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**NOT TO BE PUBLISHED IN THE OFFICIAL REPORTS**



IN THE COURT OF APPEAL OF THE STATE OF CALIFORNIA

SECOND APPELLATE DISTRICT

DIVISION SEVEN

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| KAY ECKLER,<br><br>Plaintiff and Appellant,<br><br>v.<br><br>NEUTROGENA CORPORATION,<br><br>Defendant and Respondent. | B253691<br><br>(Los Angeles County<br>Super. Ct. Nos. BC307288, JCCP4352) |
| STEVE ENGEL,<br><br>Plaintiff and Appellant,<br><br>v.<br><br>NEUTROGENA CORPORATION et al.,<br><br>Defendants and Respondents. | B253899<br><br>(Los Angeles County<br>Super. Ct. Nos. BC307288, JCCP4352) |

APPEALS from a judgment of the Superior Court of Los Angeles County, John S. Wiley, Jr., Judge. Affirmed.

Bonnett, Fairbourn, Friedman & Balint (Arizona) and Patricia N. Syverson; Bonnett, Fairbourn, Friedman & Balint (California) and Manfred P. Meucke for Plaintiff and Appellant Kay Eckler.

Abraham, Fruchter & Twersky (California), Ian D. Berg and Takeo A. Kellar; Abraham, Fruchter & Twersky (New York), Mitchell M.Z. Twersky (pro hac vice) and Lawrence D. Levit (pro hac vice) for Plaintiff and Appellant Steve Engel.

O'Melveny & Myers (Los Angeles), Richard B. Goetz and Cynthia A. Merrill; O'Melveny & Myers (Newport Beach) and Amy J. Laurendeau for Defendants and Respondents Neutrogena Corporation and Johnson & Johnson, Inc.

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This case concerns congressional intent with respect to label information on sunscreen products: is it to be determined solely by the federal agency it charged with ensuring uniform labeling for those products, or, in addition, by each state through private civil suits. Appellants Kay Eckler and Steve Engel filed separate actions against respondent Neutrogena Corporation alleging that their sunscreen products were misleadingly labeled and marketed in violation of California consumer protection statutes. Appellants alleged that Neutrogena misleadingly labeled its products with the descriptions "sunblock," "waterproof," and "sweatproof" (Labeling Terms), terms that the federal Food and Drug Administration (FDA) prohibited in a regulation published on June 17, 2011, with a compliance date of December 17, 2012. Engel contends that Neutrogena is liable for marketing products that bore the Labeling Terms before the December 17, 2012 compliance date. The Eckler matter raises an additional product labeling issue with respect to sunscreen with a sun protection factor (SPF) value greater than 50 (SPF 50+). Although Eckler does not contend that the SPF values on Neutrogena's products were inaccurate, she believes that consumers will be misled about their benefits and seeks an order that Neutrogena modify its labels and alter its advertising. The superior court sustained Neutrogena's demurrer to Eckler's complaint without leave to amend, and granted its motion for judgment on the pleadings as to Engel's complaint. The court concluded that their claims were preempted by the federal Food, Drug, and Cosmetic Act (FDCA) ( 21 U.S.C. § 379r) and implementing FDA regulations. We agree and affirm.

## Factual and Procedural Background

Appellant Engel filed suit against Johnson & Johnson and Neutrogena in December 2003, and an amended complaint in June 2003.[1] Although those pleadings focused on purported misrepresentations concerning the ability of sunscreen products to protect users from longer wavelength ultraviolet rays, the amended complaint did allege that Neutrogena's product was not truly water or sweat "proof," or a true "sunblock." Engel's action was eventually added to a Coordination Proceeding involving other parties raising claims against sunscreen manufacturers. A Corrected Amended Master Complaint dated April 2006 is the operative pleading. In that complaint Engel alleged that he purchased Neutrogena Oil Free Healthy Defense Sunblock lotion "and was damaged thereby." The suit alleged that respondents used the Labeling Terms on its packaging and marketing, which were deceptive advertising and unlawful business practices under California's Unfair Competition Law (Bus. & Prof. Code, § 17200), False Advertising Law (Bus. & Prof. Code, § 17500), and Consumer Legal Remedies Act (Civ. Code, § 1750 et seq.). According to Engel, the gravamen of his allegations is that Neutrogena's products were falsely labeled "by claiming that they: (1) were a 'sunblock' when in fact they did not block all of the sun's harmful rays and did not in fact block, but rather absorbed, the sun's rays; (2) provided 'waterproof' protection, which has been defined by the FDA to mean 'impenetrable to or unaffected by water' and 'completely resistant to water regardless of time of immersion' when the products were not impenetrable to, or unaffected by, or resisted over time to water; and (3) provided 'sweatproof' protection, which implies that they were impenetrable to or unaffected by sweat and completely resistant to sweat regardless of time of immersion or exposure, when they were not impenetrable to, unaffected by, or resistant over time to sweat." He sought injunctive, restitutionary, and other relief.

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[1] Johnson & Johnson, Inc. is the parent company of Neutrogena Corporation. We refer to the defendants-respondents collectively as Neutrogena.

In June 2011 the FDA issued a Final Rule that among other things, prohibited sunscreen product labels from stating that they were "sunblock," "sweatproof," and "waterproof." (21 C.F.R. § 201.327(g); 76 Fed.Reg. 35620 at 35661 (June 17, 2011) (Final Rule).) Ultimately the compliance date for the regulation was set for 18 months later, on December 17, 2012. Engel contends that this regulation codified a previous alleged ban on these descriptions; Neutrogena contends that it represented the first time the agency prohibited the Labeling Terms. Neutrogena moved for judgment on the pleadings, arguing, among other things, that Engel's claims were preempted by federal law. The superior court concluded that Engel's claims were entirely preempted, and that the 18 months between publication of the Final Rule and its effective date represented a "safe harbor" reflecting the FDA's cost-benefit analysis: a delay fashioned to "minimize transactions costs based on a global analysis of social welfare. That's what a cost-benefit analysis is." Engel's appeal challenges the trial court's dismissal of claims arising from purchase of products bearing the Labeling Terms with respect to three time periods: (1) before June 17, 2011 when the Final Rule was published, (2) after the Final Rule's publication but before the compliance date, and (3) after the December 17, 2012 compliance date.

Appellant Eckler also filed suit against Neutrogena under California's Unfair Competition Law and Consumer Legal Remedies Act alleging that its sunscreen product labels were misleading. Eckler complained of the same Labeling Terms as Engel did; she also contended that the package labeling on SPF 50+ products was false and misleading. Eckler did not allege that the SPF values on Neutrogena's labels were inaccurate. Rather, she asserted that labels for SPF 50+ products omitted what she claims is a material fact, that they provide no added clinical benefit compared to products rated at SPF 50. Eckler did not claim that Neutrogena affirmatively represented that SPF 50+ products conferred enhanced clinical benefits, but she avers that consumers would naturally believe so, and thus Neutrogena misled consumers by charging more for such products and not disclaiming any benefits. Eckler alleged that she purchased two of Neutrogena's sunscreen products in May 2012 after reading the labels. Her complaint further asserted

that consumers read the labels before deciding to purchase the products and are deceived by Neutrogena's allegedly false representations and failures to disclose material facts on the labels and packaging of its products. Eckler "seeks an order requiring Neutrogena to disclose on its Product labels and associated advertising that the higher SPF values in the SPF 55-100+ collection do not provide proportionately greater, or any added clinical sun protection benefit." (Appellant Eckler's Opening Brief, at pp. 17-18.) She also requested class-wide restitution and other relief.

Neutrogena demurred to Eckler's complaint on several grounds, including express and implied preemption. The court concluded that Eckler's action was preempted by federal law, sustained the demurrer without leave to amend and dismissed the action. Eckler and Engel filed timely appeals.

