No. _____

IN THE SUPREME COURT OF THE STATE OF CALIFORNIA

CENTER FOR ENVIRONMENTAL HEALTH,

Plaintiff-Appellant,

v.

PERRIGO COMPANY, et al.,

Defendants-Respondents.

Appeal from a Judgment Based on an Order Sustaining Demurrers Without Leave to Amend

Court of Appeal, First Appellate District, Division One, No. A163682
Superior Court of the State of California for the County of Alameda
Case No. RG 20-054985
The Honorable Winifred Y. Smith, Presiding

PETITION FOR REVIEW

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PETITION FOR REVIEW

ISSUES PRESENTED

1. Does the federal "duty of sameness" between brand name and generic drugs apply to toxic contaminants that were never disclosed to the U.S. Food and Drug Administration ("FDA") during the drug approval process, that the FDA confirms should be addressed outside of the drug approval process, and that are present in radically different amounts in the brand name versus generic versions?
2. Should the "duty of sameness" be applied to impliedly preempt claims under California's Proposition 65 where Congress has enacted a savings clause in the federal Food, Drug, and Cosmetic Act ("FDCA") that expressly exempts Proposition 65 from federal preemption in the over-the-counter ("OTC") drug context on grounds of "uniformity"?
3. Even if applicable, does the "duty of sameness" in "labeling" extend to every permissible method of providing a Proposition 65 warning regarding toxic chemicals in OTC drugs, such as through advertisements, shelf signs, or electronic notifications?

I. INTRODUCTION AND SUMMARY OF ARGUMENT

By improperly applying the "impossibility" doctrine of implied preemption, the Court of Appeal has denied Californians the right to enforce Proposition 65, a protective measure enacted to safeguard consumers from toxic chemicals, as to the vast majority of OTC drugs. This directly conflicts with Congress' intent to have Proposition 65 serve as a backstop to the FDCA to protect consumers from being exposed to harmful contaminants in generic OTC drugs. In expressly carving Proposition 65 from FDCA's express preemption provision, Congress emphasized that Proposition 65 was instrumental in protecting consumers from harmful contaminants in consumer products generally, including antacid products specifically. Nevertheless, the Court of Appeal ignored Congressional intent and held that Proposition 65 was preempted as applied to harmful contaminants in antacid products specifically and in all generic OTC drugs generally. This decision leaves Californians with no remedy against toxic contamination in generic OTC drugs, which constitute most of the nonprescription drugs sold in California. Supreme Court review is necessary to ensure that OTC drug safety is regulated in the way Congress intended. *See generally Southern Cal. Chapter of Assoc'd Builders v. California Apprenticeship Council* (1992) 4 Cal.4th 422, 431 n.3 (federal preemption questions present vital issues of statewide importance that should be resolved by this Court).

The Court of Appeal made three critical errors that resulted in it finding federal preemption where Congress has directed the exact opposite result. First, it applied the "duty of sameness" – a doctrine requiring uniformity between three aspects of generic and brand name drugs – to undisclosed contaminants, which are far outside those three things.

Second, by applying this duty of sameness to find preemption, it ignored this Court's determination that Proposition 65 may not be impliedly preempted by the FDA or FDCA on the basis of uniformity. Third, the Court of Appeal disregarded 75 years of statutory and regulatory activity and held that any valid Proposition 65 warning for N-nitrosodimethylamine ("NDMA") – a potent carcinogen and contaminant that is found at high levels in Respondents' OTC acid reducing medications containing ranitidine (the "Products") – would constitute FDA-regulated "labeling" and thus is preempted.

The "duty of sameness" is entirely inapplicable to the Products because this duty does not extend to undisclosed drug contaminants such as NDMA. The duty is derived from the drug approval process, which allows for a truncated approval procedure for generic drugs that dispenses with the need for generic drug manufacturers to perform their own expensive safety testing by requiring such drugs to have certain identical design features as the brand name version earlier approved by the FDA. *PLIVA, Inc. v. Mensing* (2011) 564 U.S. 604, 612-13. Generic drugs must have precisely three things in common with the brand name version: (1) active ingredient, route of administration, dosage form, and strength, (2) rate and extent of absorption, and (3) safety "labeling." *Mutual Pharm. Co. v. Bartlett* (2013) 570 U.S. 472, 477. As to all other aspects, federal law allows generic drugs to be entirely different. In particular, the FDA has clarified that drug contamination issues are addressed ***outside*** of the federal drug approval process by obligations to follow "good manufacturing practices," which need not be identical and which would have solved the NDMA problem here. To be sure, neither Congress nor the FDA require toxic contaminant levels to be consistently maintained as between generic and brand name

drugs. In fact, the FDA's own testing of NDMA levels in Products shows that these levels fluctuate greatly as between Zantac and its generic counterparts – as much as a hundredfold difference. This fact also shows why labeling to warn for contaminants need not be the same: the generic versions may contain contaminants that the brand version does not, or at higher levels. Nonetheless, the Court of Appeal ruled that the "duty of sameness" applied to essentially all aspects of generic drug composition – ***even as to contaminants that are different between the brand name and generic versions of the Products***. This holding is both legally and logically flawed.

As Respondents acknowledged below, the point of allowing an abbreviated drug approval process for generic drugs is to permit them to be sold more cheaply. Generic drugs can only compete with brand name versions when they cost less. Here, the incentives to make drugs cheaper resulted in Respondents making them cheaply. The FDA has determined that NDMA in Products results from the use of tainted ingredients, poor manufacturing practices, and improper storage of the Products. Shockingly, the FDA was never informed of the NDMA issue during the drug approval process by ***any*** manufacturer. It was not until a third-party lab found NDMA in Products and informed the FDA that the agency stepped in, calling for all ranitidine to be withdrawn from the nationwide market based on the "unacceptable" cancer risk posed by this contaminant. Respondents knew or should have known about this NDMA problem – which extends back for ***years*** – much sooner. The underlying lawsuit seeks to prevent a "race to the bottom" by generic drug manufacturers and sellers who engage in such irresponsible corner-cutting.

In further error, the Court of Appeal failed to credit the Congressional intent to save Proposition 65 from preemption in the specific context of warnings on OTC drugs. *See* 21 U.S.C. §379r(a), (c)(2), (d)(2). In enacting this savings provision, Congress not only noted the complementary role Proposition 65 plays in making federally-regulated drugs safer, but specifically emphasized its importance ***in reducing "contaminants" from "antacids."*** Not a single member of Congress suggested that the savings provision would be inapplicable to generic drugs in most situations, as the Court of Appeal ruled. Although the existence of this savings provision does not altogether preclude a finding of implied preemption, this Court has held that it does disallow preemption of Proposition 65 on grounds of "uniformity." *See Dowhal v. SmithKline Beecham Consumer Healthcare* (2004) 32 Cal.4th 910, 926. The Court of Appeal failed to appreciate that the federal "duty of sameness" is such a "uniformity" function. Thus, implied preemption on this basis is forbidden.

Lastly, there are several means by which a valid Proposition 65 warning can be provided that do not constitute "labeling" subject to a generic duty of sameness under the FDCA. This includes public advertising, point-of-sale displays, and modern electronic means such as "pop-up" messages. Although the Court of Appeal relied on a 75-year-old U.S. Supreme Court case to suggest that "labeling" applies to any communication descriptive of a drug, this overlooks the various ways in which Congress and the FDA have since distinguished the term "labeling" from other communications relating to warnings (including "advertising"). In fact, the FDA has now promulgated a regulation defining what constitutes "labeling" and "advertising" under the FDCA and does not regulate "advertisements" relating to ***OTC*** drugs at all. That drug warnings

do not constitute FDA-regulated "labeling" is evident from the record: after the NDMA issue was uncovered, several generic drug manufacturers issued ***voluntary*** warning statements about the carcinogenic risks of NDMA in Products that both preceded and differed from warning statements made by the brand name manufacturer.

Because the Court of Appeal's ruling will hamstring statewide efforts to ensure OTC drug safety, it must be overturned. Allowing the ruling to stand emboldens Respondents and other similarly-situated companies to withhold information concerning dangerous contaminants from consumers as well as the FDA without suffering the significant penalties provided for under Proposition 65. That would be bad policy, and it is not the law.

II. STATEMENT OF THE CASE

A. FACTUAL BACKGROUND

Ranitidine is a popular OTC medication for the treatment of heartburn. (1AA:0071 (¶27).)[1] NDMA is a nitrosamine that is listed under Proposition 65 as a known carcinogen – in fact, the chemical is used to induce tumors in experimental animals during laboratory research. (1AA:0070-71 (¶¶22-23).) NDMA is not a Product ingredient, but a contaminant. (1AA:0071 (¶24); *see also* 1AA:0165.) According to the FDA, NDMA can form in Products through the use of contaminated ingredients, application of inferior manufacturing processes, and improper storage after manufacture. (1AA:0071 (¶24).)

[1] Factual citations herein to the Appellant's Appendix ("AA") will be provided with the volume number first and the page number last. Accordingly, the cite above is to vol. 1, p. 71 of the AA.

In June 2019, an independent laboratory informed the FDA of high levels of NDMA it had detected in Products. (1AA:0073 (¶36).) This was not an isolated issue, but a problem extending back many years. (*E.g.*, 1AA:0145 (alleging violations from March 2017 onward).) Respondents knew or should have known about the contamination issue much earlier. (1AA:0071, 0073 (¶¶24, 34, 36); *see also* 3AA:0939, 0943-44 (¶¶22-23, 39).)

Following these highly-publicized NDMA findings, various makers and sellers of ranitidine (including Respondents) began to pull their Products from the U.S. market. (1AA:0073 (¶36).) At the time, several Respondents voluntarily issued press releases warning consumers that NDMA is a "probable human carcinogen" that had been found in their Products. (3AA:0942 (¶32).) The public warning statements issued by the generic manufacturers preceded statements regarding NDMA in Products issued by the brand name manufacturer of Zantac, and these statements were not the same. (*Compare* 1AA:0135-38; *with* 3AA:0782-84.)

In November 2019, the FDA published the results of its preliminary NDMA testing on Products, including those sold by some of the Respondents. (3AA:0778-80.) Although NDMA was found in every product tested, the levels were highly variable as between generic and brand name Products: more than a hundredfold difference in some instances. (*Id.*) Expert testing in other pending ranitidine litigation has determined that the NDMA levels in generic Products are considerably higher than in the brand name version.

In April 2020, the FDA issued a formal request that all ranitidine manufacturers immediately withdraw these drugs from the U.S. market. (1AA:0165-66 (noting that NDMA levels found were "unacceptable" due

to cancer risk).) The FDA has never stated that there would be a conflict between Proposition 65 cancer warnings on Products and any federal standard, or otherwise indicated that adding such warnings would be inconsistent with the agency's views on drug warnings generally or the cancer risks of NDMA specifically. (3AA:0940-41 (¶¶28, 31).) To the contrary, because of the cancer risk presented by NDMA in the Products, the FDA will not allow them to be sold even today. (3AA:0994.)

B. LEGAL BACKGROUND

1. Proposition 65

Proposition 65, Health & Safety Code §§25249.5 *et seq.*, was passed in a 1986 referendum by nearly two-thirds of California's voters to protect themselves from toxic chemicals. (3AA:0717-20.) The statute provides that "[n]o person in the course of doing business shall knowingly and intentionally expose any individual to a chemical known to the state to cause cancer or reproductive toxicity without first giving clear and reasonable warning to such individual[.]" Health and Safety Code §25249.6. However, Proposition 65 only requires a warning where the exposure to listed chemicals from a given product is above certain risk thresholds. *Id.* §25249.10(c). Thus, a defendant may avoid Proposition 65 liability for consumer product exposures either by (a) providing a clear and reasonable warning, or (b) taking any number of steps to eliminate or reduce the levels of the listed chemical to below the level requiring a warning. Furthermore, the warning requirement does not apply to "[a]n exposure for which federal law governs warning in a manner that preempts state authority." *Id.* §25249.10(a).[2]

[2] The Court of Appeal re-wrote this exemption to read "… preempts state law authority ***governing warning***." Op. at 17 (emphasis added). While re-

Where warnings are required, Proposition 65 provides that they "need not be provided separately to each exposed individual and may be provided by general methods such as labels on consumer products, … posting of notices, placing notices in public news media, and the like, provided that the warning accomplished is clear and reasonable." Health & Safety Code §25249.11(f). Such warning may be provided via practically any form of public communication, including "product labeling, point-of-sale signs, or public advertising." *Dowhal*, 32 Cal.4th at 918. Proposition 65's regulations provide exemplary "safe harbor" warnings, *i.e.*, non-mandatory warnings deemed presumptively to be "clear and reasonable." 27 Cal. Code Regs. ("C.C.R.") §25600 *et seq.* The safe harbor regulations for consumer products such as OTC drugs allow warnings to be provided on labels, point-of-sale displays, shelf tags, and via any electronic device or process. *Id.* §25602(a).

2. Federal OTC Drug Regulation

a. Initial Drug Approval and Post-Approval Changes

The FDCA prohibits the sale of unapproved drugs. *See* 21 U.S.C. §355(a). One method by which the FDA approves OTC drugs is a New Drug Application ("NDA"). *See id.* §355(b). Under this process, the applicant provides details to the FDA on the drug's composition, ingredients, uses, efficacy, safety, and labeling. *Id.* §355(b)(1)(A). The FDA evaluates this information and determines if the drug is suitable for sale and consumption. *Id.* §355(c)-(d).

