wrong. Sunscreen products are regulated as over-the-counter drugs, and manufacturers of nonprescription drugs are required to comply both with federal regulations pertaining specifically to their products and with federal statutory and regulatory provisions that apply to all drugs. As relevant here, the FDCA prohibits the "misbranding of any … drug," 21 U.S.C. § 331(a), and specifies that a drug is misbranded if "its labeling is false or misleading in any particular." *Id.* at § 352(a). Accordingly, even before the FDA issued the 2011 rule, the FDCA forbade sunscreen manufacturers from placing false or misleading information on their products' labeling.

In fact, here, when issuing the final rule, the FDA stated that its determination that use of those terms render sunscreen misbranded was not new. *See* FDA, Labeling and Effectiveness Testing; Sunscreen Drug Products for Over-the-Counter Human Use, 76 Fed. Reg. 35620, 35643 (June 17, 2011) ("We agree with the submissions that argue that 'sunblock,' 'waterproof," and 'sweatproof' claims are false or misleading, as we have stated in previous sunscreen rulemakings"); *id.* ("We have previously identified these claims as ones that would render a product misbranded . . ..").

Because the FDCA prohibits false or misleading labeling on drugs, regardless of whether the FDA has promulgated regulations addressing a specific term or product in particular, Mr. Engel's claims based on the premise that the sunscreen labels were false

[1]Plaintiff/Appellant Kay Eckler also brought some additional claims that are not at issue in Mr. Engel's petition.

or misleading do not seek to enforce requirements "different from or in addition to, or . . . otherwise not identical with" federal requirements. 21 U.S.C. § 379r(a)(2). To the contrary, state-law claims based on misleading labeling seek a state-law remedy for requirements that "'parallel,' rather than add to, federal requirements," *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 330 (2008) (quoting *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 495 (1996)), and therefore are not preempted. *See Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 447 (2005) (in considering a preemption provision that preempted state requirements "in addition to, or different from" federal requirements, explaining that a state-law labeling requirement is not preempted "if it is equivalent to, and fully consistent with, [the federal statute's] misbranding provisions"); *Lohr*, 518 U.S. at 45 (holding that a preemption provision that preempted state requirements "different from, or in addition to" federal requirements did not deny states the right to provide a "remedy for violations of common-law duties when those duties parallel federal requirements"); *see also*, *e.g.*, *Langan v. Johnson & Johnson Consumer Cos., Inc.*, No. 3:13-CV-01470 (JAM), 2015 WL 1476400, at *4-5 (D. Conn. Mar. 31, 2015) (rejecting argument that claims "premised on the theory that defendant's sunscreen labels are false and misleading" are preempted by 21 U.S.C. § 379r(a), because the "FDCA itself prohibits 'labeling [that] is false or misleading'" and the claims therefore "target conduct that is already prohibited under federal law").

In short, although the court of appeal is correct that "no prohibition of the Labeling Terms ever appeared as part of the Code of Federal Regulations until the publication of the Final Rule on June 17, 2011," Pet. Ex. 28, the FDCA has long prohibited false or misleading terms. Thus, if the terms "sunblock," "waterproof," and "sweatproof" are false or misleading, as the complaint alleges, and as the FDA agrees, those terms were prohibited under the FDCA's misbranding provisions at all times relevant to Mr. Engel's claims. Accordingly, those claims do not seek to enforce requirements additional to or different from federal requirements.

Furthermore, because the disputed labeling terms were prohibited by the FDCA's misbranding provisions before the 2011 rule, the rule's eighteen-month compliance period does not alter the preemption analysis. Although the rule gave sunscreen manufacturers time to comply with the rule (which contained extensive new testing and labeling requirements), that period did not suspend the operation of the FDCA's misbranding provisions. Indeed, federal agencies do not have authority to suspend the operation of federal statutes. False or misleading terms, including "sunblock," "waterproof," and "sweatproof," were prohibited by federal law throughout the eighteen-month period. Mr. Engel's claims from that period were not seeking to enforce additional or different requirements and are not preempted.[2]

[2] For similar reasons, the court of appeal erred in holding that Mr. Engel's claims pose an obstacle to the accomplishment and execution of Congress's objections. According to the court of appeal, the claims are contrary to congressional intent because they "seek[] imposition of a labeling regime before the agency