## Applicable Law

### 1. *Standard of Review for Demurrer and Motion for Judgment on the Pleadings*

We apply a de novo standard of review to a trial court's order of dismissal following an order sustaining a demurrer. (*Los Altos El Granada Investors v. City of Capitola* (2006) 139 Cal.App.4th 629, 650.) In other words, we exercise our "independent judgment about whether the complaint states a cause of action as a matter of law." (*Ibid.*) "In reviewing a judgment of dismissal after a demurrer is sustained without leave to amend, we must assume the truth of all facts properly pleaded by the plaintiffs, as well as those that are judicially noticeable." (*Howard Jarvis Taxpayers Assn. v. City of La Habra* (2001) 25 Cal.4th 809, 814.)

When a demurrer "is sustained without leave to amend, we decide whether there is a reasonable possibility that the defect can be cured by amendment: if it can be, the trial court has abused its discretion and we reverse; if not, there has been no abuse of discretion and we affirm." (*Blank v. Kirwan* (1985) 39 Cal.3d 311, 318.) Such a showing can be made for the first time before the reviewing court. (*Smith v. State Farm*

*Mutual Automobile Ins. Co.* (2001) 93 Cal.App.4th 700, 711.) "The burden of proving such reasonable possibility is squarely on the plaintiff." (*Blank, supra,* 39 Cal.3d at p. 318.)

A demurrer may be sustained without leave to amend where, "'the facts are not in dispute, and the nature of the plaintiff's claim is clear, but, under the substantive law, no liability exists.' [Citation.]" (*Seidler v. Municipal Court* (1993) 12 Cal.App.4th 1229, 1233.) "A judgment of dismissal after a demurrer has been sustained without leave to amend will be affirmed if proper on any grounds stated in the demurrer, whether or not the court acted on that ground." (*Carman v. Alvord* (1982) 31 Cal.3d 318, 324.)

"A motion for judgment on the pleadings serves the function of a demurrer, challenging only defects on the face of the complaint." (*Richardson-Tunnell v. School Ins. Program for Employees* (2007) 157 Cal.App.4th 1056, 1061.) As with a demurrer, "[t]he grounds for a motion for judgment on the pleadings must appear on the face of the complaint or from a matter of which the court may take judicial notice." (*Ibid.*, citing Code Civ. Proc., § 438, subd. (d).) We exercise our independent judgment in determining whether the challenged complaint states a cause of action. (*Gerawan Farming, Inc. v. Lyons* (2000) 24 Cal.4th 468, 515.) "In the case of either a demurrer or a motion for judgment on the pleadings, leave to amend should be granted if there is any reasonable possibility that the plaintiff can state a good cause of action." (*Gami v. Mullikin Medical Center* (1993) 18 Cal.App.4th 870, 876.)

**2. *Federal Statutory and Regulatory Scheme For Sunscreen Products***

A. *The FDCA*

The FDCA authorizes the FDA to regulate, among other things, the ingredients and labeling of nonprescription, over-the-counter (OTC) drugs such as the sunscreen products at issue. The FDCA was amended by the FDA Modernization Act of 1997 (Modernization Act), which included a provision expressly preempting state law

requirements regarding nonprescription drugs, including sunscreen products. Section 751 of the FDCA, codified at 21 United States Code section 379r(a),[2] specifically prohibits state requirements that are *not identical* with federal requirements: "no State . . . may establish or continue in effect any requirement – (1) that relates to the regulation of a drug . . . and (2) that is different from or in addition to, or that is otherwise not identical with, a requirement under this chapter. . . ." Such state "requirements" include those concerning "public information" or "public communication relating to a warning." (*Id.* at subd. (c).) [3]

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[2] Section 379r falls under Part F of Subchapter VII of the FDCA titled: "National Uniformity for Nonprescription Drugs and Preemption for Labeling or Packaging of Cosmetics." (Pub. L. No. 105-115 (Nov. 21, 1997), 111 Stat. 2296 at pp. 2374-2375.)

[3] Section 379r, titled "National uniformity for nonprescription drugs," provides, in pertinent part:

> "(a) In general
>
> "Except as provided in subsection (b), (c)(1), (d), or (f) of this section, no State or political subdivision of a State may establish or continue in effect any requirement –
>
> "(1) that relates to the regulation of a drug that is not subject to the requirements of section 353(b)(1) or 353(f)(1)(A) of this title; and
>
> "(2) that is different from or in addition to, or that is otherwise not identical with, a requirement under this chapter, the Poison Prevention Packaging Act of 1970 (15 U.S.C. 1471 et seq.), or the Fair Packaging and Labeling Act (15 U.S.C. 1451 et seq.).
>
> ". . . .
>
> "(c) Scope
>
> ". . . .
>
> "(2) Safety or effectiveness
>
> "For purposes of subsection (a) of this section, a requirement that relates to the regulation of a drug shall be deemed to include any requirement relating to public information or any other form of public communication relating to a warning of any kind for a drug."

A savings clause excepts from preemption product liability suits (§ 379r(e).)[4] Further, the statute permits state enforcement of "a requirement that is identical to a requirement of this chapter." (*Id.* at subd. (f).)

Section 379r reflects Congress's express intention generally to preempt state requirements on the labeling of nonprescription drugs such as the sunscreen products at issue. This intent is amply supported by the legislative history of the Modernization Act. The language in section 379r was added by amendment in the Senate Committee on Labor and Human Resources. (Sen. Rep. 105-43 (filed June 27, 1997) at p. 13.) The Senate Report on the Modernization Act stated that "[a]n essential element of a nationwide marketplace is a national uniform system of regulation. It is intended that the FDA provide national leadership in assuring the safety, effectiveness, and proper labeling and packaging for nonprescription drugs and cosmetics marketed throughout the country . . . ." (*Id.* at p. 63.) The report also emphasized that states may not impose different or additional requirements relating to labeling and advertising: "No State or local government is permitted to impose different or additional requirements that relate to the subject matter covered by the three Federal laws as they apply to nonprescription drugs and cosmetics. These include requirements imposed on product manufacture or composition, labeling, advertising, or any other form of public notification or communication." (*Id.* at p. 64.)[5] The Conference Committee on the Senate bill adopted

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4 These appeals do not arise from claims for personal injury or damage to property and thus the section 379r(e) savings clause does not apply. (See *Kanter v. Warner-Lambert Co.* (2002) 99 Cal.App.4th 780, 790-791 (*Kanter*).)

5 The Senate Report explained the reason for federal preemption in this area: "Under our Federal system, it is important that State and local officials enforce the same regulatory requirements for products as do our Federal officials. Different or additional requirements [at] the State or local level can work against our national marketplace, confuse consumers, raise prices, undermine public confidence in our regulatory system and in products important to the public health, and result in divergent public health protection throughout the country." (Sen. Rep. 105-43, *supra*, at p. 64.)

the preemption language added by the Senate. (House of Representatives Conference Report No. 105-399 (Nov. 9, 1997) (Conference Report) at pp. 81-83.) The Conference Report reiterated that the "scope of national uniformity" applied to "state requirements that relate to labeling and packaging or, if they go beyond labeling and packaging, to requirements relating to warnings." (*Id.* at p. 103.)

The 1997 legislation, as part of a major reform of all food, drug and cosmetic regulation, also singled out sunscreen products for future FDA regulatory action. Section 129 of the Modernization Act provided: "Not later than 18 months after the date of enactment of this Act, the Secretary of Health and Human Services shall issue regulations for over-the-counter sunscreen products for the prevention or treatment of sunburn."[6] (21 U.S.C. § 393 note; 111 Stat. 2331.)

B. *FDA regulations concerning sunscreen products*

Sunscreen products have been the subject of exhaustive federal regulatory action for many years. The FDA's regulations cover, among other topics, permissible active ingredients, highly technical standards for the testing and measurement of sun protection, and required and prohibited statements on product packaging. During over three decades of proposed rules, comments, new data, and reconsiderations, the agency's view has evolved with medical and chemical advances, and in response to the data and comments it has received in the rulemaking process.[7]

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6 The Conference Report notes that the conferees "recognize that various technical and scientific issues may take longer to resolve than other aspects of the rulemaking," and that they did "not intend that all regulation in this area be complete or comprehensive by a specified date." (Conference Report at p. 96.)