All of the Products at issue in this appeal were approved under the derivative equivalent of the NDA process for generic drugs – an

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writing a voted-enacted initiative to constrict its application is clearly wrong, this legal error is not central to this Petition.

Abbreviated New Drug Application ("ANDA") – applicable to ranitidine specifically. *See id.* §355(j). This ANDA process, as part of the contemporary federal regime for generic drug approval, was established in 1984 by the "Hatch-Waxman Act." Op. at 9. An ANDA is essentially a tag-along to a pre-existing NDA under which a generic drug manufacturer "can gain FDA approval simply by showing equivalence to a reference listed drug that has already been approved by the FDA." *Mensing*, 564 U.S. at 612-13 (explaining that "[t]his allows manufacturers to develop generic drugs inexpensively, without duplicating the clinical trials already performed on the equivalent brand-name drug"). In particular, the proposed generic drug and its approved brand-name counterpart must be identical in three – ***and only three*** – regards. They must (1) "have the same active ingredient …, route of administration, dosage form, and strength"; (2) "have the same rate and extent of absorption"; and (3) contain the same "labeling" based on these attributes. *Bartlett*, 570 U.S. at 477 (citing 21 U.S.C. §355(j)(2)(A)(ii)-(iv)) (internal quotations and brackets removed). This has been termed the "duty of sameness." *Mensing*, 564 U.S. at 613.

However, this "duty of sameness" does not extend to ***all*** aspects of generic drugs. *See* 21 U.S.C. §355(j)(2)(A). One example is ***inactive*** drug ingredients, which need not be the same as those found in the brand name version. *Compare id.* §355(j)(2)(A)(ii), *with id.* §355(j)(4)(H). Another example is undisclosed contaminants that may be present in the drug, which are not evaluated as part of the NDA/ANDA process. Accordingly, in a set of published guidelines on "impurities in drug substances" in the NDA/ANDA context, the FDA has stated that "extraneous contaminants … are more appropriately addressed as good manufacturing practice issues" and not as drug approval issues. (3AA:0733-34; 3AA:0751-53.)

Once a drug has been approved for sale by the FDA, changes to the NDA or ANDA – including "labeling" changes – can only be made in accordance with FDA regulations. *See* 21 C.F.R. §§314.70, 314.97. These regulations do not apply to matters that were never part of the NDA or ANDA to begin with.

b. The FDCA's Exclusive Savings Provision for Proposition 65 as Applied to OTC Drugs

In 1997, Congress added an express preemption provision to the FDCA entitled "National Uniformity for Nonprescription Drugs." 21 U.S.C. §379r. This provision broadly proclaims that "no State or political subdivision of a State may establish or continue in effect ***any*** requirement … that is ***different from*** or ***in addition to***, or that is otherwise ***not identical with***, a requirement under this Act." *Id.* §379r(a) (emphases added). Congress further specified that "[f]or purposes of subsection (a), 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." *Id.* §379r(c)(2) (emphases added). Thus, in the interest of promoting nationwide consistency, state-based requirements relating to as to OTC drugs are in most instances precluded by the operation of federal law. It is undisputed by the parties that all Proposition 65 claims as to NDMA in Products would be expressly preempted if 21 U.S.C. §379r ended there.

However, Congress also included an express savings clause: the prohibition in 21 U.S.C. §379r(a) "shall not apply to a State requirement adopted by a State public initiative or referendum enacted prior to September 1, 1997." 21 U.S.C. §379r(d)(2). "Proposition 65 is the ***only*** state enactment that falls within the savings clause." *Dowhal*, 32 Cal.4th at

919 (emphasis added). Thus, while Section 379r(a) broadly precludes the vast majority of state regulations that might bear upon OTC drugs in the name of national uniformity, Congress believed the public policies to be achieved by Proposition 65 to be so compelling that it ***uniquely*** preserved this California enactment from preemption under Section 379r(d)(2).

c. The Scope of OTC Drug Labeling

Under the FDCA, a drug "label" is "a display of written, printed, or graphic matter upon the immediate container of any article." 21 U.S.C. §321(k). In turn, the FDCA defines "labeling" as "all labels and other written, printed, or graphic matters (1) upon any article or any of its containers or wrappers, or (2) accompanying such article." *Id.* §321(m).

Like the "duty of sameness," the FDCA's definition of "labeling" is limited in scope. In particular, "labeling" does not extend to every method of providing a safety warning on a drug product. For instance, although drug warnings may be provided in advertisements, the FDCA expressly distinguishes "advertising" from "labeling" throughout the statute. *E.g.*, 21 U.S.C. §321(m) & (n) (defining "labeling" but referring to "labeling or advertising" as separate concepts).[3] Moreover, the FDCA does not in any way regulate ***OTC*** drug advertisements. *See*, *e.g.*, 21 U.S.C. §352(n)

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[3] *See also, e.g.*, 21 U.S.C. §331(n) (prohibiting reference to certain information "in labeling, advertising or other sales promotion"); *id.* §331(tt) (prohibiting certain representations "in a label or labeling or through the media or advertising" of tobacco products); *compare id.* §352(a)(1), (c), (e)(1)(B), (f)-(h), (j), (m), (p), (s), (v), (w), (z), (dd) (drugs and devices that are misbranded by "labeling"), *with id.* §352(q) & (bb) (drugs and devices that are misbranded by "advertising"); *id.* §354(b) (misbranding of veterinary feed directive drugs by "labeling" versus "advertising"); *id.* §360e(c)(2)(A)(iv) (applicant seeking premarket approval of Class III device must provide proposed "labels, labeling, and advertising").

(setting forth restrictions on "prescription drug advertising," but not OTC drugs); *id.* §352(x) (setting forth restrictions on "nonprescription drugs" without mentioning "advertising").[4] Thus, "[a]dvertisers of OTC drugs are not limited to using FDA-approved labeling language when advertising an OTC drug for an FDA-approved purpose." *Terry*, 2015 U.S. Dist. LEXIS 153970, at *8. The FDA does regulate ***prescription*** drug advertisements, but even in that context its regulations contain restrictions as to "contraindications" or "warnings" that may or must be included in such advertisements – including that such warnings must be the same as that "contained in required, approved, or permitted labeling for the advertised drug dosage form" – but specify that these warnings are ***not*** "labeling." 21 C.F.R. §202.1(e)(3)(iii), (l).

C. PROCEDURAL HISTORY

In February 2020, Appellant Center for Environmental Health ("CEH") filed its original Complaint regarding NDMA in Products, alleging violations of Proposition 65 for exposing Californians to known carcinogens without a warning. (1AA:0025-26.) CEH asserted claims against Respondents, as well as the brand name manufacturers. (1AA:0068-69.) All of the defendants below, including Respondents, demurred to CEH's then-operative Second Amended Complaint.

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[4] The FDA itself has confirmed this fact. (*E.g.*, 3AA:0769 ("The FDA ***does not*** oversee the advertising of over-the-counter (OTC) drugs. The Federal Trade Commission (FTC) is responsible for regulating OTC drug ads. The FDA regulates advertising only for prescription drugs.") (emphasis in original); 2AA:0399 (n.25) ("The [FTC] has primary responsibility for regulating the advertising of nonprescription drug products.").) Numerous cases are in accord. *E.g., Mylan Pharms., Inc. v. Procter & Gamble Co.* (S.D.N.Y. 2006) 443 F.Supp.2d 453, 460; *Terry v. McNeil-PPC, Inc.* (E.D. Pa. Nov. 13, 2015) 2015 U.S. Dist. LEXIS 153970, at *8.

(1AA:0077; 1AA:0244; 1AA:0263; 2AA:0325; 2AA:0526; 2AA:0625; 2AA:0643.) The lower court sustained the demurrers from Respondents without leave to amend, but allowed CEH leave to amend its pleadings against the brand name manufacturers to address whether the FDA regulations would allow a labeling change to add a Proposition 65 warning without FDA approval. (3AA:0907; 3AA:0921-22; 3AA:0925.)[5]

On appeal, the appellate panel upheld the lower court's demurrer ruling. First, the Court of Appeal ruled that Respondents' ability to add or strengthen a warning on the labeling for the Products is governed by the federal "duty of sameness" announced in *Bartlett* and *Mensing* even where the warning relates to the presence of contaminants in generic drugs. Op. at 20-23, 27-28. The Court suggested that CEH would have to pursue its relief against the brand name manufacturers instead. *Id.* at 12-13. Second, despite acknowledging that Proposition 65 may not be preempted on the grounds that state and federal warnings are not identical, the Court held that the generic "duty of sameness" is ***not*** such a uniformity requirement but a "consumer safety" requirement. *Id.* at 24-27. Third, while conceding that not all methods of publicly communicating a warning about a drug necessarily qualify as "labeling" subject to the "duty of sameness," the Court concluded that Proposition 65 claims are nonetheless preempted as impossible because CEH had identified no method of giving a "clear and reasonable" Proposition 65 warning that would not constitute such "labeling." *Id.* at 3, 38. Thus, the Court held that there is no way for

[5] Subsequently, CEH filed another amended pleading and survived a second preemption challenge on demurrer. (3AA:0934; 3AA:0951; 3AA:1195.) As a result, CEH's Proposition 65 enforcement action is still proceeding in the trial court, but against the brand name manufacturers only.

Respondents to comply simultaneously with state and federal law in providing cancer warnings on Products. *Id.* at 38.

In rendering its opinion, the Court of Appeal ignored the intent of Congress expressed as to each of these issues, which directly cut against its holding. It also made a series of incorrect statements of law, including that (1) Proposition 65 does not address contaminants, but only chemicals that are "deliberately added" to products (Op. at 12), (2) the onus is on CEH at the pleading stage to identify any and all methods of permissible warning that would circumvent Respondents' preemption defense (*id.* at 38); and (3) the only methods of warning that are clear and reasonable under Proposition 65 are those identified as "safe harbor" methods (*id.* at 35-36). Although these further statements are not dispositive to this Petition, they do evidence the Court's fundamental misunderstanding of many of the legal issues at play.

CEH hereby petitions this Court for further review.[6]

III. ARGUMENT IN SUPPORT OF REVIEW

This case presents several issues of statewide importance that had not previously been addressed by any California court at any level. Because the Court of Appeal's errors will profoundly limit the state law remedies available to California citizens seeking to avoid exposures to toxic contaminants in OTC drug products, the Court should review that decision.

A. The Court of Appeal Wrongly Construed the Federal Duty of Sameness to Apply to Undisclosed Contaminants in Drug Products.

The "duty of sameness" between generic drugs and their brand name

[6] CEH has not moved for a Petition for Rehearing before the Court of Appeal.

counterparts, despite this sweeping name, is not all-encompassing. Because it is wholly a creature of the FDCA and its implementing regulations, the duty is subject to numerous exceptions that allow generic drugs to be different from the brand name version. One example noted above is that inactive ingredients do not need to be the same, nor do warnings regarding such ingredients need to be the same due to different risks they may pose. *See* 21 C.F.R. §314.94(a)(8)(iv) (generic version of federally regulated drug may have different labeling from brand name counterpart based on different "formulation"); *Zeneca, Inc. v. Shalala* (4th Cir. 2000) 213 F.3d 161, 169 (different warning allowed on generic drug labeling based on inactive ingredients not found in brand name version).

As the Court acknowledged, "NDMA is a contaminant, not an intended ingredient of the drugs at issue." Op. at 11. This fact is dispositive in the present action because – like inactive ingredients – the federal duty of sameness does not apply to drug contaminants. Rather, the duty of sameness is premised on the assumption that the brand name and generic equivalents of the same drugs will have the same therapeutic effects and potential risks. This is the source of the cost-saving benefit of allowing generic drug manufacturers to piggyback on safety testing earlier done by the brand name manufacturer. Because any drug as designed by the brand name manufacturer has already been vetted by the FDA, an essentially identical generic version of that drug need not be subject to any further vetting. This is also the reason that the drug labeling must be the same: were this not so, "a labeling difference could 'inaccurately imply a therapeutic difference between the brand and generic drugs and thus could be impermissibly 'misleading.'" *Id.* at 10 (citing *Mensing*, 564 U.S. at 615).

Here, however, there ***is*** a "therapeutic difference" between brand name ranitidine and generic versions: they contain vastly different amounts of toxic NDMA. Indeed, the concentrations of NDMA found by the FDA in various ranitidine products differ from each other by as much as several orders of magnitude. (3AA:0778-80.) These facts demonstrate that the amount of NDMA in a particular Product is related to something ***outside*** the four corners of any FDA-approved NDA or ANDA.

Furthermore, it is undisputed that the presence of NDMA was never disclosed to the FDA during the NDA or ANDA process. Rather, NDMA is present in the drugs only as a result of shoddy manufacturing and storage processes or cheap, contaminated ingredients.[7] Thus, the FDA never had any opportunity to determine whether the cancer risks of ingesting ranitidine containing NDMA was acceptable during the drug approval process and, if so, what warnings should be included. The fact that the FDA agrees with CEH that the levels of NDMA found in the Products are "unacceptable" because of the cancer risk they present demonstrates that the agency would have had no objection to providing Proposition 65 cancer warnings.