II. The Decision Below Is Inconsistent with a Recent Ninth Circuit Decision.

The court of appeal's interpretation of the FDCA and the scope of preemption under it is inconsistent with a recent Ninth Circuit decision holding that California state-law causes of action that create remedies for false or misleading labels are not preempted by an FDCA preemption provision preempting state requirements that are "different from or in addition to, or [] otherwise not identical to" federal requirements, *Astiana v. Hain Celestial Group*, 783 F.3d 753 (9th Cir. 2015). Because of this disagreement, the determination whether the FDCA preempts California state-law claims alleging that an over-the-counter drug or cosmetic is falsely labeled when the FDA has not yet promulgated regulations on the specific terms at issue may depend on whether the case is brought in state or federal court.

Astiana concerned cosmetic products that were labeled "all natural," "pure natural," or "pure, natural & organic." *Id.* at 756. Consumers sued the products' manufacturers under, among other things, California's unfair competition and false advertising laws, alleging that, contrary to their labels, the cosmetics contained synthetic and artificial ingredients. In response, the defendants argued that the consumers' state-law claims were preempted by 21 U.S.C. § 379s, an FDCA preemption provision that applies to cosmetics. Section 379s contains nearly identical language to the language in § 379r that applies to over-the-counter drugs, preempting any state "requirement for labeling or packaging of a cosmetic that is different from or in addition to, or that is otherwise not identical with, a requirement specifically applicable to a particular cosmetic or class of cosmetics" under federal law.

The Ninth Circuit rejected the preemption argument. The court pointed out that the FDCA proscribes "labeling that is 'false or misleading in any particular,'" *Astiana*, 683 F.3d at 757 (quoting 21 U.S.C. § 362(a)), and explained that the "FDCA does not preempt state laws that allow consumers to sue cosmetic manufacturers that label or package their products in violation of federal standards." *Id.* (citing *Medtronic*, 518 U.S. 470, and *Bates*, 544 U.S. 431). The court then specifically rejected the argument that the FDA's failure to issue regulations on the use of "natural" on cosmetic labels was equivalent to an FDA decision to allow all use of such terms. "This argument proves too much," the court explained. *Id.* at 758. "By this logic, a manufacturer could make any claim—wild, untruthful, or otherwise—about a product whose contents are not addressed by a specific regulation. The statute, however, prohibits statements that are 'false or misleading in any particular,' not statements that are 'prohibited by specific FDA

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required manufacturers like Neutrogena to comply with it." Pet. Ex. 29. To the contrary, the FDCA has at all times required sunscreen manufacturers to comply with its prohibition on false or misleading labels, and state-law claims imposing liability for manufacturers' violation of that requirement do not frustrate congressional objectives.

regulations.'" *Id.* The court allowed the consumers' claims that the cosmetic products "were labeled in a way that was 'false or misleading in any particular'" to proceed. *Id.* at 759.

Astiana and the decision below disagree about whether state-law claims asserting that product labels are false or misleading are preempted when the FDA has not promulgated regulations specifically addressing the labeling terms at issue. Whereas the court below held that, because, until 2011, the FDA had not promulgated a final rule on the use of the terms "waterproof," "sweatproof," and "sunblock" on sunscreen, Neutrogena's use of those terms "compli[ed] with federal law," Pet. Ex. 28, and state-law claims alleging the terms were misleading were different from or in addition to federal requirements, the Ninth Circuit recognized that the FDA's failure to promulgate a final rule on the use of a term does *not* mean that any use of the terms is permitted, that use of the term could still be prohibited by the FDCA's prohibition on statements that are "false or misleading in any particular," and that state-law claims that the products at issue are labeled in a false or misleading way are not enforcing requirements different from or in addition to federal requirements. This Court should grant review to ensure consistency between California and Ninth Circuit case law in line on this issue.

III. The Decision Below Will Prevent California Consumers from Holding Accountable Drug Manufacturers that Place False and Misleading Information on Their Products.