7 See, e.g. 43 Fed.Reg. 38206 (Aug. 25, 1978); 58 Fed.Reg. 28194 (May 12, 1993); 64 Fed.Reg. 13254 (Mar. 17, 1999); 64 Fed.Reg. 27666 (May 21, 1999); 68 Fed.Reg. 33362 (June 4, 2003); 72 Fed.Reg. 49070 (Aug. 27, 2007).

For example, in 1978 the FDA issued a proposed rule based on a panel recommendation concerning sunscreen products. (43 Fed.Reg. 38206 (Aug. 25, 1978).) Among other things, the proposal stated that sunscreen products that satisfy testing procedures may be labeled "waterproof," and those that satisfy sweat resistance testing procedures may be labeled "sweat resistant." (*Id.* at 38215.)

In 1993, in another notice of proposed rulemaking, the agency issued a "Tentative Final Monograph" based on its consideration of comments to the 1978 proposed rule. (58 Fed.Reg. 28194 (May 12, 1993).) The FDA stated that it was concerned that "the term 'waterproof,' as used in the Panel's recommended monograph, may be confusing or misleading to consumers . . . ." The FDA continued: "Therefore, the agency is not proposing the labeling claim 'waterproof,' but is proposing instead the term 'very water resistant.'" (*Id.* at 28228.) The proposed rule also provisionally authorized use of the term "sunblock." "The agency agrees with the comment that the descriptive term 'sunblock' would be informative to users of OTC sunscreen drug products. The agency believes that the term 'sunblock' may be used as an additional statement of product performance on sunscreen drug products that contain the ingredient titanium dioxide and provide an SPF of 12 or higher." (*Id.* at 28240.) No changes in the Code of Federal Regulations concerning the Labeling Terms were made in 1993.

In 1999 the FDA published as a final rule a Final Monograph regarding sunscreen products. (64 Fed.Reg. 27666 (May 21, 1999).) This monograph provided that sunscreens with SPF values over 30 be labeled no higher than 30+. (*Id.* at 27675.) The agency found that data was lacking to "support or dismiss limiting the maximum SPF value in this final rule." (*Id.* at 27674.) Based upon the comments it received, the agency concluded that "OTC sunscreen products with SPF values above 30 should be available for those sun-sensitive consumers who require such products . . . ." (*Id.* at 27675.) The 1999 final rule, however, was stayed and never went into effect. (See 69 Fed.Reg. 53801 (Sept. 3, 2004).)

In 2007, the FDA issued another proposed rule, described as a proposed amendment to the final monograph. (72 Fed.Reg. 49070 (Aug. 27, 2007).) That

document proposed a new labeling system, as well as adding combinations of ingredients, and proposing new testing procedures. The FDA stated it "plans to grant an extended compliance period when this proposed rule is finalized" because "some manufacturers may not have sufficient time to incorporate labeling changes without disrupting their production schedules." (*Id.* at 49109.) In the 2007 publication, the FDA did not propose a prohibition on the Labeling Terms.

The 2007 proposed rule also explained its preemptive effect, both express and implied. The FDA explained that a final rule would preclude state requirements on labeling of sunscreen products that were not identical to it:

> This proposed rule, if finalized as proposed, would amend the labeling and include new UVA testing for OTC sunscreen drug products. Any final rule would have a preemptive effect in that it would preclude states from issuing requirements related to the labeling and testing of OTC sunscreen drug products that are different from or in addition to, or not otherwise identical with a requirement in the final rule. This preemptive effect is consistent with what congress set forth in section 751 of the act [21 U.S.C. § 379r]. Section 751(a) of the act displaces both State legislative requirements and State common law duties. We also note that even where the express preemption provision in section 751(a) of the act is not applicable, implied preemption may arise (see *Geier v. American Honda Co.*, 529 US 861 (2000)).
> (72 Fed Reg. 49109.)

Four years later, the FDA issued its Final Rule on sunscreen labeling.

(i) *FDA 2011 Final Rule*

Simultaneously in 2011 the FDA issued a Final Rule on labeling and effectiveness testing for sunscreen products, and a Proposed Rule that invited comments concerning limiting the labeling of sunscreen products to SPF 50. The Final Rule addressed the labeling and effectiveness testing issues raised by nearly 2,900 submissions received in response to the August 27, 2007 proposed rule. It promulgated two new federal regulations: 21 Code of Federal Regulations, sections 201.327 and 310.545, which set

labeling requirements, specified effectiveness testing, and identified false and misleading claims that render a product misbranded. (76 Fed.Reg. 35620 (June 17, 2011) (*Labeling and Effectiveness Testing: Sunscreen Drug Products for Over-the-Counter Human Use*) (Final Rule).)[8] FDA described this regulation as "a labeling rule, and not a monograph." (76 Fed. Reg. 35622.) Thus, it prescribed labeling requirements that reflected the FDA's "current determination on appropriate regulation on these aspects of sunscreens." (*Id.* at 35620-35621.) The Final Rule mandated that sunscreen labels state the SPF value resulting from the detailed testing procedure described in the regulation. (21 C.F.R. § 201.327(a)(1) & (I) [specifying testing procedure to arrive at appropriate SPF values and

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8 Reflecting the lengthy rulemaking process, the FDA noted that among other things, the Final Rule required over-the-counter sunscreen products to comply with the requirements for drug labeling contained in a final rule published March 17, 1999 (64 Fed.Reg. 13254) by lifting a delay of implementation date published on September 3, 2004 (69 Fed.Reg. 53801). (76 Fed.Reg. 35620.)

The FDA explained the scope and purpose of the Final Rule as follows: "This final rule establishes the labeling and testing requirements for OTC sunscreen products containing specific ingredients or combinations of ingredients . . . . The requirements in this final rule will help ensure that these currently marketed sunscreen products are appropriately labeled and tested for both UVA and UVB protection. In addition, the requirements in this final rule will help ensure the proper use of these sunscreens and greater consumer protection from the damaging effects of UV radiation. This final rule also identifies claims that render a product that is subject to this rule misbranded or not allowed on any OTC sunscreen drug product marketed without an approved application." (76 Fed. Reg. 35621.)

Summarizing the regulatory impact of the rule, the FDA explained: "The purpose of this rule is to finalize labeling and testing conditions under which OTC sunscreen drug products marketed without approved applications are not misbranded. This rule addresses labeling and testing requirements for both UVB and UVA radiation protection. The rule modifies the existing SPF test, specifies a test for broad spectrum protection, and requires changes to the product label that affect both the front of the package (the principal display panel or PDP) and the Drug Facts section. . . . all manufacturers of sunscreens will incur some labeling costs due to revisions to both the PDP and the Drug Facts section of the product label. . . ." (76 Fed. Reg. 35654.)

providing labels "shall" state the SPF value].) The FDA codified in 21 C.F.R. part 201 certain requirements for OTC sunscreen products, including "specific claims that render a covered product misbranded or are not allowed on any OTC sunscreen drug product marketed in the United States without an approved application." (*Ibid.*) Accordingly, sunscreen products cannot include on labels the descriptions "sunblock," "sweatproof," and "waterproof." (21 C.F.R. § 201.327(g).) The regulation promulgated by the Final Rule expressly provides that the numerical SPF value resulting from the FDA-mandated SPF testing procedure must be placed on a sunscreen product's principal display panel (see 21 C.F.R. § 201.327(a)(i)(A), (ii)).

The labeling requirements in the Final Rule are detailed. Products that pass the broad spectrum test of 21 Code of Federal Regulations section 201.327(j) must state "Broad Spectrum SPF" with the numerical SPF value appearing as "continuous text with no intervening text or graphic" all in the "same font style, size and color, with the same background color." (21 C.F.R. § 201.327(a)(1)(B).) The rule specifies warnings about keeping the product out of eyes, and not using it on damaged or broken skin. (21 C.F.R. § 201.327(d).) The rule also prohibits certain statements, such as any implication that use, alone, reduces the risk of skin cancer or early skin aging, and use of the terms "sweatproof," "waterproof," and "sunblock." (21 C.F.R. § 201.327(c)(3) & (g).) The Final Rule does not include as being a false or misleading claim accurately labeling a product with an SPF value above 50. (*See* § 201.327(c)(3), (g).)