The panel's opinion attempts to explain away these facts by

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[7] Respondents argued to the Court of Appeal that the Hatch-Waxman Act was designed to "bring[] more drugs more quickly and cheaply to the public." Opp. at 20. The ugly downside to this process is that generic manufacturers have incentives to use cheaper manufacturing process and cheaper ingredients, and then to withhold any attendant risks from the FDA. This appears to be what happened with NDMA in ranitidine. Certainly, there is no indication that Congress or the FDA believe that the policy aims to be served by allowing a truncated ANDA for generic drugs should ever allow consumers to be exposed to readily preventable levels of toxic contaminants.

suggesting that they merely show that certain generic ranitidine manufacturers must be ***violating*** the applicable duty of sameness. Op. at 28 n.17. This view has been squarely rejected by the FDA in a set of guidelines it published on "impurities in drug substances" in the NDA/ANDA context. As the FDA explained therein, "[e]xcluded from this document are … extraneous contaminants," which "are more appropriately addressed as good manufacturing practice issues" rather than in the drug approval process. (3AA:0733-34; 3AA:0751-53.) In other words, ***any*** drug manufacturer – whether brand name or generic – may take steps to reduce contaminants in their products at any time ***without*** FDA permission or approval. Were contaminants subject to a duty of sameness, then any time unwanted impurities were discovered in the brand name version of a product, a generic manufacturer would have a duty under federal law to ***introduce*** the same contaminants to their Products. This is not the law. Likewise, where manufacturers of generic drug products introduce harmful contaminants that are not present in the brand name version (or are found in greater concentrations), they cannot avoid taking action simply because the brand name manufacturer has done nothing.

The panel suggested that the sting of its preemption ruling would be softened by the fact the CEH still has viable Proposition 65 claims pending in the trial court against the brand name manufacturers. Op. at 12. But this ignores that the brand name version of ranitidine contains different levels of NDMA as compared to the generic versions. (3AA:0778-80.) In fact, the brand name manufacturer intends to argue to the trial court that Zantac contains levels of NDMA that are sufficiently low such that no Proposition 65 warning is required at all. *See generally* Health and Safety Code

§25249.10(c).[8] Thus, a Proposition 65 warning may be required on generic drugs where it is ***not*** required on the brand name counterpart. It makes no sense whatsoever to impose a duty of sameness on labeling for drugs that are not, in fact, the same.

Respondents have cited no case law from any jurisdiction applying the duty of sameness to contaminants other than a single opinion issued by the federal trial court in a pending product liability MDL relating to NDMA in ranitidine. *See In re Zantac (Ranitidine) Prods. Liab. Litig.* (S.D. Fla. 2021) 548 F.Supp.3d 1225. But there, the plaintiffs alleged that "ranitidine is a defectively designed molecule" that inevitably forms NDMA. *See id.* at 1251-52 ("Plaintiffs' design-defect theory remains … at the center of all of the Plaintiffs' claims," including their failure to warn claims). This "design-defect" allegation runs directly afoul of *Bartlett*, since drug re-design requires FDA approval and thus implicates "duty of sameness" concerns. *See Bartlett*, 570 U.S. at 483-84. CEH makes no such allegations here. (1AA:0071 (¶24).) And, as a further matter, the MDL's preemption decision is presently being appealed to the Eleventh Circuit, so it may not stand in any event.

The federal "duty of sameness" does not extend to aspects of drugs that are inherently not the same, and the FDA has specifically confirmed that contamination issues can and should be addressed completely outside of drug approval process without seeking the agency's blessing. To nonetheless maintain the fiction that this duty applies but has been

[8] In other pending litigation involving personal injury claims relating to NDMA in Products, the brand name manufacturer has already presented evidence that its ranitidine contains considerably less NDMA than generic ranitidine.

"violated," as the panel suggests, robs California citizens of a valuable tool in protecting themselves against undisclosed contaminants.

B. Applying the Impossibility Doctrine to Preempt Proposition 65 Claims Based on the Duty of Sameness Runs Contrary to Congressional Intent.

Compounding the error of its overbroad reading of the duty of sameness, the Court of Appeal ruled that this duty compels the application of implied impossibility preemption despite the Congressional decision to expressly – and uniquely – ***save*** Proposition 65 from preemption as to OTC drugs. Op. at 24-27 (discussing 21 U.S.C. 379r(d)(2)). But as this Court held in *Dowhal*, this savings provision prohibits federal preemption on the basis of uniformity. As applied to drug labeling, the duty of sameness ***is*** a uniformity rationale. Accordingly, the Court of Appeal's decision cannot stand.

The intent to preempt state law must be the "clear and manifest purpose of Congress." *Smiley v. Citibank (South Dakota) N.A.* (1995) 11 Cal.4th 138, 148. If there is any doubt about that intent as applied to the case at hand, implied preemption should be rejected. *See Solus Indus. Innovs., LLC v. Sup. Ct.* (2018) 4 Cal.5th 316, 332 (applying "presumption against preemption" of state law). Implied preemption is especially disfavored where a federal statute contains an express preemption clause because such express language "'implies' – *i.e.*, supports a reasonable inference – that Congress did not intend to pre-empt other matters." *Farm Raised Salmon Cases* (2008) 42 Cal.4th 1077, 1091-92.

In *Dowhal*, this Court specifically considered the impact of the savings provision in Section 379r(d)(2), finding that the existence of an express savings provision did not necessarily preclude the application of

implied preemption. *See* 32 Cal.4th at 926. However, this Court rejected the argument that "the savings clause, by nullifying the preemptive effect of 21 [U.S.C. §]379r(a), left the law of implied preemption, so far as Proposition 65 is concerned, as if neither were enacted." *Id.* Instead, to give effect to Congressional intent, this Court ruled that "[i]f the FDA's directive here prohibiting nonidentical labels is to be sustained, it must be on a basis relevant to consumer health, and not because the Proposition 65 label would frustrate the FDA's policy favoring national uniformity." *Id.*

Here, as applied to labeling, the duty of sameness is plainly a uniformity policy. It exists so drug consumers will not be misled into believing that generic drugs are different from their brand name counterparts. This is the same policy underlying uniformity. Indeed, in passing Section 379r(a), Congress emphasized that ensuring nationwide uniformity would "keep prices down" while "protect[ing] the public health" since there would be "no difference in the safety [or] proper labeling of OTC drugs from one state to another." 143 Cong. Rec. at S9821, S9845. These are precisely the same policy considerations as noted for the duty of sameness during the passage of the Hatch-Waxman Act: "Under this law, 'generic drugs' can gain FDA approval simply by showing equivalence to a reference listed drug that has already been approved by the FDA. … This allows manufacturers to develop generic drugs inexpensively[.]" *Mensing*, 564 U.S. at 612; *see also id.* at 612-13 ("A generic drug application must also show that the safety and efficacy labeling proposed is the same as the labeling approved for the brand-name drug.") (internal brackets and ellipses removed).[9] "Uniformity" and "sameness" are synonyms, and both of these

[9] Respondents agree: "Congress's intent in enacting the generic-drug duty of sameness was to ensure the provision of widespread and inexpensive

aspects of federal drug regulation serve the same function. Under these circumstances, to apply implied impossibility preemption effectively overrides the precisely expressed intent of Congress, to the detriment of California's citizens.

In finding CEH's claims nonetheless to be preempted, the Court of Appeal found that the "duty of sameness" should apply notwithstanding Section 379r(d)(2) because observing this duty "ensures that generic drugs are of the same safety … as their branded counterparts." Op. at 25-26. In the first place, it is demonstrably untrue that generic ranitidine is of the "same safety" as brand name Zantac, since the two sets of drugs contain vastly differing amounts of NDMA as a contaminant. No amount of testing on the brand name counterpart during drug approval would or could ensure the safety of contaminated generic versions. Secondly, the fact that the duty of sameness may, like the national uniformity provision of 21 U.S.C. §379r, have some effect on consumer safety (*e.g.*, by promoting the cheaper development of drugs, thereby rendering them more generally accessible) does not mean this duty is no longer a demand for "uniformity" between state and federal law.

The Court of Appeal's opinion runs afoul of *Dowhal* in a further way. In ruling there that the plaintiff's claims were preempted, this Court observed that *Dowhal* presented "an ***unusual case***; in most cases FDA warnings and Proposition 65 warnings would ***serve the same purpose*** – informing the consumer of the risks involved in use of the product – and ***differences in wording would not call for federal preemption***." 32 Cal.4th

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drugs to consumers[.]" Resp. Answer to AG Amicus Curiae Brief (Sept. 21, 2022), at 26.

at 934 (emphases added). *Dowhal* is an outlier among Proposition 65 preemption cases as it involved direct agency statements confirming the unavoidable conflict between state and federal law. It also confirms that preemption of Proposition 65 warnings by the FDCA is supposed to be rare, not something that should be widely presumed to apply to all generic OTC drugs.

Throughout the passage of Section 379r, not one member of Congress expressed the view – much less a "clear and manifest" view – that the savings provision for Proposition 65 would only be effective where a brand name manufacturer acted first to provide a warning. This is notable because Congress was perfectly aware of the Hatch-Waxman scheme established a decade earlier.[10] To the contrary, because Proposition 65 assists and strengthens federal law, Congress chose to preserve this statute alone when it comes to providing cancer warnings on OTC drug products. In fact, Congress contemplated ***the precise regulatory case at issue here***. As U.S. Senator Barbara Boxer explained during the passage of Section 379r, "Proposition 65 has successfully reduced ***toxic contaminants*** in a number of consumer products sold in California and it has even led the FDA to adopt more stringent standards for some consumer products." 143 Cong. Rec. S9811, S9843 (Sept. 24, 1997) (emphasis added). U.S. Senator Dianne Feinstein echoed these sentiments, specifically noting the removal of lead (a contaminant) from ***antacids*** as one of the statute's crowning achievements. *Id.* at S9844 (emphasis added).[11] These statements confirm

[10] The Court of Appeal speculated that this is because "section 379r was enacted several years before *Mensing*" (Op. at 26 n.16), but in that case the Supreme Court was simply announcing what Congress intended in 1984 when Hatch-Waxman was enacted.

[11] Surprisingly, the Court of Appeal appears to suggest that Proposition 65

that Congress believed concurrent regulation of OTC drugs under Proposition 65 and the FDCA would ***improve*** – not impede – federal policies regarding OTC drugs. They also confirm that Proposition 65 should be retained to provide complementary protections beyond those afforded by federal law in the specific context of ***"toxic contaminants" in "antacids."*** Congressional intent could not more clearly cut against preemption here.

Because the Court of Appeal's ruling does significant violence to the expressed intent of Congress in preserving Proposition 65, it should be rejected.

C. There Are Several Methods of Providing Valid Proposition 65 Warnings for NDMA in Products that Are Not "Labeling" Under the FDCA.

Even if one were to assume that the duty of sameness is applicable to contaminants and that uniformity concerns should be allowed to override the express savings provision for Proposition 65, it remains possible for Respondents to have provided valid Proposition 65 warnings through several means that do not constitute "labeling" under the FDCA. This is

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is not intended to regulate contaminants at all. Op. at 12 (emphasizing that "Proposition 65 is intended to regulate toxic substances that are ***deliberately*** added or put into the environment by human activity") (emphasis in original) (internal brackets and quotations removed). This is belied both by the Congressional statements above as well as by dozens of judicially-enforceable consent judgments entered into by the AG relating to contaminants in consumer products, including lead in antacids. *See* https://oag.ca.gov/prop65/litigation; https://oag.ca.gov/sites/all/files/agweb/pdfs/prop65/people_v_3m_antacids.pdf. The focus on "deliberately added" chemicals also overlooks a recent Court of Appeal ruling that Proposition 65 applies both to chemicals that a defendants knows about as well as those it reasonably ***should know*** about. *See Lee v. Amazon.com, Inc.* (2022) 76 Cal.App.5th 200, 236-37.

pertinent because impossibility preemption may only be found if "***all*** possible consumer product warnings that would satisfy Proposition 65 conflict with provisions of [federal law]." *Committee of Dental Amalgam Mfrs. & Distribs. v. Stratton* (9th Cir. 1996) 92 F.3d 807, 810 (emphasis in original). Because the Court of Appeal overlooked such methods, its decision was in error.

The Court of Appeal (unlike Respondents) recognized that "labeling" does not necessarily encompass all methods of providing a warning. Op. at 38. To be sure, there are many methods of providing "clear and reasonable" Proposition 65 warnings that do not involve statements on a drug label or in materials that accompany a drug product, such as by public advertising (which is an approved warning method under Proposition 65) or by shelf signs (which are allowed by Proposition 65's implementing regulations). *See* Health & Safety Code §25249.11(f); 27 C.C.R. §25602.[12] However, the Court of Appeal held that, even if not all warnings are "labeling," CEH's claims were preempted because "CEH fails to demonstrate that the generic-drug defendants could give Proposition 65 warnings by any method that would not constitute 'labeling' under the FDCA." Op. at 38. This is incorrect for several reasons.

As an initial matter, the Court of Appeal placed undue emphasis on a 75-year-old U.S. Supreme Court ruling suggesting that "labeling" includes broader communications (such as advertising) that "perform[] the function of labeling." *Kordel v. United States* (1948) 335 U.S. 345, 350-51. According to the Court, *Kordel* stands for the proposition that "labeling" is

[12] Other "general methods" by which any of the Respondents could have provided valid Proposition 65 warnings include postings on websites or over social media. Health & Safety Code §25249.11(f).

any communication that "supplements or explains" the drug in ***any*** regard, so long as "designed for use in the distribution and sale of the drug." Op. at 29. However, the Court ignored several statutory and regulatory developments in the intervening decades that significantly limit *Kordel*'s reach.