This case presents an important issue regarding when drug manufacturers can be held accountable for placing false or misleading information on their products' labels. The court of appeal's determination that, until the effective date of a final FDA rule declaring that a term will render an over-the-counter drug false or misleading, manufacturers' use of that term is "in compliance with federal law"—despite the FDCA's prohibition on labels that are "false or misleading in any particular"—immunizes nonprescription drug manufacturers from state-law liability for using false or misleading labeling, unless the FDA has specifically told them not to. As the Ninth Circuit has explained, "[b]y this logic, a manufacturer could make any claim—wild, untruthful, or otherwise—about a product whose contents are not addressed by a specific regulation." *Astiana*, 783 F.3d at 758. People who relied on the wild or untruthful statement to buy or pay more for the product would then be denied remedies for their injuries, and manufacturers would have a reduced incentive to be truthful about their products—all to the detriments of California consumers.

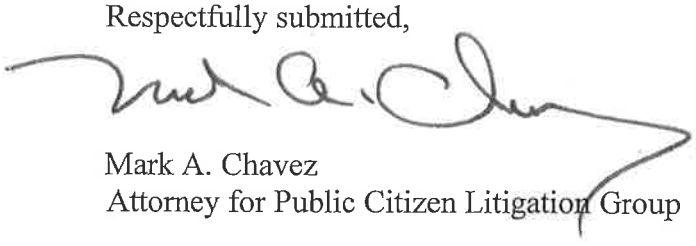
Further, because of the court of appeal's emphasis on the FDA's regulatory process and its eventual 2011 rulemaking, lower courts are most likely to find the court of appeal's decision applicable in cases where the agency eventually addresses and prohibits the terms at issue. It makes particularly little sense, however, to hold that such cases are based on state requirements that differ from federal requirements because these are cases

in which the FDA *agrees* that the manufacturers made statements on their labels that were false or misleading, although the agency had not yet said so in the format of a final rule at the time of the challenged conduct. Courts in such cases do not need to determine themselves whether the products would be considered misbranded under the FDCA's misbranding provisions (which were fully effective at the time of the challenged conduct); the agency has already explained that they do.

Moreover, if the passage of a final rule declaring certain terms false or misleading immunized manufacturers who had previously placed those terms on their products, the FDA would not be able to promulgate final rules aimed at the most egregious violators—those who place claims on their label that they know or should know are false or misleading—without providing a benefit to those violators in the form of protection from state-law claims. Here, in identifying the terms "sunblock" "waterproof," and "sweatproof" as false and misleading in its final rule, the agency explained that it had "previously identified these claims as ones that would render a product misbranded," but that it was "addressing them again in this document because OTC sunscreen products currently marketed without approved applications continue to contain the claims." 76 Fed. Reg. at 35643 (italics added). If manufacturers continue to place false or misleading terms on their products even after they know or should know that the terms render their products misbranded, and if the agency responds to the flagrant violations by specifically codifying those terms as false or misleading in the code of federal regulations, the agency's response to the violations should not serve to protect the violators from claims based on their prior illegal activity.

As Neutrogena stated to the court of appeal in its motion to have the court of appeal's decision published, the issues in this case "almost certainly will arise again in cases involving sunscreen and also in other food, drug and cosmetic cases." Mot. to Pub. at 2. As the history of the 2011 final rule on sunscreen demonstrates, FDA regulatory processes can take years, or even decades. Drug manufacturers who place false or misleading information on their products while the regulatory process is proceeding, in violation of the FDCA's misbranding provisions, should not be protected against liability under state law for their violations. This court should grant review to settle the important question of law presented in this case about the preemption of state-law claims alleging that nonprescription drug manufacturers placed false or misleading labels on their products.

Respectfully submitted,



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I am employed in the County of Marin, State of California. I am over the age of 18 years and not a party to the within action; my business address is Chavez & Gertler LLP, 42 Miller Avenue, Mill Valley, CA 94941.

On September 2, 2015, I served the foregoing documents:

- **AMICUS LETTER IN SUPPORT OF PETITION FOR REVIEW**

on the interested parties in this action by placing the true copy thereof in a sealed envelope addressed to each as follows:

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Executed on September 2, 2015, at Mill Valley, California.

I declare under penalty of perjury under the laws of the State of California that the above is true and correct. I declare that I am employed in the office of a member of the bar of this court at whose direction the service was made.

Patti Pomerantz