Noting that often additional product label information can cause more confusion than clarity, the Final Rule repeatedly reflected a balancing of concerns. For instance, the Final Rule eliminated a statement proposed in 2007 that "higher SPF products give more sun protection, but are not intended to extend the time spent in the sun." The FDA "concluded that [this] statement, although truthful, is not necessary." (76 Fed Reg. 35642.) (See also, 76 Fed. Reg. 35626 ["UVA star rating would likely be confusing in conjunction with the numerical SPF rating"]; *id.* at 35627 ["a 'No UVA Protection' statement is not necessary and could be misleading"]; *id.* at 35628 [proposed label requirement explaining two types of ultraviolet rays was "potentially confusing"].) The

FDA cited 82 studies and reports on dermatology, photochemistry, and other fields in support of its technical judgments. (*Id.* at 35658-35660.)

In discussions pertinent to this appeal, the FDA Final Rule confirmed its expressly preemptive impact except as to claims based on state product liability law. The FDA noted that it addressed the preemption issue in its 2007 Proposed Rule. That rule noted that 21 United States Code section 379r "is an express preemption provision." (72 Fed. Reg. 49070 at 49109 (Aug. 27, 2007).) While clarifying that by its terms the Modernization Act did not preempt product liability claims, whether based on statutes or common law, the FDA emphasized: "However, it is important to note that [section 379r] exempts only those common law claims that are based on State product liability law." (76 Fed. Reg. 35624.) The agency also noted that "although implied preemption may arise, such scenarios are necessarily case specific." (*Ibid.*) Thus, in the Final Rule the FDA made clear that section 379r requires preemption of suits based on state law (other than product liability actions) that would seek to impose any labeling or advertising requirements not identical to those contained in the Final Rule.

The Final Rule was initially to have a compliance date (for products with annual sales of $25,000 or more) of June 18, 2012. This date was extended to December 17, 2012. Engel contends that during the 18-month period from publication of the Final Rule on June 17, 2011 to the compliance date of December 17, 2012, Neutrogena should face liability for non-compliant products. In extending the compliance date, the FDA stated that "granting manufacturers additional time to complete testing and relabeling is in the public interest." (77 Fed.Reg. 27591 at 27592 (May 11, 2012).) This was consistent with what the FDA had announced four years earlier. "FDA plans to grant an extended compliance period when this proposed rule is finalized." (72 Fed.Reg. 49109.) Moreover, it had always been the FDA's intention that products already on the market remain and not be recalled. Recognizing that non-compliant products were in the stream of commerce, the FDA reiterated that those products could remain on the market: "In the 2007 proposed rule, we indicated that sunscreen products which are already distributed by the effective date of the final rule would not be expected to be relabeled or retested in

conformity with the final rule conditions unless these products were subsequently relabeled or repackaged after the effective date (72 F.R. 49070 at 49109). Consistent with this statement, we do not expect non-compliant products introduced or delivered for introduction into interstate commerce prior to the compliance dates specified for this final rule to be removed from the market." (76 Fed.Reg. 35624.)

(ii) *FDA 2011 Proposed Rule*

On the same day it published the Final Rule, the FDA published a proposed rule titled "Revised Effectiveness Determination; Sunscreen Drug Products for Over-the-Counter Human Use." (76 Fed.Reg. 35672 (June 17, 2011) (Proposed Rule).) The Proposed Rule would further modify 21 Code of Federal Regulations section 201.327 to limit the maximum labeled SPF value for over-the-counter sunscreen drug products to "50+." The agency stated that "this proposal is part of FDA's ongoing review of these products to ensure their safety and effectiveness." In its discussion of the Proposed Rule, the FDA noted that in 1999 it had proposed a maximum SPF of 30+, and in 2007 proposed a maximum of 50+, in part because of a concern that "products with SPF test values above 50 could not be tested with acceptable accuracy and reproducibility." (76 Fed.Reg. 35672.) The Proposed Rule noted that submissions in response to the 2007 proposal demonstrated the accuracy and reproducibility of test values as high as SPF 80. The FDA stated that "because the record continues to lack data demonstrating that sunscreen products with SPF values above 50 provide additional clinical benefit compared to SPF 50 products," it was again proposing "a maximum labeled [SPF] value of '50+.'" (*Ibid.*)

The Proposed Rule noted that "[c]onsumers have learned to associate higher SPF values with greater sun protection. Consumers would likely assume that a product with an SPF value higher than 50 provides greater protection than a product with an SPF value of 50 (*e.g.*, assume that an SPF 80 sunscreen provides greater protection than an SPF 50 sunscreen). However, we lack evidence that a product with an SPF value higher than 50

provides additional clinical benefit compared to a product with an SPF value of 50. In the absence of data demonstrating additional clinical benefit, we are concerned that labeling a product with a specific SPF value higher than 50 would be misleading to the consumer." (76 Fed.Reg. 35674.) In the Proposed Rule, the agency stated that it needed further data and invited comments. "[W]e are requiring data sufficient to support a general conclusion that sunscreen products with specific SPF values above 50 provide additional protection over SPF 50 sunscreen products. If we receive such data, and sufficient accompanying data regarding accuracy and reproducibility of testing, we may be able to allow those specific SPF values to be included in labeling." (*Id.* at 35675.)

The Proposed Rule acknowledged the potential value of sunscreen products with SPF values over 50: "We recognize that sunscreen products with SPF values above 50 could have utility for consumers in certain settings, such as skiing at high altitudes, or with certain conditions that predispose them to developing skin cancer. If such products are needed in unique situations but not in typical situations of sunscreen use (e.g., beach or gardening), it is possible that different labeling may be necessary for these unique situations. . . . Additional data would enable us to identify the appropriate target population . . . for sunscreen products with SPF values above 50." (76 Fed.Reg. at 35675.)

In summary, the Proposed Rule declared no final FDA position on the safety and effectiveness of products with SPF values over 50. While the agency expressed concerns about the efficacy of such products, it lacked scientific evidence to issue a rule. Accordingly, the Proposed Rule invited relevant data.[9] Since the publication of the 2011

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9 One study on the topic was cited in the Proposed Rule. Its title summarizes its findings: Russak, et al, "*A comparison of sunburn protection of high-sun protection factor (SPF) sunscreens: SPF 85 sunscreen is significantly more protective than SPF 50*," 62 Journal American Academy of Dermatology 348 (Feb. 2010). The FDA concluded that the single study did not provide an adequate basis to make broader policy. (76 Fed.Reg. 35674-35675 ["we cannot determine from the study summary the amounts of sunscreen products applied, length of sun exposure for individual subjects, or the time

Proposed Rule, the FDA has issued no Final Rule limiting the maximum SPF that can appear on sunscreen labels.

### 3. *Principles of Preemption*

Under the supremacy clause of the United States Constitution, "[w]hen a state statute, administrative rule, or common-law cause of action conflicts with a federal statute, it is axiomatic that the state law is without effect. [Citations]" (*Geier v. American Honda Motor Co.*, (2000) 529 U.S. 861, 894) *(Geier)*.) "In determining whether federal law preempts state law, a court's task is to discern congressional intent. [Citation.] Congress's express intent in this regard will be found when Congress explicitly states that it is preempting state authority. [Citation.] Congress's implied intent to preempt is found (i) when it is clear that Congress intended, by comprehensive legislation, to occupy the entire field of regulation, leaving no room for the states to supplement federal law [citation]; (ii) when compliance with both federal and state regulations is an impossibility [citation]; or (iii) when state law 'stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.' [Citations.]" (*Bronco Wine Co. v. Jolly* (2004) 33 Cal.4th 943, 955; see *Dowhal v. Smithkline Beecham Consumer Healthcare* (2004) 32 Cal.4th 910, 923 (*Dowhal*)).) In addition, federal agency regulation with the force of law can preempt conflicting state requirements. (*Geier, supra*, 529 U.S. at pp. 874-884; *Wyeth v. Levine* (2009) 555 U.S. 555, 576.) A state "requirement" may include state suits based on common law or statutory provisions. (*Cipollone v. Liggett Group, Inc.* (1992) 505 U.S. 504, 521-522; *Kanter v. Warner-Lambert Co.* (2002) 99 Cal.App.4th 780, 792.)