The first is the subsequent amendment of the FDCA to clarify that "labeling" does not extend generally to all communications about a drug. *Kordel* was decided nearly 40 years before Congress amended the FDCA to distinguish between labeling and advertisements as applied to prescription versus OTC drugs. *See* discussion *supra* Section II.B.2.c. Accordingly, courts that cite to *Kordel* nonetheless hold that "labeling" does not encompass all "advertising." *E.g., In re Lipitor Atorvastatin Calcium Mktg., Sales Practices, & Prods. Liab. Litig.* (D.S.C. 2016) 185 F.Supp.3d 761, 771-72. The FDA does not regulate advertising for OTC drugs at all, and even as to prescription drugs, the FDA not only recognizes but requires that communications ***defined*** as "advertisements" include warnings without being "labeling."[13] 21 C.F.R. §202.1(e)(3)(iii), (l). *Kordel* was also decided 50 years before Congress indicated in 21 U.S.C. §379r(c)(2) that "labeling" is narrower than "any … public communication relating to a warning of any kind." If Congress believed that labeling included all warnings, it would have used the term "labeling" here, as it did dozens of other times during the 1997 amendments to the FDCA. *See Roy v. Sup. Ct.* (2011) 198 Cal.App.4th 1337, 1352 (where Legislature uses different terminology, it means different things). The underlying legislative history

[13] While Respondents argue that the FDA's prescription drug regulation has no import on OTC drugs, that argument implies that the same defined term "labeling" means different things in different parts of the law.

confirms this interpretation: "The scope of national uniformity is modified to only apply to state requirements that relate to labeling and packaging or, if they go ***beyond labeling and packaging***, to requirements relating to ***warnings***." H.R. Rep. No. 105-399, at 103 (1997) (emphases added); *see also* 143 Cong. Rec. S9811, S9845 (Sept. 24, 1997) (distinguishing between "notification requirements" found "in ***labeling***, packaging or ***other form of public communication***") (emphases added). Any implication that *Kordel* governs all drug warnings thus is illegitimate.

The FDA has likewise limited *Kordel*'s sway by regulation. In direct response to the *Kordel* decision, the FDA promulgated a regulation defining "labeling" for prescription drugs as "[b]rochures, booklets, mailing pieces, detailing pieces, file cards, bulletins, calendars, price lists, catalogs, house organs, letters, motion picture films, film strips, lantern slides, sound recordings, exhibits, literature, and reprints and similar pieces of printed, audio, or visual matter." 21 C.F.R. §202.1(l)(2); *see also* 60 Fed. Reg. 42,581, 42,581 (Aug. 16, 1995) (confirming that this list of "examples" was meant to conform to same types of items at issue in *Kordel*). Notably, this regulation does ***not*** mention in-store signs or displays. Under the principle of *ejusdem generis*, courts should not read additional items of a different nature into such a particularized list. *See Kraus v. Trinity Mgmt. Servs., Inc.* (2000) 23 Cal.4th 116, 141. Thus, warnings may be provided on shelf signs without being construed as "labeling" under *Kordel*.

In reaching a different conclusion, the Court of Appeal relied on *American Meat Institute v. Leeman* (2009) 180 Cal.App.4th 728, a case decided under the federal Meat Inspection Act ("MIA"). The MIA requires all "labeling" to be approved by the U.S. Department of Agriculture ("USDA") prior to use. *Id.* at 737 (citing 9 C.F.R. §317.4(a)). There, the

USDA had expressly interpreted such "labeling" to include point-of-sale materials, and had stated that "it would likely regard as misleading any Proposition 65 warnings made in connection with meat inspected and approved by the USDA." *Id.* at 742, 751. Here, in contrast, the FDA has promulgated a regulation clarifying that point-of-sale materials are ***not*** "labeling" under the FDCA, there was no FDA pre-approval of any "labeling" relating to NDMA in Products, and the FDA has never stated that it believes Proposition 65 warnings for NDMA on Products would be inappropriate. Furthermore, the MIA contains no express savings clause as to Proposition 65, as does the FDCA, thus providing a further point of distinction. Accordingly, in circumstances more akin to the case at bar, courts have held that Proposition 65 warnings on point-of-sale signs are not "labeling." *E.g.*, *Chemical Specialties Mfrs. Ass'n, Inc. v. Allenby* (9th Cir. 1992) 958 F.2d 941, 944-46.

To the extent there is any doubt on the question of whether Respondents may provide warnings by general methods, the conduct of certain Respondents themselves following the third-party NDMA findings reveals that they can and did make public communications about this contamination without running afoul of FDA regulations. Respondent Apotex Corp. issued a press release in September 2019 announcing its "voluntary" recall of ranitidine, stating that NDMA is a "probable human carcinogen" and that this chemical had been found in its ranitidine. (1AA:0135-36.) These representations indisputably constitute a "warning," yet there was no prior FDA approval for these "warning" statements and no subsequent FDA admonishment. Indeed, since NDMA contamination was not part of any NDA or ANDA process for ranitidine, communications such as these show that Respondents are perfectly able to communicate with the

public using language that was not approved by the FDA at any time. Tellingly, the brand name manufacturer issued its own warning about NDMA in ranitidine a month later, but using completely different language. (3AA:0782-84.) If all communications relating to warnings were "labeling" subject to the duty of sameness, this would not have been possible.

The Court of Appeal considered the Apotex press release (and similar public statements by other generic manufacturers), but found them irrelevant because such warnings would not be "likely to be seen, read, and understood by an ordinary individual under customary conditions of purchase or use" so as to qualify as "clear and reasonable" under Proposition 65. Op. at 35 (citing 27 C.C.R. §25601(c)); *id.* at 38. This overlooks that warnings under Proposition 65 need not be perfect – they just need to reach enough individuals to meaningfully inform consumers of the risk. *See* Health & Safety Code §25249.11(f). Simply put, a regulated entity "does not have to use the best warning method to comply with Proposition 65." *People ex rel. Lungren v. Cotter & Co.* (1997) 53 Cal.App.4th 1373, 1380 (rejecting contention that Proposition 65 is "a de facto labeling statute"). Similar to class action notices sent to putative class members, advertisements, social media posts, or other general communications of a "push-media" nature can be made so as to reach practically all affected consumers. For instance, modern technology can enable "pop-up" warnings to be displayed to a putative consumer when that individual searches for a specific product online. The Court of Appeal's refusal to even consider such options essentially cuts off the public's right to protect themselves from these toxic exposures.

Puzzlingly, the Court of Appeal placed the burden ***on CEH*** to identify non-preempted methods of providing a Proposition 65 warning that would pass muster under the FDCA. Op. at 38. But this is not CEH's job – rather, "[t]he party who claims that a state statute is preempted by federal law bears the burden of demonstrating preemption." *Bronco Wine Co. v. Jolly* (2004) 33 Cal.4th 943, 956. This is especially true at the demurrer stage, where it is black letter law that a plaintiff is not required to anticipate and "plead around" a defendant's affirmative defenses. *See Stowe v. Fritzie Hotels, Inc.* (1955) 44 Cal.2d 416, 422. The adequacy of a Proposition 65 warning is a ***factual*** issue that should be developed and resolved initially by the trial court. At a minimum, CEH should be allowed discovery on what modes of public communications about drugs are presently used by Respondents, as well as what additional modes may be possible using contemporary technology. To deny CEH's right to relief entirely, as the Court of Appeals did, was improper.

For all of these reasons, the Court was wrong to say that Respondents could not have provided valid Proposition 65 warnings by means other than "labeling."

IV. CONCLUSION

The Court of Appeal's ruling will have devastating effects on the regulation of OTC drugs on a statewide basis. For all of the reasons stated herein, this Court should step in to prevent this unfortunate result.

Dated: April 18, 2023

Respectfully submitted,

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CERTIFICATE OF WORD COURT

I, Joseph Mann, hereby certify that this brief was produced on a computer, and that it contains 8,303 words, exclusive of tables, this Certificate, and the proof of service, but including footnotes, as calculated by the word count of the computer program used to prepare this brief.

Executed April 18, 2023, at San Francisco, California.

/s/ Joseph Mann
Joseph Mann

Attachment

Filed 3/9/23

CERTIFIED FOR PUBLICATION

IN THE COURT OF APPEAL OF THE STATE OF CALIFORNIA

FIRST APPELLATE DISTRICT

DIVISION ONE

CENTER FOR ENVIRONMENTAL HEALTH, Plaintiff and Appellant, v. PERRIGO COMPANY et al., Defendants and Respondents.	A163682 (Alameda County Super. Ct. No. RG20-054985)

Appellant Center for Environmental Health (CEH) sued respondents, various manufacturers and retailers of generic over-the-counter (OTC) antacids, claiming they failed to warn consumers that the products contained a known carcinogen under Proposition 65, the Safe Drinking Water and Toxic Enforcement Act of 1986, Health and Safety Code section 25249.5 et sequitur (Proposition 65).[1] CEH also sued two manufacturers of Zantac, the brand-name version of respondents' products.[2]

[1] Respondents are Dr. Reddy's Laboratories, Inc., and Dr. Reddy's Laboratories Louisiana, LLC (collectively, Dr. Reddy's), Perrigo Company, Target Corporation, Apotex Corp., Granules USA, Inc., and 7-Eleven, Inc. All further statutory references are to the Health and Safety Code unless otherwise noted.

[2] The brand-name manufacturers sued are Sanofi-Aventis U.S. LLC and Chattem Inc. Although they are not parties to this appeal, we discuss issues related to them to provide relevant context.

Respondents, whom we will refer to as the generic-drug defendants, demurred to the complaint on the basis that the federal Food, Drug, and Cosmetic Act, 21 United States Code section 301 et sequitur (FDCA), preempted CEH's claim. The remaining defendants, whom we will refer to as the brand-name defendants, demurred on the same basis. The trial court sustained the generic-drug defendants' demurrers without leave to amend and entered judgment in their favor. But the court sustained the brand-name defendants' demurrers with leave to amend, and CEH's action against them is proceeding below.

On appeal, CEH contends the trial court erred by ruling that conflict preemption bars CEH's claim against the generic-drug defendants on the basis that it would be impossible for them to comply with both state and federal law.[3] The court determined that the generic-drug defendants cannot give a Proposition 65 warning about the products without violating the federal duty of sameness, which requires the generic version of a drug to have the same "labeling" as the brand-name version. (See *PLIVA, Inc. v. Mensing* (2011) 564 U.S. 604, 612–613 (*Mensing*).) Given the broad definition of "labeling" under the FDCA, the court concluded there was no permissible method of giving a Proposition 65 warning without the manufacturer of the brand-name equivalent doing so first.

We affirm the dismissal of the action against the generic-drug defendants. Due to the unusual interplay between an express preemption provision governing OTC drugs and Proposition 65, the viability of CEH's suit against the generic-drug defendants turns on whether federal law governs warning in a manner that preempts state law governing warning.

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[3] The Attorney General filed an amicus curiae brief in support of CEH, as authorized under California Rules of Court, rule 8.200(c)(7).

We conclude that it does. Although we do not hold that *all* methods of publicly communicating a warning about a drug necessarily qualify as "labeling," CEH fails to identify any method by which the generic-drug defendants could provide a warning about their consumer products that would satisfy both Proposition 65 and the federal duty of sameness. As a result, until brand-name manufacturers give a Proposition 65 warning on their products' labeling, the generic-drug defendants cannot be required to do so.

I.
FACTUAL AND PROCEDURAL BACKGROUND

This lawsuit concerns OTC antacids with the active ingredient ranitidine. The following facts are taken from CEH's second amended complaint (SAC), and we accept them as true in reviewing whether the generic-drug defendants' demurrers were properly sustained. (See *Ace American Ins. Co. v. Fireman's Fund Ins. Co.* (2016) 2 Cal.App.5th 159, 164.)

The generic-drug defendants either manufacture or sell generic versions of ranitidine-containing antacids, which are also sold under the brand name Zantac. The chemical n-nitrosodimethylamine (NDMA), a known carcinogen that "is used in laboratory research to induce tumors in experimental animals[,] . . . can . . . form during the manufacturing process of certain drug products, such as those containing ranitidine."

In September 2019, after an independent laboratory found "significant quantities of NDMA" in ranitidine-containing antacids, the United States Food and Drug Administration (FDA) issued a public alert. Some

manufacturers voluntarily recalled their products.[4] A subsequent FDA analysis "determined that NDMA formation can occur in ranitidine through the use of contaminated materials and ingredients, the application of inferior drug manufacturing processes, and improper drug storage after manufacture." FDA testing also confirmed the presence of NDMA at varying levels in the generic-drug defendants' ranitidine products.

In April 2020, the FDA "request[ed that] manufacturers withdraw all prescription and [OTC] ranitidine drugs from the market immediately." CEH alleges that despite "the publicity and recalls," the generic-drug defendants "continued to expose individuals to NDMA without prior clear and reasonable warnings regarding the carcinogenic hazards of NDMA," and that this failure to warn is ongoing.[5]

CEH, as a nonprofit corporation acting in the public interest, originally sued Perrigo and Target in February 2020.[6] (See § 25249.7, subd. (d).) The remaining respondents, as well as the brand-name defendants, were subsequently added as defendants. The brand-name defendants manufacture and sell Zantac; Perrigo, Apotex, Granules, and Dr. Reddy's manufacture generic versions of Zantac; and 7-Eleven and Target sell generic versions of Zantac.