The party who asserts that state law is preempted bears the burden of so demonstrating. (*Viva! International Voice for Animals v. Adidas Promotional Retail*

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of day during which subjects were exposed to the sun"].) In any case, the study was supported in part by a grant from Neutrogena.

*Operations, Inc.* (2007) 41 Cal.4th 929, 936.) Moreover, consideration of issues under the supremacy clause starts with the presumption that state laws are not to be preempted by a federal statute unless it is the clear and manifest purpose of Congress to do so. (*Cipollone v. Liggett Group, Inc., supra,* 505 U.S. at p. 516.)

By its terms, 21 United States Code section 379r expressly preempts state requirements not identical with the federal requirements. The FDA maintains that pursuant to section 379r, its sunscreen labeling regulations preempt state law requirements not identical to the Final Rule. (76 Fed.Reg. 35624.)

A. *California cases interpreting 21 United States Code section 379r*

Two published California appellate cases have considered the preemptive effect of section 379r on lawsuits aimed at enforcing state statutory requirements. Both found that the suits were preempted, although under different theories. In *Dowhal, supra,* 32 Cal.4th 910, our Supreme Court held that a suit to require a Proposition 65 warning on nicotine replacement therapy products was preempted despite a savings clause in section 379r that exempted Proposition 65. The Court found that section 379r did not expressly preempt the claim that the state law warning was required because of the savings clause. However, because the state and federal requirements directly conflicted, the Proposition 65 requirement was impliedly preempted.

Proposition 65, enacted through ballot initiative in 1986, prohibits businesses from knowingly exposing anyone to a chemical known to cause reproductive toxicity without a warning. Regulations to implement the initiative required that products containing nicotine warn users that it contained a chemical known to the state "to cause reproductive harm." In contrast to this state requirement, the FDA label for nicotine replacement therapy products warned a pregnant or breast-feeding mother that smoking can seriously harm her child, and urged cessation of smoking without using nicotine replacement medicine, but also stated that "the risks to your child from this medicine are not fully known." (*Dowhal, supra,* 32 Cal.4th at pp. 918-919.) Plaintiff Dowhal, acting on behalf

of the public, sued to bar sale of defendant's nicotine replacement products without the Proposition 65 warning.

In considering whether the state warning requirement was preempted by federal law, the Supreme Court explained that express preemption, and implied preemption based on pervasive federal regulation that occupies the field, did not apply. "The savings clause in the Modernization Act demonstrates both that Congress did not expressly preempt California law, and that it did not occupy the field of labeling of over-the-counter drugs. Thus, the issue here is the third form of preemption, referred to as 'conflict preemption.'" (*Dowhal, supra,* 32 Cal.4th at p. 924.) The Supreme Court reasoned that there was a direct conflict between the required Proposition 65 warning and the FDA's mandates because it was impossible for the manufacturer to comply with both requirements. Relying on the United States Supreme Court decision in *Geier v. American Honda Motor Co., supra,* 529 U.S. 861, our Supreme Court concluded in *Dowhal* that the savings clause "does not entirely exclude conflict preemption" (*Dowhal, supra,* 32 Cal.4th at p. 926), and accordingly, the FDA's directive could invalidate a Proposition 65 label "on a basis relevant to consumer health," although not to pursue a policy of "national uniform labeling." (*Ibid.*) The Supreme Court deferred to the FDA's balancing of competing risks, observing that this was "an unusual case." (*Id.* at p. 934.) While in most cases the FDA and Proposition 65 warnings would both inform the consumer of the risks involved in using a product, in this instance, the "FDA's objection to labels warning that nicotine 'can' harm the baby is not that they are false, but that consumers may give too much weight to the warnings and decide to continue smoking instead of using [the product] to stop smoking." (*Id.* at p. 931.) Thus, the suit to require the Proposition 65 warning was preempted.

*Dowhal* is our Supreme Court's only interpretation of the statute at issue here, but it is significant because it concluded that the doctrine of implied preemption foreclosed enforcement of a state ballot initiative even when the federal statute contained a savings clause crafted specifically to exempt that initiative. (*See Dowhal, supra,* 32 Cal.4th at p. 926, fn. 6.) And, relevant to this case concerning sunscreen rules, *Dowhal* indicates that

without the unique savings clause in that case, that is, with the express preemption provisions of section 379r in force, the federal statute preempts state requirements that depart from "national uniform labeling." (*Id.* at p. 926.) Finally the *Dowhal* decision reflects a cautious deference to the policy tradeoffs considered by the federal agency.

In the second California decision on the preemptive effect of section 379r, the First District Court of Appeal affirmed summary judgment in favor of defendant manufacturers of over-the-counter drugs for the treatment of head lice. (*Kanter, supra,* 99 Cal.App.4th 780.) Plaintiffs alleged that the products were falsely labeled. The trial court found that the claims were preempted by section 379r, and the Court of Appeal agreed. (*Id.* at pp. 795-797.) The FDA had approved labeling for the product, but plaintiffs alleged that the labels were inaccurate, and accordingly, defendants breached warranties, and were guilty of fraud and false advertising. Plaintiffs sought relief under, among other statutes, Business and Professions Code sections 17200 and 17500, and the Consumer Legal Remedies Act. The *Kanter* court noted that the underlying legal theories were based on the assertion that the FDA-approved label was inadequate and should be changed. The court concluded that "when a state law claim, however couched, would effectively require a manufacturer to include additional or different information on a federally approved label, it is preempted." (*Id.* at p. 795.) The court held that the plaintiffs' state law claims were expressly preempted by section 379r because "[e]ach cause of action would result in the establishment of a state requirement regarding labeling that would be 'different from' and 'otherwise not identical with' the federally required label. . . ." (*Id.* at pp. 796-797.) Because the court concluded that section 379r expressly preempted the suit, it declined to reach the issue of implied conflict preemption.

*Dowhal* and *Kanter* indicate that under section 379r: (1) the FDA may require uniform labeling of products; (2) ordinarily, suits that seek alternatives to the FDA's uniform labels are expressly preempted; and (3) even without express preemption, when state litigation poses an obstacle to the objectives of the federal agency, the suit may be foreclosed by implied preemption.

B. *Federal cases interpreting 21 United States Code section 379r*

Most of the cases on preemption under the FDCA have arisen in federal court. Two recent district court decisions in California considered the issue raised by Eckler, that the California consumer protection statutes were violated by the merchandising of sunscreen products with SPF values over 50.

In *Corra v. Energizer Holdings, Inc.* (E.D. Cal. 2013) 962 F.Supp. 2d 1207 (*Corra*), a consumer sued a sunscreen distributor alleging violations of Business and Professions Code section 17200, Civil Code section 1750, and breach of express warranty. The plaintiff alleged that defendant distributed sunscreen products which had SPF values over 85, but that, while defendant charged a premium for them, such products do not provide superior protection compared to lower SPF products. The district court denied defendant's motion to dismiss based on preemption.[10] The court did not examine the language of 21 United States Code section 379r, but considered the FDA's Final Rule regarding sunscreen products. (76 Fed.Reg. 35620 et seq. (June 17, 2011).) The court concluded that the preemption doctrine did not foreclose the suit, noting that plaintiffs did not seek to prohibit use of SPF ratings over 50 or change the product label: "Rather, Plaintiff alleges the way Defendants marketed their sunscreen products *beyond* simply providing an SPF rating – in effect, combining the use of SPF ratings with price differentials and claims of proportionally greater protection – misled consumers into purchasing more expensive, higher SPF-rated products . . . ." (962 F.Supp.2d at p. 1214.) The court believed that if the plaintiff were to prevail under the state consumer protection statutes, "Defendant's SPF labeling duties would remain unchanged." (*Id.* at p. 1215.) The court also rejected defendant's argument that 21 Code of Federal Regulations section 201.327 was a further reason to find preemptive intent. That section, listing the types of