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[4] CEH filed a request for judicial notice of announcements by four companies, three of whom are generic-drug defendants, of voluntary recalls of ranitidine products. We deny the request as unnecessary to our decision.

[5] At oral argument, CEH's counsel stated that respondents stopped selling contaminated products several years ago.

[6] The presence of NDMA in Zantac and generic ranitidine products is also the subject of a multidistrict litigation in federal court. (See *In re Zantac (Ranitidine) Products Liability Litigation* (S.D. Fla. 2021) 548 F.Supp.3d 1225, 1228–1229.)

In January 2021, CEH filed the SAC, which alleged a cause of action for injunctive relief under Proposition 65 to prevent the defendants from selling the products "without providing prior clear and reasonable warnings" about "the carcinogenicity of NDMA." CEH also sought civil penalties and attorney's fees and costs.

All the defendants demurred to the SAC on the basis that CEH's claim was preempted by federal law. The brand-name defendants contended that it was impossible for them to add Proposition 65 warnings to their labeling unilaterally without violating federal law. Similarly, the generic-drug defendants contended that it was impossible to satisfy Proposition 65 without violating federal law governing labeling for generic drugs, which must always be the same as the labeling for the drugs' brand-name equivalents.[7]

In May 2021, the trial court issued an order sustaining the brand-name defendants' demurrers with leave to amend and the generic-drug defendants' demurrers without leave to amend. The following month, CEH filed a third amended complaint against the brand-name defendants only. A judgment dismissing the complaint against the generic-drug defendants was entered in August 2021, from which CEH appealed.

II.
DISCUSSION

A. General Legal Standards

1. Federal preemption and standard of review

"The Supremacy Clause provides that the laws and treaties of the United States 'shall be the supreme Law of the Land . . . any Thing in the Constitution or Laws of any state to the Contrary notwithstanding.' " (*Mut.*

[7] Apotex also unsuccessfully argued that CEH's claim was moot and failed due to field preemption. Apotex does not challenge the trial court's rejection of these arguments.

Pharm. Co. v. Bartlett (2013) 570 U.S. 472, 479 (*Bartlett*), quoting U.S. Const., art. VI, cl. 2.) Thus, "[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." (*Geier v. American Honda Motor Co., Inc.* (2000) 529 U.S. 861, 894.) "Similarly, federal agencies, acting pursuant to authorization from Congress, can issue regulations that override state requirements." (*Quesada v. Herb Thyme Farms, Inc.* (2015) 62 Cal.4th 298, 308.)

Express preemption occurs when Congress provides by statute that state law is preempted. (*Crosby v. National Foreign Trade Council* (2000) 530 U.S. 363, 372.) There are also various forms of implied preemption. Field preemption occurs "[w]hen Congress intends federal law to 'occupy the field.' " (*Ibid.*) And conflict preemption occurs in two main situations: (1) "where it is impossible for a private party to comply with both state and federal law" and (2) "where 'under the circumstances of [a] particular case, [the challenged state law] stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.' " (*Id.* at pp. 372–373.) Here, we are concerned only with the first type of conflict preemption, which we will refer to as impossibility preemption.

"Consideration of issues arising under the Supremacy Clause 'starts with the assumption that the historic police powers of the States [are] not to be superseded by . . . Federal Act unless that [is] the clear and manifest purpose of Congress.' " (*Cipollone v. Liggett Group* (1992) 505 U.S. 504, 516.) Since " ' "[c]ourts are reluctant to infer preemption, . . . it is the burden of the party claiming that Congress intended to preempt state law to prove it." ' " (*Viva! Internat. Voice for Animals v. Adidas Promotional Retail Operations,*

Inc. (2007) 41 Cal.4th 929, 936.) Congressional intent " ' "is the ultimate touchstone" ' of pre[]emption analysis." (*Cipollone*, at p. 516.)

We review de novo an order sustaining a demurrer. (*T.H. v. Novartis Pharmaceuticals Corp.* (2017) 4 Cal.5th 145, 162 (*T.H.*).) Likewise, whether state law is federally preempted is "a pure question of law" that we independently review. (*Farm Raised Salmon Cases* (2008) 42 Cal.4th 1077, 1089, fn. 10.) In deciding whether a demurrer was properly sustained, "[w]e are not bound by the trial court's stated reasons, if any, supporting its ruling; we review the ruling, not its rationale." (*Mendoza v. Town of Ross* (2005) 128 Cal.App.4th 625, 631.)

2. Proposition 65

"Proposition 65, which was passed as a ballot initiative in 1986, requires the state to develop and maintain a list of chemicals 'known to the state to cause cancer or reproductive toxicity.' " (*American Meat Institute v. Leeman* (2009) 180 Cal.App.4th 728, 735 (*Leeman*), quoting § 25249.8, subd. (a).) NDMA is listed as a known carcinogen. (Cal. Code Regs., tit. 27, § 27001, subd. (b).)[8]

Proposition 65 provides that "[n]o person in the course of doing business shall knowingly and intentionally expose any individual to a chemical known to the state to cause cancer or reproductive toxicity without first giving clear and reasonable warning to such individual, except as provided in Section 25249.10." (§ 25249.6.) In turn, section 25249.10 provides that section 25249.6 does not apply to "[a]n exposure for which the person responsible can show that the exposure poses no significant risk assuming lifetime exposure at the level in question for substances known to

[8] All further references to "Regulations" are to title 27 of the California Code of Regulations.

the state to cause cancer." (§ 25249.10, subd. (c).) Nor does section 25249.6 apply to "[a]n exposure for which federal law governs warning in a manner that preempts state authority." (§ 25249.10, subd. (a).)

The required warning under section 25249.6 "need not be provided separately to each exposed individual and may be provided by general methods such as labels on consumer products, . . . posting of notices, placing notices in public news media, and the like, provided that the warning accomplished is clear and reasonable." (§ 25249.11, subd. (f).) Regulations implementing Proposition 65 "describe optional 'safe harbor' warnings that are deemed to be clear and reasonable." (*Dowhal v. SmithKline Beecham Consumer Healthcare* (2004) 32 Cal.4th 910, 918 (*Dowhal*); see Regs., § 25600 et seq.) The safe-harbor warning for carcinogens reads, "This product can expose you to chemicals including [name of one or more chemicals], which is [are] known to the State of California to cause cancer. For more information go to www.P65Warnings.ca.gov." (Regs., § 25603, subd. (a)(2)(A).)

An action under Proposition 65 "fundamentally seeks a form of declaratory relief—that the product requires a warning." (*DiPirro v. Bondo Corp.* (2007) 153 Cal.App.4th 150, 182 (*DiPirro*).) Other remedies include injunctive relief and civil penalties. (§ 25249.7, subds. (a) & (b).)

3. The FDCA

The FDCA " 'regulates the manufacture, use, or sale of drugs.' " (*Merck KGaA v. Integra Lifesciences I, Ltd.* (2005) 545 U.S. 193, 196.) Under the FDCA, "a manufacturer seeking federal approval to market a new drug must prove that it is safe and effective and that the proposed label[ing] is accurate and adequate. [Citations.] Meeting those requirements involves costly and lengthy clinical testing." (*Mensing*, *supra*, 564 U.S. at p. 612, fn. omitted; 21 U.S.C. § 355(b)(1), (d).) A new drug application (NDA) "will be refused if

the FDA determines that the labeling is false or misleading in any particular, if the application contains an untrue statement of a material fact, or if the proposed labeling does not comply with . . . [applicable] regulations." (*Kanter v. Warner-Lambert Co.* (2002) 99 Cal.App.4th 780, 785, citing 21 U.S.C. § 355(d)(7) & 21 C.F.R. § 314.125(b)(6)–(8); see 21 U.S.C. § 352(a)(1) [drug is considered misbranded "[i]f its labeling is false or misleading in any particular"].)

The 1984 Drug Price Competition and Patent Term Restoration Act, 98 Stat. 1585 (21 U.S.C. § 355(j)), also known as the Hatch-Waxman Act, authorizes "a prospective generic drug manufacturer to file an abbreviated new drug application (ANDA) asserting the generic drug's bioequivalence to an existing listed drug that has already been approved by the FDA. . . . The streamlined application relieves the generic manufacturer of the need to duplicate the clinical trials previously submitted for the equivalent brand-name drug." (*T.H.*, *supra*, 4 Cal.5th at p. 157; *Mensing*, *supra*, 564 U.S. at p. 612.) Thus, manufacturers can develop generic drugs more cheaply and pass those savings to consumers. (See *Mensing*, at p. 612; *Andrx Pharmaceuticals, Inc. v. Biovail Corp.* (Fed. Cir. 2002) 276 F.3d 1368, 1370–1371.)

In addition to asserting bioequivalence, an ANDA "must also 'show that the [safety and efficacy] labeling proposed . . . is the same as the labeling approved for the [brand-name] drug.' " (*Mensing*, *supra*, 564 U.S. at pp. 612–613, quoting 21 U.S.C. § 355(j)(2)(A)(v).) The FDCA defines "labeling" as "all labels and other written, printed, or graphic matters (1) upon any article or any of its containers or wrappers, or (2) accompanying such article." (21 U.S.C. § 321(m).) While the brand-name manufacturer "bears responsibility for the accuracy and the adequacy of its label 'as long as the

drug is on the market,' " a generic manufacturer "is responsible only for 'an ongoing federal duty of "sameness." ' " (*T.H.*, *supra*, 4 Cal.5th at p. 157; *Mensing*, at p. 613.) The duty of sameness requires a generic manufacturer to ensure that its labeling is the same as the brand-name manufacturer's, both when its labeling is approved and thereafter. (*Mensing*, at p. 613; *T.H.*, at p. 157.) Otherwise, a labeling difference could "inaccurately imply a therapeutic difference between the brand and generic drugs and thus could be impermissibly 'misleading.' " (*Mensing*, at p. 615.)

In certain circumstances, the manufacturer of a brand-name drug can change the drug's labeling without FDA approval. "Generally speaking, a manufacturer may only change a drug label after the FDA approves a supplemental application." (*Wyeth v. Levine* (2009) 555 U.S. 555, 568; 21 C.F.R. § 314.70.) But under "the FDA's 'changes-being-effected' (CBE) process," a manufacturer can make certain changes to a drug's labeling without needing to "wait for preapproval by the FDA." (*Mensing*, *supra*, 564 U.S. at p. 614; 21 C.F.R. § 314.7(c)(6).) These include any "[c]hange[] in the labeling to reflect newly acquired information" that will "add or strengthen a contraindication, warning, precaution, or adverse reaction." (21 C.F.R. § 314.70(c)(6)(iii)(A).) Although the manufacturer of a generic drug can use the CBE process to "change[] its label to match an updated brand-name label or to follow the FDA's instructions," unlike a brand-name manufacturer it cannot use the process "to unilaterally strengthen [its] warning label[]." (*Mensing*, at p. 614.)

The FDCA contains a provision expressly preempting state law regarding OTC drugs. 21 United States Code section 379r (section 379r), titled "National uniformity for nonprescription drugs," provides that "no State or political subdivision of a State may establish or continue in effect

any requirement . . . [¶] (1) that relates to the regulation of a [nonprescription] drug . . . and [¶] (2) that is different from or in addition to, or that is otherwise not identical with, a requirement under this Act." (§ 379r(a).) For purposes of section 379r(a), "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." (§ 379r(c)(2).)

Proposition 65 is exempted from express preemption under section 379r by "a savings clause designed specifically to preserve [it]." (*Dowhal*, *supra*, 32 Cal.4th at p. 919.) Under the savings clause, section 379r does "not apply to a State requirement adopted by a State public initiative or referendum enacted prior to September 1, 1997." (§ 379r(d)(2).)[9] "Proposition 65 is the only state enactment that falls within the savings clause." (*Dowhal*, at p. 919.)

B. The Limited Nature of Our Holding

Before we analyze CEH's claims of error, we mention two aspects of this case that distinguish it from cases involving similar issues and that limit our holding and its practical effect. First, NDMA is a contaminant, not an intended ingredient of the drugs at issue. The SAC alleges that the products have been subject to recalls, but it also alleges that the generic-drug defendants continue to sell products containing NDMA. Although for

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[9] Section 379r also contains a second savings clause, under which nothing in the statute "shall be construed to modify or otherwise affect any action or the liability of any person under the product liability law of any State." (21 U.S.C. § 379r(e).) It is undisputed that this savings clause does not apply because CEH's claim does not involve California product-liability law, under which "injury to the plaintiff from a defective product is an essential element of a cause of action." (*Kanter v. Warner-Lambert Co.*, *supra*, 99 Cal.App.4th at p. 790.)

purposes of our review we must accept the allegation that contaminated drugs continue to be sold, our record does not reveal how the generic-drug defendants could continue to sell them without running afoul of the FDA. A lawsuit seeking to require warnings that the products contain NDMA—which, again, is not supposed to be in them at all—seems a poor way to address the potential danger to consumer health. Consumers would likely be better protected by removing the contaminated drugs from the market than by allowing the drugs' sale, even with a warning, in a contaminated state.

Proposition 65 is intended "to regulate toxic substances [that] are *deliberately* added or put into the environment by human activity." (*Nicolle-Wagner v. Deukmejian* (1991) 230 Cal.App.3d 652, 659, italics added.) Thus, regardless of preemption issues, a Proposition 65 warning about NDMA would only be required if it became acceptable for the drugs to contain the contaminant and the generic-drug defendants continued selling contaminated products. As a result, resolving whether CEH's claim is preempted because it seeks to impose a state-law "labeling" requirement is something of a theoretical exercise; as a practical matter, no such labeling is likely to result from this litigation.

Second, this appeal concerns only the generic-drug defendants. As we have said, CEH's claim against the brand-name defendants is proceeding below, based on the possibility that they could unilaterally add a Proposition 65 warning to their products through the CBE process. Putting aside the contamination issue, if CEH were to prevail and the brand-name defendants were required to provide a Proposition 65 warning on their products' labeling, then the generic-drug defendants would have to do so as well to comply with the federal duty of sameness. Thus, our holding that CEH's claim against the generic-drug defendants is preempted does not

foreclose the possibility that a Proposition 65 warning could be required for their products, so long as such a warning was first required of manufacturers of brand-name equivalents.

C. The Effect of the Statutory Preemption Provisions

We now turn to the preemption-related provisions of the FDCA and Proposition 65. It is undisputed that if not for the savings clause of section 379r, that statute would preempt CEH's claim because the claim seeks to establish a "requirement relating to public information or any other form of public communication relating to a warning of any kind for [an OTC] drug" that "is different from or in addition to, or . . . otherwise not identical with, a requirement under [the FDCA]." (21 U.S.C. § 379r(a)(2), (c)(2).) But because the savings clause of section 379r provides that the statute does not apply to Proposition 65 (21 U.S.C. § 379r(d)(2)), federal law does not expressly preempt suits under Proposition 65 involving OTC drugs.

Dowhal held that although section 379r's savings clause excludes Proposition 65 from express preemption, the clause "does not entirely exclude conflict preemption," that is, impossibility or obstacle preemption. (*Dowhal*, *supra*, 32 Cal.4th at pp. 923–924, 926.) *Dowhal* determined that *Geier v. American Honda Motor Co., Inc.*, *supra*, 529 U.S. 861 "established a general rule upholding conflict preemption even if the applicable federal law contains a savings clause" exempting a state requirement from express preemption. (*Dowhal*, at pp. 925–926.) Thus, if a Proposition 65 requirement is "in direct conflict with . . . or frustrate[s] the purpose of" an FDA requirement, the state requirement is preempted. (*Id.* at pp. 924, 926.)

Dowhal quoted, but did not discuss the effect of, Proposition 65's provision that section 25249.6 does not apply to "[a]n exposure for which federal law governs warning in a manner that preempts state authority."

(§ 25249.10, subd. (a); *Dowhal*, *supra*, 32 Cal.4th at p. 918.) Referring to this provision as Proposition 65's "self-exception," the trial court here concluded that it "does more than state the obvious, which is that federal law preempts state law." The court interpreted it to mean "that if federal law on warning preempts state law on warning, then there is no liability for an exposure under [section] 25249.6," regardless of the basis for that liability, "and thus the court cannot order any non-warning injunctive relief or award any penalties." Later in the order, the court also indicated that even if "the FDCA might not prevent the [manufacturers] from voluntarily putting Proposition 65 warnings in advertisements for the [p]roducts, the FDCA's regulation of warnings on labels and in label[]ing means that 'federal law governs warning in a manner that preempts state authority,' which means that [Proposition 65's] self-exception applies."

CEH claims the trial court erred by interpreting Proposition 65's self-exception to "compel[] preemption even in circumstances where the federal Constitution does not, *e.g.*, where the violations could be rectified by means other than providing a warning (such as reformulation), or where certain types of warnings may be precluded but others are not (*e.g.*, a label warning versus an advertisement warning)." In other words, CEH contends the court interpreted Proposition 65's self-exception "to mean that where federal law preempts ***any*** aspect of state authority under Proposition 65, Proposition 65 is wholly preempted."

We review issues of statutory interpretation de novo. (*Lopez v. Ledesma* (2022) 12 Cal.5th 848, 857.) Under " 'the ordinary rules and canons of statutory construction,' " which also apply to initiative measures, " '[w]e look first to the language of the statute, giving the words their ordinary meaning, and construing the statutory language in the context of the statute

as a whole and the overall statutory scheme.' . . . ' "We give the language its usual and ordinary meaning, and '[i]f there is no ambiguity, then we presume the lawmakers meant what they said, and the plain meaning of the language governs.' . . . Ultimately we choose the construction that comports most closely with the apparent intent of the lawmakers, with a view to promoting rather than defeating the general purpose of the statute." ' " (*DiPirro, supra*, 153 Cal.App.4th at pp. 190–191.) As " 'a remedial law, designed to protect the public,' " Proposition 65 must be " 'construe[d] . . . broadly to accomplish that protective purpose.' " (*Lee v. Amazon.com, Inc.* (2022) 76 Cal.App.5th 200, 226.)

It is not clear that the trial court interpreted Proposition 65's self-exception as broadly as CEH claims it did. In any event, the generic-drug defendants disclaim any interpretation under which Proposition 65 is wholly preempted if even one method of satisfying it is preempted. We agree with the parties that the self-exception does not mean that section 25249.6 would be inapplicable if federal law were to preempt a single type of warning that would otherwise be required under Proposition 65 but not other types of Proposition 65 warnings. For example, there is no dispute that federal law bars the manufacturer of a generic OTC drug from unilaterally putting a Proposition 65 warning on its product's container. Even though federal law thus governs warning in a manner that preempts *some* state authority, we decline to conclude that Proposition 65's self-exception therefore establishes a manufacturer cannot be liable for failing to warn in a manner that federal law *would* allow. Such a reading is inconsistent not only with the principle that Proposition 65 be interpreted in a manner that effectuates its remedial purpose but also with section 379r's savings clause, which expresses a congressional intent to permit Proposition 65 warnings involving OTC drugs.

The true dispute on appeal is whether Proposition 65's self-exception means, as CEH claims, that "compliance with Proposition 65 by any means must be completely impossible for Proposition 65 to be entirely preempted," or, as the generic-drug defendants claim, that a defendant is not liable under section 25249.6 if all possible *warnings* are preempted by federal law. We conclude that the generic-drug defendants have the better argument.

To begin with, the parties disagree about the potential methods of complying with section 25249.6. CEH claims that "a defendant may avoid Proposition 65 liability" for exposing consumers to consumer products that contain carcinogens "either by (a) providing a clear and reasonable warning, or (b) taking any number of steps to eliminate or reduce the levels of the listed chemical to below the level requiring a warning."[10] Similarly, the trial court indicated that a defendant can "avoid liability by either providing a warning or ensuring that its products have chemical exposure below the 'no significant risk' level."[11] The generic-drug defendants, however, reject this "novel 'dual compliance' construction of Proposition 65," arguing that "a duty to warn is the *only* duty imposed by [section 25249.6]." Likewise, in his

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[10] CEH identifies numerous examples of how manufacturers could reduce the amount of NDMA in the products at issue, including by "adopting better drug manufacturing practices," "storing the [p]roducts at lower temperatures," or "spot-testing [p]roducts . . . and not selling those that are found to contain high NDMA levels." For the sake of simplicity, we will refer to any action that would result in the products no longer containing an amount of NDMA requiring a warning as "reformulation."

[11] Elsewhere in the order, the trial court stated that "liability for an exposure under [section] 25249.6" may be "based on either lack of warning or knowing exposure to chemicals." This statement is puzzling, since "knowing exposure to chemicals" is not enough to establish liability. To the contrary, an entity is free to "knowingly and intentionally expose" consumers to carcinogens so long as it "first giv[es] clear and reasonable warning" it is doing so. (§ 25249.6.)

amicus curiae brief the Attorney General argues that "reformulation is not a statutory duty or requirement" under Proposition 65.[12]

In our view, the parties' positions on this issue do not substantively conflict. Section 25249.6 does "not apply" to an exposure to a low-enough level of a carcinogen (§ 25249.10), meaning CEH is correct that reformulation is one way to avoid liability under Proposition 65. But the generic-drug defendants and the Attorney General are correct that section 25249.6 itself does not impose a duty to reformulate, because exposures below a certain level are exempted from that statute's reach.

This is significant because even if reformulation is a potential remedy for a violation of section 25249.6, a suit under that provision fundamentally seeks to impose a state-law *warning* requirement, not a reformulation requirement. (See *DiPirro*, *supra*, 153 Cal.App.4th at p. 182.) In turn, Proposition 65's self-exception provides that section 25249.6 is inapplicable to an exposure if "federal law governs *warning* in a manner that preempts state authority." (§ 25249.10, subd. (a), italics added.) Thus, the most reasonable interpretation of Proposition 65's self-exception is that if federal law governs warning in a manner that preempts state law authority governing warning, there is no liability for exposing consumers to a regulated substance—meaning that *no* remedy, including reformulation, is available. CEH's interpretation, in contrast, would mean that even if it were impossible to comply with both federal and state warning requirements, a suit under

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[12] CEH also filed a request for judicial notice of the Attorney General's amicus curiae brief filed in another Proposition 65 appeal. CEH claims the brief shows that the Attorney General agrees that Proposition 65 "plainly contemplates two methods of compliance: providing a clear and reasonable warning ***or*** not exposing persons to listed chemicals." We deny the request, because whatever the Attorney General's position on this issue may be in a different case is not relevant to our decision.

section 25249.6 would never be preempted by the self-exception because federal law would never "govern[] *warning*" in a manner that preempted reformulation.

In sum, we conclude that Proposition 65's self-exception applies, and CEH's action against the generic-drug defendants cannot go forward, if federal law governs warning in a manner that preempts state law governing warning. Thus, the determinative issue is whether it is possible for the generic-drug defendants to provide warnings about their products that satisfy both Proposition 65 and federal law. If it is possible, then federal law governing warning does not preempt state authority governing warning, Proposition 65's self-exception does not apply, and CEH's suit may proceed. If it is not possible, then federal law governing warning preempts state authority governing warning despite section 379r's savings clause, Proposition 65's self-exception does apply, and CEH's suit against the generic-drug defendants may not proceed. Therefore, we turn to whether the generic-drug defendants could give warnings about their products that comply with both Proposition 65 and federal law.

D. CEH Identifies No Method by Which the Generic-drug Defendants Could Both Comply With the Federal Duty of Sameness and Give Warnings that Satisfy Proposition 65.

1. The generic-drug defendants' duties under state and federal law

Impossibility preemption exists "where 'compliance with both federal and state regulations is a physical impossibility.' " (*Arizona v. United States* (2012) 567 U.S. 387, 399.) The first step in determining whether this form of preemption applies is to identify a defendant's duty under state law. (*Bartlett*, *supra*, 570 U.S. at p. 480; *Trejo v. Johnson & Johnson* (2017) 13 Cal.App.5th 110, 153.) As noted above, Proposition 65 requires a company

to "giv[e] clear and reasonable warning" before "knowingly and intentionally expos[ing] any individual" to a carcinogen. (§ 25249.6.) The required warning "need not be provided separately to each exposed individual and may be provided by general methods such as labels on consumer products, . . . posting of notices, placing notices in public news media, and the like, provided that the warning accomplished is clear and reasonable."[13] (§ 25249.11, subd. (f).)

Regulations implementing Proposition 65 identify acceptable methods of providing warnings, although a party may "provid[e] a warning using . . . methods other than those specified . . . that nevertheless complies with [s]ection 25249.6." (Regs., § 25600, subd. (f).) For consumer products, "exposure warnings must be prominently displayed on a label, labeling, or sign, and must be displayed with such conspicuousness as compared with other words, statements, designs[,] or devices on the label, labeling, or sign, as to render the warning likely to be seen, read, and understood by an ordinary individual under customary conditions of purchase or use." (*Id.*, § 25601, subd. (c).) In addition to being placed "on the label," a warning may be conveyed "on a posted sign, shelf tag, or shelf sign, for the consumer

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[13] The potential liability for failure to give a Proposition 65 warning is more limited for retailers of consumer products than it is for manufacturers of those products. (See § 25249.11, subd. (f); Regs., § 25600.2; *Lee v. Amazon.com, Inc.*, *supra*, 76 Cal.App.5th at p. 231.) The parties do not address this distinction, and we therefore do not differentiate between the manufacturer respondents and the retailer respondents in our discussion of state-law duties. Likewise, although retailers of generic OTC drugs are not subject to FDA oversight, we follow the parties' lead and focus on the federal-law duties of manufacturers of those drugs. Ultimately, because we conclude that CEH's claim is preempted as to the manufacturer respondents, we need not determine whether there are additional reasons the claim fails as to the retailer respondents.

product at each point of display of the product"; or by "any electronic device or process that automatically provides the warning to the purchaser prior to or during the purchase of the consumer product, without requiring the purchaser to seek out the warning." (*Id.*, § 25602, subd. (a)(1)–(4).) If a product is sold by internet or catalog, a warning must also be provided through the website or in the catalog. (*Id.*, § 25602, subds. (b)–(c).)