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10 The court also denied the motion to dismiss based on primary jurisdiction, standing, and the notice provision of the Consumer Legal Remedies Act. It concluded that the complaint failed to plead a violation of express warranty and dismissed that claim with leave to amend. (962 F.Supp.2d at pp. 1215-1220.)

representations that were forbidden, was prefaced with the phrase "[t]hese claims include but are not limited to." This non-exclusive list, reasoned the court, "clearly evince[d] no intent to preempt state consumer fraud claims." (*Ibid.*)

A contrary result was reached by a different federal district court in *Gisvold v. Merck & Co., Inc.* (S.D. Cal. Nov. 25, 2014, Case No. 14cv1371 DMS) 2014 WL 6765718, 2014 U.S. Dist. Lexis 168955 (*Gisvold*). As in *Corra*, the plaintiff in *Gisvold* alleged that sunscreen products with an SPF over 50 do not provide any increase in clinical benefit over SPF 50 products, and thus contended that labels stating SPF values over 50 are false and misleading under Business and Professions Code section 17200, Civil Code section 1750, and express warranty. Gisvold sought an order that defendants charge the same price for the SPF 50+ products as SPF 50 products "and/or that they include 'a disclaimer on the label or packaging that a SPF value above 50 does not provide proportional clinical benefits.'" Just as Eckler requests here, Gisvold sought an order that the company "engage in a corrective advertising campaign." (Slip. Op. at 2.)

In *Gisvold*, the district court concluded that the plaintiff's claims were preempted. In contrast to the *Corra* decision, the *Gisvold* court reviewed the express preemption language in the federal statute: "The FDCA, which includes an express pre-emption statute, is unambiguous and broad in scope" and quoted section 379r. The court also reviewed the FDA's final rule regarding labeling and effectiveness of sunscreen products, noting that they mandate the SPF value. The court found that the plaintiff's argument was broader than her pleading: "the essence of Plaintiff's claim is that 'Merck's SPF 55, 70+, 80 or 100+ representations . . . *on its Coppertone SPF 55-100+ collection* are false, misleading and reasonably likely to deceive the public.'" (*Gisvold*, *supra*, slip op. at 5; italics in original.) The court concluded that "in seeking to provide greater consumer protections, Plaintiff targets Merck's sunscreen label (which complies with current FDA regulations), and proposes a disclaimer regarding the level of sunscreen effectiveness beyond SPF 50. Because the proposed disclaimer plainly adds to and is not identical with the FDA requirements, Plaintiff's action is expressly pre-empted under 21 U.S.C. § 379r." (Slip. Op. at 5; fns. omitted.)

The *Gisvold* court was unpersuaded by the *Corra* decision, pointing out that *Corra* did not consider whether a disclaimer regarding clinical benefits would "add to or be identical with FDA's labeling requirements." (*Gisvold, supra,* Slip Op. at 6.)[11] It also interpreted more narrowly than the *Corra* court the FDA's regulation on false or misleading claims at 21 Code of Federal Regulations section 201.327(g). That regulation prohibits use on product labels or other advertising the terms "sweatproof," "waterproof," and "sunblock," or "similar claims." The district court in *Gisvold* reasoned: "Although the regulation does not purport to provide an exclusive list of false and/or misleading claims, its scope is limited to claims *similar* to those listed. Plaintiff does not argue, nor could she, that premium pricing or the lack of a disclaimer regarding proportional clinical benefits of SPF 50+ products are similar to the claims precluded by the regulation." (*Ibid.*; italics in original.) Accordingly, the court granted defendant's motion to dismiss on grounds of express preemption.[12] The timing of compliance with the 21 Code of Federal Regulations section 201.327(g) prohibition was not before the court.

Neither federal decision is binding on us, but *Gisvold* is the more persuasive because that case, like this one, involved a plaintiff seeking a change in product labeling and advertising. In *Corra* the court assumed that a change in labeling was not involved.

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[11] *Gisvold* also distinguished a Florida district court case that found preemption commencing with publication of the Final Rule but not before. (See *Lombardo v. Johnson & Johnson Consumer Cos., Inc.* (S.D. Fla. Sept. 10, 2014, Civ. No. 13-60536-Civ-Scola) 2014 U.S. Dist. Lexis 156881.) The court in *Gisvold* noted: "'Lombardo is not attempting to enforce any sort of state labeling requirement in addition to the Final Rule.'" (*Gisvold, supra,* Slip. Op. at 6.)

[12] *Gisvold* also dismissed the complaint based on the doctrine of primary jurisdiction. (Slip. Op. at 6-8.)

Other federal cases have considered the preemptive effect of section 379r with respect to different nonprescription drug products. Over-the-counter cold medications were the target in *Carter v. Novartis Consumer Health, Inc.* (C.D.Cal. 2008) 582 F.Supp.2d 1271 (*Carter*). In that case plaintiffs claimed that the medications were unsafe and ineffective for children under age six, although they alleged no injury from use of the medications and sought recovery only for the money they paid for them. Their actions were brought under New Jersey consumer fraud statutes and common law claims for false and misleading advertising, deceptive business practices and breach of warranty. The complaint requested an injunction preventing defendants from falsely advertising and marketing the cold medicine as safe and effective for children under the age of six. The court observed that these medications are governed by FDA regulations, which, after a lengthy evaluation process, were issued on a range of subjects, including permissible active ingredients, dosages and mandatory labeling. The FDA determined that the medications should bear a warning that they not be administered to children under the age of two. (*Id.* at p. 1276.)

The court in *Carter* found that the claims were expressly preempted under section 379r and dismissed them. The court found that the relief sought by suits under state law constitute "requirements" that may be subject to preemption, citing Supreme Court cases that gave an "expansive reading" to that term. (*Carter, supra,* 582 F.Supp.2d at p. 1281.) And, turning to section 379r itself, the district court reasoned that subdivision (c)(2) "expands the universe of potentially preempted state law claims to include that those require additional warnings in the advertising for nonprescription drugs, and not only on the labeling." (*Id.* at p. 1282.)[13] The plaintiffs in *Carter* "do not allege that Defendants

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[13] Section 379r(c)(2) defines a "requirement that relates to the regulation of a drug" to include "any requirement relating to public information or any other form of public communication relating to a warning of any kind for a drug." The *Carter* court recognized that this provision did not mean that all advertising requirements are "automatically preempted," but that state requirements relating to public warnings that are "different from or in addition to" federal requirements *are* expressly preempted. (*Carter, supra,* 582 F.Supp.2d at pp. 1281-1282.)

fail to comply with FDA regulations as they currently exist, so none of their claims are parallel enforcement claims." (*Id.* at p. 1282.) (See § 379r(f) [no prohibition on state enforcement of a requirement identical to a requirement under the FDCA].) The court rejected the plaintiffs' argument that the relief they sought fell outside of federal requirements based on a purported general duty on defendant's part "not to deceive." (*Id.* at pp. 1282-1283.) It found that plaintiffs' interpretation of authority was mistaken, and failed to acknowledge the breadth of preemption embodied in section 379r: "The touchstone of preemption under § 379r is the *effect* that a finding of liability on a particular claim would have on the Defendants, and not the particular common law or state law theory upon which that claim was brought. As long as that claim imposes a 'requirement' that is at variance with FDA regulations, it is preempted." (*Id.* at p. 1283; italics in original.) Thus, a suit to add to product labels or alter "public information" or "public communication" from that required by the federal agency is foreclosed under section 379r.

The *Carter* decision is pertinent to the appeals considered here for another reason. Engel claims, based on comments in proposed regulations, that the FDA "banned" the use of the Labeling Terms long before it actually issued a regulation doing so. Eckler claims as a fact the lack of clinical benefit of SPF 50+ products, although the agency expressed merely a lack of sufficient evidence one way or the other on that issue. Both arguments are based on distortions of agency comments. In *Carter*, the plaintiff similarly sought to stretch the meaning of a proposal published in the Federal Register, a non-final recommendation that the agency did not adopt. (*Carter*, *supra*, 582 F.Supp.2d at p. 1276.) *Carter* recognizes that courts should avoid engaging in their own rulemaking when the agency's work is in progress.

Other federal cases applying section 379r follow *Carter*. In *Crozier v. Johnson & Johnson Companies, Inc.* (D.N.J. 2012) 901 F.Supp.2d 494, plaintiffs sued under New Jersey consumer statutes claiming that a first aid antiseptic spray, which accurately identified on its label the antiseptic ingredients, did not contain antibiotics. Plaintiffs contended that defendant's manner of marketing and advertising the product confused

and misled consumers to assume that an antibiotic was an ingredient. The district court held that claims pertaining to the product's label were expressly preempted under section 379r, although it declined to do so with respect to marketing claims. (*Id.* at pp. 503-505.)

In *Bowling v. Johnson & Johnson* (S.D.N.Y. Nov. 4, 2014, Case No. 14-CV-3727 (SAS)) 2014 WL 5643955, 2014 U.S. Dist. Lexis 155899 (*Bowling*), plaintiffs filed suit under state and federal consumer and warranty statutes claiming that defendant's mouthwash bore a label falsely representing that it "restored enamel." The court held that these claims were preempted by section 379r: "the FDA has issued a monograph directly on point but declined . . . to indicate . . . that 'Restores Enamel' is misleading. If successful, this litigation would do exactly what Congress, in passing section 379r of the FDCA, sought to forbid: using state law causes of action to bootstrap labeling requirements that are 'not identical with' federal regulation." (*Id*. Slip. op. at p. 9.) The district court explained that "the whole point of section 379r is that it is not up to private litigants – or judges – to decide what is 'false or misleading.' It is up to the FDA." (*Id*. Slip. op. at p. 11.) Concluding that the suit sought to "supercede the FDA's regulatory authority," the court held that plaintiff's claim was foreclosed.

Cases that have declined to find preemption have done so under statutory exceptions, or because label uniformity was not at issue. For example, the district court found no preemption in *Delarosa v. Boiron, Inc.* (C.D.Cal. 2011) 818 F.Supp.2d 1177. In that case plaintiffs used defendant's "natural" or "homeopathic" cold medicine but stayed sick. Unlike non-homeopathic over-the-counter drugs, however, homeopathic OTC drugs are not evaluated by the FDA at all. (*Id.* at p. 1182.) The court concluded that the homeopathic medicine was excepted from preemption under section 379r(d). (*Id.* at pp. 1186-1187.) Alternatively, the court found that for this product, there were no federal requirements that could be added to or departed from. Thus, the homeopathic cold remedy differed from the products in *Kanter* and *Carter* which – like the sunscreen

products at issue here – were drugs subject to FDA's comprehensive efficacy and labeling regulations. (*Id.* at p. 1189.)[14]

The intent of Congress expressed in the Modernization Act, both the history and terms of the FDA's regulations, and California and federal decisions establish a clear standard: State suits seeking to require product labels inconsistent with the federal objective of national labeling uniformity, and not congruent with the FDA's balanced effort to achieve such uniformity, are preempted. The question is whether under this standard appellants' suits are foreclosed.

**Appellants' claims are preempted**

With respect to Engel's action, the question is whether Neutrogena is liable for marketing products bearing the Labeling Terms before the FDA required it to stop doing so.

Placing into commerce a package of sunscreen bearing the terms "waterproof," "sweatproof," and "sunblock" became non-compliant with a federal regulation for the first time on December 17, 2012. Engel, however, insists that the FDA "banned" these Labeling Terms 18 year before the Final Rule. He is mistaken.

Contrary to Engel's contention, the FDA did not ban the labeling terms in 1993, 18 years before the Final Rule. As recounted above, for a time the FDA proposed permitting the terms "waterproof" and "sunblock," provided certain ingredient or testing conditions were met. In the August 27, 2007 proposed rule that preceded the Final Rule,

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[14] Other cases that have concluded that section 379r did not require preemption are inapposite. (See *Hunt v. McNeil Consumer Healthcare* (E.D.La. 2014) 6 F.Supp.3d 694, 699 [products liability action was expressly excepted from preemption by section 379r(e)]; *Dapeer v. Neutrogena Corp.* (S.D.Fla. Mar. 25, 2015, No. 14-22113-Civ.) 2015 WL 1395253, 2015 U.S. Dist. Lexis 37644 [in consumer claim against sunscreen manufacturer, plaintiff disavowed seeking change in how SPF is displayed on label]; *Langan v. Johnson & Johnson Consumer Cos., Inc.* (D.Conn. Mar. 31, 2015, No. 3:13-cv-01470(JAM)) 2015 WL 1476400 [challenge to use of "natural" on sunscreen labels; removing term would not impose state requirement different from that of FDCA].)

the FDA did not propose that the Labeling Terms be prohibited. (See 72 Fed.Reg. 49113-49114.) What Engel refers to as a ban by the FDA in 1993 was a proposed rule issuing a tentative final monograph to which further comments were invited. (58 Fed.Reg. 28194 (May 12, 1993).) The tentative final monograph was not an "order," as Engel argues, nor was it in any sense final. This proposed rule did not "ban" any of the Labeling Terms. The agency did express concern that "waterproof" could be confusing or misleading and proposed using the term "very water resistant" instead. (58 Fed.Reg. 28228.) But the FDA did not propose that "waterproof" be prohibited on sunscreen labels. The term "sweatproof" was not addressed at all, although the agency proposed the use of the term "sweat resistant." (*Ibid.*) And, contrary to appellants' contention, the FDA agreed that the "descriptive term 'sunblock' would be informative to users of OTC sunscreen drug products," and proposed how the term could be used in certain circumstances. (58 Fed.Reg. 28240.) To be sure, in the Final Rule, the FDA states that the Labeling Terms "are false or misleading, as we have stated in previous sunscreen rulemakings (58 FR 28194 at 28228; 64 FR 27666 at 276767 through 27680)." (76 Fed.Reg. 35643.) But a review of those previous comments, issued in conjunction with proposed rules and a monograph that never became effective, do not support that broad characterization. In any case, 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.

Engel seeks to declare that product descriptions on sunscreen labels that were, until the FDA's Final Rule, in compliance with federal law, nevertheless violated California law. He therefore seeks enforcement of a state requirement "that is different from or in addition to, or that is otherwise not identical with" a requirement under the FDCA, and thus, his suit is subject to section 379r's express preemption provision. (See *Kanter, supra,* 99 Cal.App.4th at p. 796 (assertion that approved label is inadequate and should be changed results in "establishment of a state requirement regarding labeling that would be 'different from' and 'otherwise not identical with' the federally required label

. . . is therefore preempted"); *Bowling, supra,* [2014 WL 5643955, 2014 U.S. Dist. Lexis 155899, Slip. op. at p. 11.] ["the whole point of section 379r is that it is not up to private litigants – or judges – to decide what is 'false or misleading.' It is up to the FDA."].)

Engel argues, however, that Neutrogena should be liable for non-compliant Neutrogena products marketed during the 18-month period after publication of the Final Rule to the December 17, 2012 compliance date. This was the period that the superior court concluded was a safe harbor reflecting a utilitarian cost-benefit analysis. As discussed above, the FDA assured manufacturers that they would have time to comply with the new testing and labeling regime and that non-compliant products could remain on the market. (76 Fed.Reg. 35624.) Engel, in other words urges that states may compel compliance with a federal requirement before the federal agency requires. This conflict is what Congress meant to avoid. The superior court was correct in concluding that the FDA intended to permit a reasonable time to achieve compliance and that the preemption doctrine nullifies a suit seeking to impose a requirement inconsistent with the agency's regulations. (See *Carter, supra,* 582 F.Supp.2d at p. 1283 ["touchstone of preemption under § 379r is the *effect* that a finding of liability on a particular claim would have on the Defendants . . . . As long as that claim imposes a 'requirement' that is at variance with FDA regulations, it is preempted."; italics in original]; *Lombardo v. Johnson & Johnson Consumer Cos. Inc.* (S.D. Fla. Dec. 19, 2013, Case No. 13-60536-Civ-Scola) 2013 U.S. Dist. Lexis 189043 [finding express preemption regarding sunscreen products sold after date Final Rule enacted and labeled before December 17, 2012 compliance date].)