Next, we address a generic manufacturer's duty to warn under federal law. (See *Bartlett*, *supra*, 570 U.S. at p. 486.) As *Mensing* discussed at length, a generic manufacturer has an ongoing duty to "ensur[e] that its warning label is the same as the brand name's." (*Mensing*, *supra*, 564 U.S. at p. 613.) We note that *Mensing* concerned generic prescription drugs, not OTC drugs. (*Id.* at p. 610.) But as another court observed in applying *Mensing* to OTC drugs, "[t]he key distinction in the relevant regulatory structure and case law is not between prescription and non-prescription drugs but between NDA holders and ANDA holders. The distinction makes a difference because of the [CBE] regulation, which permits NDA holders—but not ANDA holders—to 'add or strengthen' a warning on the product's label [citation], without waiting for preapproval from the FDA." (*Greager v. McNeil-PPC, Inc.* (N.D.Ill. 2019) 414 F.Supp.3d 1137, 1142.) Thus, we agree with the generic-drug defendants that the duty of sameness also applies to manufacturers of generic OTC drugs.

To be approved, an ANDA must include, with exceptions that are not relevant here, "information to show that the labeling proposed for the new drug is the same as the labeling approved for the [brand-name] drug." (21 U.S.C. § 355(j)(2)(A)(v); 21 C.F.R. § 314.94(a)(8)(iv).) An OTC drug's label must have a "Warning" or "Warnings" section that includes all applicable warnings from a specified list. (21 C.F.R. § 201.66(c)(5).) That list includes

warnings about particular side effects, contraindications for the product's use, and the need to consult a medical professional before taking the product. (*Ibid.*) Unlike a brand-name manufacturer, a generic manufacturer cannot "use[] the CBE process to unilaterally strengthen [its] warning labels." (*Mensing*, *supra*, 564 U.S. at p. 614.) Thus, a generic manufacturer can list on its labeling only warnings that are identical to the warnings listed on the brand-name manufacturer's labeling.[14]

Mensing concerned state-law tort claims that manufacturers of generic prescription drugs "fail[ed] to provide adequate warning labels" about the risk of a particular side effect. (*Mensing*, *supra*, 564 U.S. at pp. 608–610.) After explaining a generic manufacturer's ongoing duty of sameness, the Supreme Court concluded the manufacturers could not "use a different, stronger label than the label they actually used" without violating federal law, which "prevented [them] from independently changing their generic drugs' safety labels." (*Id.* at pp. 617–618.) Therefore, impossibility preemption barred the consumers' claims. (*Id.* at p. 618.)

In reaching this holding, *Mensing* rejected the consumers' arguments that the manufacturers could have complied with both state and federal law by (1) using the CBE process to change their labels, (2) using " 'Dear Doctor' letters to send additional warnings to prescribing physicians and other

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[14] As a result, a lawsuit may be preempted merely because it concerns a generic version instead of a brand-name version of the same drug. (See *Mensing*, *supra*, 564 U.S. at p. 625.) Here, the trial court relied on this distinction when it dismissed the suit against the brand-name manufacturers without prejudice and gave CEH leave to amend for it to allege, if possible, that the NDMA exposure was serious enough that the brand-name manufacturers could unilaterally add a Proposition 65-compliant warning to their labeling through the CBE process. (See 21 C.F.R. §§ 201.57(c)(6)(i), 314.70(c)(6)(iii)(A).)

healthcare professionals," or (3) "ask[ing] the FDA for help in strengthening the corresponding brand-name label."[15] (*Mensing*, *supra*, 564 U.S. at pp. 614–616, 619–620.) The Supreme Court determined that the first two methods were not available to the manufacturers. (*Id.* at pp. 614–615.) Specifically, deferring to the FDA's interpretation of its regulations, the Court concluded that generic manufacturers cannot use the CBE process to change warning labels unilaterally, and "Dear Doctor" letters qualify as "labeling" under the FDCA and its regulations. (*Ibid.*)

As for the third method, asking the FDA to change the labeling, *Mensing* concluded that it was insufficient to avoid impossibility preemption. (*Mensing*, *supra*, 564 U.S. at p. 621.) Even assuming the FDA was correct that generic manufacturers had a duty to propose "stronger warning labels to the agency if they believed such warnings were needed," preemption was not avoided based on the mere "possib[ility] that, had the [m]anufacturers asked the FDA for help, they might have eventually been able to strengthen their warning label." (*Id.* at pp. 616, 620.) The Supreme Court concluded that "[t]he question for 'impossibility' is whether the private party could *independently* do under federal law what state law requires of it," not whether "a third party or the Federal Government *might* do something that makes it lawful for a private party to accomplish under federal law what state law requires of it." (*Id.* at p. 620, some italics added.) The consumers' claims were preempted because state law required the generic manufacturers to strengthen their labels and federal law prevented them from doing so unilaterally. (*Id.* at pp. 623–624.)

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[15] "Dear Doctor" letters are mailings that drug manufacturers may be required to send to medical professionals conveying "important information about their products." (*Teva Pharmaceuticals USA, Inc. v. Superior Court* (2013) 217 Cal.App.4th 96, 104; see 21 C.F.R. § 200.5.)

Two years later, *Bartlett* applied *Mensing* to hold that "state-law design-defect claims that turn on the adequacy of a drug's warnings are pre-empted by federal law." (*Bartlett*, *supra*, 570 U.S. at p. 476.) The plaintiff sued the manufacturer of a generic prescription drug after she became "severely disfigured" by using it. (*Id.* at p. 478.) The First Circuit Court of Appeals held that her claim was not preempted, because "generic manufacturers facing design-defect claims could simply 'choose not to make the drug at all' and thus comply with both federal and state law." (*Id.* at p. 479.)

The Supreme Court reversed, concluding the manufacturer could not comply with both its state-law duty to ensure its product was not " 'unreasonably dangerous' " and its federal-law duty not to change its product's label unilaterally. (*Bartlett*, *supra*, 570 U.S. at pp. 480, 482.) The state-law duty could be satisfied only by redesigning the drug or changing its labeling. (*Id.* at p. 482.) Redesigning the drug was impossible because of the federal duty of sameness and because any altered composition "would be a new drug that would require its own NDA to be marketed in interstate commerce." (*Id.* at p. 484.) As a result, "the only way for [the manufacturer] to ameliorate the drug's 'risk-utility' profile," and thereby avoid liability under state law, "was to strengthen 'the presence and efficacy of [the drug's] warning' in such a way that the warning 'avoid[ed] an unreasonable risk of harm from hidden dangers or from foreseeable uses.' " (*Ibid.*) But that was impossible under *Mensing*, because the manufacturer could not unilaterally change its labeling to differ from the brand-name version's labeling. (*Bartlett*, at p. 486.) Finally, the Supreme Court rejected the " 'stop-selling' rationale" for finding no impossibility preemption as "incompatible with [the Court's] pre-emption jurisprudence." (*Id.* at p. 488.)

2. The effect of *Dowhal*

Before considering whether it is possible for the generic-drug defendants to give warnings that comply with both Proposition 65 and the federal duty of sameness, we address the Attorney General's argument that *Dowhal*, *supra*, 32 Cal.4th 910 provides the proper "framework for analyzing the preemption question in this case." According to the Attorney General, under *Dowhal*, section 379r's savings clause "preserves Proposition 65 from preemption in this case because [the] addition of a Proposition 65 warning for NDMA does not present any conflict with FDA requirements relevant to consumer health." *Dowhal* cannot sustain the weight the Attorney General places on it.

Dowhal addressed whether the FDCA preempted a claim that manufacturers of OTC "products containing nicotine sold . . . as aids to stop smoking" were required to place Proposition 65 warnings on the products. (*Dowhal*, *supra*, 32 Cal.4th at pp. 917–918.) Since "California listed nicotine as a chemical known to cause reproductive toxicity," Proposition 65 required the manufacturers to warn of the danger of reproductive harm. (*Id.* at p. 918.) The FDA, however, refused to permit the manufacturers to put such a warning on their products, because it did not want to discourage pregnant women from using the products to quit smoking. (*Id.* at pp. 918–919.) The FDA informed the manufacturers that they could warn only that nicotine might increase a baby's heart rate and advise pregnant women to seek professional advice before using the products. (*Id.* at p. 920.)

Dowhal held that the FDA's labeling policy preempted Proposition 65's warning requirement. (*Dowhal*, *supra*, 32 Cal.4th at p. 918.) The Supreme Court recognized that section 379r's savings clause still permits impossibility or obstacle preemption of Proposition 65. (*Dowhal*, at p. 924.) If a

Proposition 65 requirement is "in direct conflict with . . . or frustrate[s] the purpose of" an FDA requirement, the state law is preempted. (*Id.* at pp. 924, 926.) Since the FDA had "established a federal policy prohibiting [the] defendants from giving consumers any warning [about use during pregnancy] other than the one approved by the FDA . . . , the use of a Proposition 65 warning would conflict with that policy," and the suit was therefore preempted. (*Id.* at p. 929.)

Dowhal was careful to note that "a Proposition 65 warning cannot be preempted solely because it is not identical with [a] federal requirement," since section 379r's legislative history revealed that the provision's savings clause was intended to allow Proposition 65 warnings even if they resulted in different labeling in California. (*Dowhal, supra*, 32 Cal.4th at p. 926.) Thus, an FDA requirement can preempt a Proposition 65 warning only "on a basis relevant to consumer health, and not because the [warning] would frustrate the FDA's policy favoring national uniformity." (*Ibid.*)

The Attorney General claims that under *Dowhal*, Proposition 65 cannot be preempted in this case unless there is "a conflict, relevant to consumer health, between providing a Proposition 65 cancer warning for NDMA exposure . . . and the FDA's regulation of the[] products under the FDCA." He argues that the federal duty of sameness "serves the FDCA's national uniformity policy," not consumer health, and therefore "cannot be used to evade the savings clause" of section 379r.

We do not agree with the Attorney General's characterization of the federal duty of sameness. The duty of sameness "ensures that generic drugs are of the same *safety and effectiveness* as their branded counterparts." (*Fulgenzi v. PLIVA, Inc.* (6th Cir. 2013) 711 F.3d 578, 585, italics added.) By making it easier to obtain FDA approval for generic drugs, the Hatch-

Waxman Act "recognized that conducting new human clinical trials for generic drugs was 'unnecessary and wasteful' where demonstrating sameness was enough to show the drug to be 'safe and effective.' [Citation.] The Hatch-Waxman Act's cost savings, therefore, were accomplished without [compromising] the FDCA's core safety policies." (*Fulgenzi*, at p. 586.) Thus, the duty of sameness is meant to ensure consumer safety, not merely uniformity in labeling.

Moreover, *Dowhal*'s conclusion that "a Proposition 65 warning cannot be preempted solely because it is not identical with [a] federal requirement" was based on the need to give effect to section 379r's savings clause. (*Dowhal*, *supra*, 32 Cal.4th at p. 926.) Our state Supreme Court rejected the argument that "any nonidentical state warning would constitute misbranding," as that "would nullify the savings clause . . . , which plainly permits Proposition 65 warnings that differ from the FDA warnings." (*Id.* at p. 934.) But here, a determination that the federal duty of sameness prevents the generic-drug defendants from unilaterally adding Proposition 65 warnings to their labeling would not nullify section 379r's savings clause. Rather, the clause preserves the ability of brand-name manufacturers to use the CBE process to add a Proposition 65 warning that is not identical to federal requirements.[16] In turn, if brand-name manufacturers added

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[16] CEH claims it would be "a surprising result" if section 379r's savings clause preserved Proposition 65 claims against brand-name manufacturers only, since nothing in the legislative history of section 379r suggests Congress thought the savings clause "would be wholly inoperative for generic OTC drugs unless the brand[-]name manufacturers provided such warnings." But section 379r was enacted several years before *Mensing* made clear that even if it may seem arbitrary, due to the federal duty of sameness a claim against a generic manufacturer may be preempted where the identical claim against a brand-name manufacturer is not preempted. (See *Mensing*, *supra*, 564 U.S. at p. 625.)

Proposition 65 warnings to their ranitidine products, the generic manufacturers would have to do so as well.

It is also significant that *Dowhal* was decided several years before *Mensing* and *Bartlett* clarified that impossibility preemption bars a claim if a defendant cannot *independently* comply with state law without violating federal law. In *Dowhal*, the manufacturers sought approval from the FDA to add a Proposition 65 warning, but the FDA denied the requests, offering the policy justification on which our state Supreme Court relied to find conflict preemption. (*Dowhal*, *supra*, 32 Cal.4th at pp. 920–921, 922, 929.) Thus, *Dowhal* had no reason to address whether the suit was preempted for the separate reason that the manufacturers could not add a Proposition 65 warning without first obtaining FDA approval. But here, even if the mere lack of identity between a Proposition 65 warning about NDMA and federally required labeling does not suffice to establish preemption under *Dowhal*, CEH's claim is still preempted if it would require the generic-drug defendants to obtain FDA approval before giving such a warning.

In short, we do not agree that *Dowhal* is determinative. Therefore, we proceed to address whether it is impossible for the generic-drug defendants to comply with their federal-law duties and Proposition 65's warning requirement.