Engel's claims are also impliedly preempted because they pose an obstacle to the accomplishment and execution of the full purposes and objectives of Congress and its delegated agency. (See *Dowhal, supra,* 32 Cal.4th at p. 923.) Engel seeks imposition of a labeling regime before the agency required manufacturers like Neutrogena to comply with it. This is contrary to Congress's intention of enacting uniform national labeling for nonprescription drugs, which the FDA is charged with implementing. As the recitation above of the history of FDA's regulatory process demonstrates, before it issued the Final Rule, the agency sifted through thousands of comments, reviewed scientific studies,

changed its position on the very terms in question – "waterproof" and "sunblock" – and determined what label information was necessary, truthful but unnecessary, and misleading. Appellant seeks to disrupt the careful weighing of conflicting considerations that Congress entrusted the agency to undertake. As our Supreme Court explained in *Dowhal,* enforcement of the Proposition 65 notice requirements – even with an express savings clause – were impliedly preempted by federal disclosure rules that reflected a nuanced balance of the need to provide accurate product information while not discouraging use of a product that could help pregnant women stop smoking. The state-required warning label in that case – even though truthful – could be prohibited because it conflicted with the federal purpose. (*Dowhal, supra,* 32 Cal.4th at pp. 928-931.) In this case, Engel seeks to usurp the federal agency's careful consideration of appropriate label requirements and restrictions, and its determination of the most reasonable phase-in of labeling requirements.[15] His suit conflicts with federal law by posing an obstacle to Congress's objective of national labeling uniformity.

Eckler's claim about the Labeling Terms falls with Engel's. Eckler's second labeling claim is that while Neutrogena accurately states the SPF value on its products, she maintains that consumers are likely to be misled about the efficacy of SPF 50+ products. Eckler requests that labels and advertising correct the allegedly misleading omission. Does Eckler's state law suit seek requirements in addition to or not identical to federal law? The answer is yes, and thus her suit is also expressly preempted. (See *Kanter, supra,* 99 Cal.App.4th at p. 795 ["when a state law claim . . . would effectively require a manufacturer to include additional or different information on a federally approved label, it is preempted"].) Eckler's SPF 50+ claim is based on a distorted reading of FDA regulations and on speculation about what consumers believe. Further,

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[15] Engel also asserts that he should be able to pursue claims for alleged violations after the compliance date. But Engel's 2006 complaint could not allege purchase of a non-compliant product after December 17, 2012, and thus he pleaded no injury or any basis for standing. Based on the pleadings before it, the trial court properly dismissed Engel's complaint with respect to this narrow time period as well.

in contrast to the claim arising from the Labeling Terms, her allegations about the efficacy of SPF 50+ products have never been endorsed by the FDA. It is true that in 1999, in a monograph that never took effect, the FDA proposed capping the SPF value at 30. The 2011 Proposed Rule considerably raises that limit. (76 Fed.Reg. 35672 (June 17, 2011).) In any case, the Proposed Rule is simply that: it offers a proposal, but asserts no final conclusions; it requests data. Eckler's suit would involve the state court in precisely the type of scientific inquiry and policy balancing that is within the expert agency's proper purview.

Eckler seeks disclosure language added to Neutrogena's product label and a corrective advertising campaign. Such an order is expressly preempted by section 379r(a) and (c). The conclusion of the *Gisvold* case, *supra*, is persuasive: "[I]n seeking to provide greater consumer protections, Plaintiff targets Merck's sunscreen label (which complies with current FDA regulations), and proposes a disclaimer regarding the level of sunscreen effectiveness beyond SPF 50. Because the proposed disclaimer plainly adds to and is not identical with the FDA's requirements, Plaintiff's action is expressly pre-empted under 21 U.S.C. § 379r." (*Gisvold, supra,* 2014 WL 6765718, 2014 U.S. Dist. Lexis 168955 (Slip. Op. at p. 4); fns. omitted.) Eckler's claim also seeks to impose state requirements "relating to public information" and is on that basis as well expressly preempted by section 379r(c)(2). (See *Carter, supra,* 582 F.Supp.2d at p. 1282 [section 379r(c)(2) "expands the universe of potentially preempted state law claims to include those that require additional warnings in the advertising for nonprescription drugs, and not only on the labeling"].)[16]

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16 Beyond the injunctive relief they seek, appellants' claims for purported economic injury are inextricably linked to their labeling and marketing claims. Eckler points to no affirmative representations by Neutrogena concerning added benefits of SP 50+ products, but she assumes that consumers will believe that a higher price "reinforced the deceptive message." (Eckler Reply at p. 24.) Eckler insists she is not alleging a "price premium misrepresentation." (*Ibid.*) Her claim of economic injury, like her efforts to modify public communications and product labeling, is preempted.

Finally, for the same reasons discussed concerning Engel's suit, we conclude that Eckler's action is foreclosed under the doctrine of implied preemption. That the FDA has not issued a final determination on the issue of products with SPF values above 50 is not a reason to permit suits like Eckler's. It is a reason to allow the federal agency to complete its Congressionally mandated objectives without states imposing a premature patchwork of disparate requirements. The FDA is evaluating the safety and effectiveness of SPF 50+ products because it had insufficient data; it therefore invited public comment. (See 76 Fed. Reg. 35672.) At this point, it is neither Congress's nor the FDA's objective to ban SPF 50+ products. The agency acknowledged that "sunscreen products with SPF values above 50 could have utility for consumers in certain settings. . . ." (76 Fed.Reg 35675.) It thus left open consideration of a labeling program that specifies when use of SPF 50+ products would be beneficial. Eckler's suit, on the other hand, demands that Neutrogena's products bear a label that denies any added benefit, for anyone, under any circumstances. Her suit would thus impose an obstacle to the FDA's goal of offering choices to consumers with different needs. The agency's interest in providing such choices is comparable to the circumstances underlying the implied preemption holding of the United States Supreme Court in *Geier*, *supra*, 529 U.S. 861. The Court held that a federal auto safety standard that required manufacturers to install either automatic seatbelts, airbags, or some other passive restraint device in their vehicles preempted a California tort suit seeking to hold a carmaker liable for failing to install airbags. The Supreme Court observed that the federal Department of Transportation deliberately permitted manufacturers "to choose among different passive restraint mechanisms." (*Id.* at p. 878.) Reasoning that a rule of state tort law requiring a single system of passive restraints "would have presented an obstacle to the variety and mix of devices that the federal regulation sought," the Court held that the state tort suit conflicted with the objectives of the federal standards and was, under the doctrine of implied preemption, foreclosed. (*Id.* at p. 881.) In the case before us, the benefits and uses of SPF 50+ products, and the appropriate range of choices that will be open to consumers, are what the FDA is investigating and is yet to pass judgment on. Eckler, though, denies such

investigation is needed and that such choices are desirable. Eckler's suit presents an obstacle to the agency's express interest in determining if such products may be advantageous in certain circumstances. Until the FDA issues a final rule on this topic, Eckler's claim usurps Congress's express goal of uniform national labeling and the FDA's mandate of determining efficacy based on scientific evidence and making balanced public policy judgments. Accordingly, Eckler's claim concerning SPF 50+ products is preempted. The superior court correctly dismissed the appellants' complaints. We need not address the other grounds urged for affirmance, including standing and primary jurisdiction, raised in respondent's brief.

**Disposition**

The judgment of the superior court is affirmed. Respondents are awarded their costs on appeal.

**IWASAKI, J.***

**We concur:**

**PERLUSS, P. J.** **ZELON, J.**

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*Judge of the Los Angeles Superior Court, assigned by the Chief Justice pursuant to article VI, section 6 of the California Constitution.