3. CEH's claim is preempted.

The generic-drug defendants argue that CEH's claim is preempted under *Mensing* and *Bartlett* because those cases, and subsequent decisions applying them, stand for the proposition that "any state-law claim that imposes a legal duty to issue some *other* type of warning that is *not* on the brand-name label conflicts with federal law and is preempted." We need not decide whether *Mensing* and its progeny establish such a sweeping principle

or whether, as CEH claims, the trial court incorrectly determined that "***any and all*** communications involving a warning are properly characterized as 'labeling' that require FDA approval." Rather, because CEH fails to identify a method by which the generic-drug defendants could give a Proposition 65 warning that would not constitute "labeling" under the FDCA, we conclude that the federal duty of sameness renders it impossible for the generic-drug defendants to comply with both state and federal law under *Mensing*.[17]

Our determination rests on the broad definition of "labeling" under the FDCA. We begin by discussing two decisions that are crucial to our analysis, *Kordel v. United States* (1948) 335 U.S. 345 (*Kordel*) and *Leeman*, *supra*, 180 Cal.App.4th 728. We then explain why the two primary methods CEH proposes in which the generic-drug defendants could give Proposition 65 warnings without violating the duty of sameness—point-of-sale displays and "public advertising"—do not avoid preemption.

a. *Kordel* and *Leeman*

As noted above, the FDCA defines "labeling" as "all labels and other written, printed, or graphic matters (1) upon any article or any of its containers or wrappers, or (2) accompanying such article." (21 U.S.C.

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[17] In reaching this conclusion, we reject CEH's argument that the duty of sameness does not apply because this case involves the generic-drug defendants' "undisclosed contamination of the [p]roducts with NDMA." The fact that the generic-drug defendants may have *violated* the duty of sameness by selling products that contained different amounts of NDMA than did the brand-name versions does not mean that the duty is inapplicable to Proposition 65 warnings about NDMA. Rather, because CEH's suit seeks to impose a warning requirement, we must consider whether the generic-drug defendants could give a Proposition 65 warning while complying with the duty of sameness, even though reformulation is the more realistic response to contamination. For the same reason, the possibility of reformulation cannot save CEH's claim from preemption if all possible methods of giving Proposition 65 *warnings* would conflict with federal law.

§ 321(m).) In *Kordel*, the United States Supreme Court addressed this definition in the context of a criminal case. (*Kordel*, *supra*, 335 U.S. at pp. 346–348.) The defendant was found guilty of introducing misbranded drugs into interstate commerce, which required a finding that the drugs' " 'labeling [was] false or misleading in any particular' " or did not "bear[] 'adequate directions for use.' " (*Id.* at pp. 346–347.) "The alleged misbranding consist[ed] of statements in circulars or pamphlets" about the products' efficacy. (*Id.* at p. 346.) The defendant provided the materials to vendors, who in turn "distributed [them] to consumers" through means including displaying them in stores, giving them away with the sale of the products, or mailing them. (*Id.* at pp. 346–347.) The issue was whether the fact that some of this "literature . . . was shipped separately from the drugs and at different times . . . saved the drugs from being misbranded" because the literature did not "accompany[] such article" and was therefore not "labeling" under the statutory definition. (*Id.* at pp. 347–349.)

Kordel held "that the phrase 'accompanying such article' is not restricted to labels that are on or in the article or package that is transported." (*Kordel*, *supra*, 335 U.S. at p. 349.) The Supreme Court reasoned that the phrase did not by its terms require labeling to be on or in the same package or container as the drugs: "One article or thing is accompanied by another when it supplements or explains it, in the manner that a committee report of the Congress accompanies a bill. No physical attachment [of] one to the other is necessary." (*Ibid.*) Since "[t]he false and misleading literature . . . was designed for use in the distribution and sale of the drug[s]" as part of "an integrated distribution program," it qualified as "labeling." (*Ibid.*)

In *Leeman*, the Fourth District Court of Appeal relied on *Kordel* in holding that the Federal Meat Inspection Act (FMIA) "expressly preempts point of sale warning requirements imposed by Proposition 65 with respect to meat." (*Leeman*, *supra*, 180 Cal.App.4th at pp. 735, 752–753.) The FMIA's preemption statute provides in relevant part that " 'labeling . . . requirements in addition to, or different than, those made under this chapter may not be imposed by any State.' " (*Leeman*, at pp. 748–749, quoting 21 U.S.C. § 678.) The *Leeman* plaintiff did not "dispute that a Proposition 65 warning is in addition to, or different than, any requirement set forth in the FMIA," nor "that a Proposition 65 warning affixed directly to a package containing meat would constitute 'labeling' within the meaning of the FMIA's preemption provision." (*Leeman*, at p. 749, italics omitted.) Rather, she argued that "point of sale warnings do not constitute 'labeling,' and thus, Proposition 65 does not create 'labeling . . . requirements in addition to, or different than, those made under [the FMIA].' " (*Ibid.*, italics omitted.)

Leeman rejected the plaintiff's position, holding that point-of-sale warnings qualify as "labeling requirements" under the FMIA's preemption provision. The definition of "labeling" under the FMIA was taken from the FDCA, and likewise provides that the term means " 'all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article.' " (*Leeman*, *supra*, 180 Cal.App.4th at p. 752 & fn. 27, quoting § 21 U.S.C. § 601(p).) The Fourth District determined that in importing the FDCA's definition to the FMIA, Congress intended that *Kordel*'s interpretation of "labeling"—to refer to "material that accompanies a product in the sense that it 'supplements or explains it,' but is not necessarily physically attached"—applies to the FMIA as well. (*Leeman*, at p. 757.) *Leeman* then concluded that under

Proposition 65 "a properly designed point of sale warning will 'supplement[] or explain[]' the meat offered for sale in that it will give consumers additional information about the product" and "will necessarily be 'designed for use in the distribution and sale' of the product," meaning a point-of-sale warning qualifies as "labeling" under *Kordel*. (*Leeman*, at p. 761, quoting *Kordel*, *supra*, 335 U.S. at p. 350.)

b. Point-of-sale warnings

We agree with *Leeman* that "labeling," as interpreted by *Kordel*, includes point-of-sale warnings under Proposition 65. A point-of-sale warning is "designed for use in the distribution and sale of the drug" and "supplements or explains" the drug. (*Kordel*, *supra*, 335 U.S. at p. 350.) Indeed, some of the material that *Kordel* found to be "labeling" under the FDCA was "literature . . . displayed in stores in which the [defendant's] products were on sale." (*Id.* at p. 346.) In turn, since the manufacturer of a generic drug cannot deviate from the labeling of the brand-name version of the drug, it would be impossible for the generic-drug defendants to give a Proposition 65 point-of-sale warning without violating the federal duty of sameness.

CEH attempts to distinguish *Leeman* from this case but does not explain why the identified distinctions suggest *Leeman*'s interpretation of "labeling" to include point-of-sale warnings is inapplicable. For example, it is not apparent why it matters that "the FDA has never stated that it believes Proposition 65 warnings for NDMA on [the generic-drug defendants' products] would be inappropriate." As *Mensing* makes clear, the duty of sameness makes it "impossible" for a generic manufacturer to change its labeling unilaterally even if the FDA has no specific objection to the change. Nor is it apparent why the fact that the FMIA has no express savings clause

matters. As *Dowhal* makes clear, a Proposition 65 claim involving OTC drugs may be preempted despite section 379r's savings clause.

CEH also states that "*Leeman* failed to note the . . . observation in *Dowhal* that 'point-of-sale signs' are ***not*** 'product labeling.' " In the cited portion of *Dowhal*, however, our state Supreme Court was not addressing the FDCA's definition of "labeling" but merely summarizing the content of a former Proposition 65 regulation as providing that a "warning may be communicated through product labeling, point-of-sale signs, or public advertising." (*Dowhal*, *supra*, 32 Cal.4th at p. 918.) The fact that the Court differentiated between these three categories sheds no light on the definition of "labeling" under the FDCA. In any case, to the extent *Dowhal* could be read to suggest that point-of-sale signs are not "labeling," that would conflict with *Kordel*'s conclusion that materials displayed in stores *are* "labeling." (See *Kordel*, *supra*, 335 U.S. at pp. 346, 350.)

CEH also points out that the Ninth Circuit Court of Appeals rejected a "broad reading of *Kordel*" and suggests we do the same. In *Chemical Specialties Mfrs. Ass'n, Inc. v. Allenby* (9th Cir. 1992) 958 F.2d 941 (*Allenby*), the Ninth Circuit addressed an action in which the plaintiff trade association sought a declaratory judgment that the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) preempted Proposition 65 warning requirements. (*Allenby*, at pp. 942, 945.) FIFRA defines "labeling" in relevant part as "all labels and all other written, printed, or graphic matter—[¶]
(A) accompanying the pesticide or device at any time; or [¶] (B) to which reference is made on the label or in literature accompanying the pesticide or device." (7 U.S.C. § 136(p)(2).) Thus, like the FDCA, FIFRA includes material "accompanying" the product in its definition of "labeling." (7 U.S.C. § 136(p)(2); 21 U.S.C. § 321(m).)

The trade association argued that Proposition 65 was preempted because "FIFRA expressly prohibits states from imposing labeling requirements that differ from those registered with the [Environmental Protection Agency (EPA)]," and "the warnings required under Proposition 65 fall squarely within FIFRA's definition of 'labeling.' " (*Allenby*, *supra*, 958 F.2d at p. 945.) The Ninth Circuit disagreed, concluding that point-of-sale warnings are not "labeling" under FIFRA. (*Id.* at pp. 946–947.) *Allenby* determined that "FIFRA's definition of labeling cannot encompass every type of written material accompanying the pesticide at any time. If this were true, then price stickers affixed to shelves, sheets indicating that a product is on sale, and even the logo on the exterminator's hat would all constitute impermissible labeling." (*Id.* at p. 946.) Rather, relying on a Second Circuit Court of Appeals decision that interpreted "labeling" under FIFRA, *Allenby* held that point-of-sale signs did not qualify because they were "not attached to the immediate container of a product and [would] not accompany the product during the period of use." (*Allenby*, at p. 946; *New York State Pesticide Coalition, Inc. v. Jorling* (2d Cir. 1989) 874 F.2d 115, 119 [signs posted on site where pesticides used not "labeling" because "FIFRA 'labeling' is designed to be read and followed by the end user"].)

In reaching its holding, *Allenby* declined to adopt *Kordel*'s definition of "labeling," finding that decision distinguishable. (*Allenby*, *supra*, 958 F.2d at p. 946.) The Ninth Circuit explained: "First, the written materials in *Kordel* were aimed at the ultimate user of the drug, not the purchaser that is targeted by Proposition 65. [Citation.] Second, the materials at issue in *Kordel* contained directions for use, which the EPA had clearly stated must be on the label. [Citation.] Finally, the context of the manufacturer's

mailings in that case suggested that the manufacturer was attempting to circumvent the [FDCA] rather than supplement it." (*Id.* at pp. 946–947.)

We agree with *Leeman* that "*Allenby*'s attempt to distinguish *Kordel* [is not] . . . persuasive" (*Leeman*, *supra*, 180 Cal.App.4th at p. 758, fn. 36), and we decline to follow a Ninth Circuit decision interpreting a different statute instead of binding United States Supreme Court precedent interpreting the FDCA. Although *Allenby*'s focus on materials accompanying a pesticide during use may have been appropriate under FIFRA, "we see no basis for importing that focus into the [FDCA]." (*Leeman*, at p. 758.) Rather, similar to the FMIA, the FDCA's primary purpose is to protect consumers from harmful products. (See *Wyeth v. Levine*, *supra*, 555 U.S. at p. 574; *Leeman*, at p. 758.) Consistent with this purpose, *Kordel* focused on whether the materials at issue there—which, again, included in-store displays—were "designed for use in the distribution and sale of the drug[s]." (*Kordel*, *supra*, 335 U.S. at pp. 346, 350; *Leeman*, at p. 758, fn. 36.)

Our conclusion is not altered by CEH's argument that "an all-encompassing definition of 'labeling' " cannot be reconciled with section 379r's savings clause. In CEH's view, since section 379r preempts state-law requirements "relating to public information or any other form of public communication relating to a warning of any kind for a drug" (§ 379r(c)(2)), the term "labeling" must have a narrower meaning than that phrase or else Congress would have simply stated that all "labeling" requirements are preempted. As we have said, we need not decide whether "labeling" includes all forms of public communication related to drug warnings but only whether the term includes all valid methods of conveying a Proposition 65 warning involving generic OTC drugs. And we perceive nothing in section 379r suggesting an intent to reject *Kordel*'s interpretation of "labeling" which,

while broad, is not equivalent to any public communication about any drug warning. Because point-of-sale warnings qualify as "labeling" under *Kordel*, we conclude that the generic-drug defendants cannot unilaterally provide them without violating the federal duty of sameness.

c. Public advertising

Finally, we turn to whether the generic-drug defendants could comply with federal and state law by conveying Proposition 65 warnings in advertising or similar communications to the public.[18] We conclude they cannot, and CEH's claim is therefore preempted.

Initially, it is not obvious to us that public advertising can ever be a sufficient method of providing a Proposition 65 warning about a consumer product. True, as CEH observes, Proposition 65 provides that a warning "need not be provided separately to each exposed individual and may be provided by general methods such as labels on consumer products, . . . posting of notices, placing notices in public news media, and the like, provided that the warning accomplished is clear and reasonable." (§ 25249.11, subd. (f).) Although this provision is broad enough to include public advertising, a Proposition 65 regulation pertaining to consumer products in particular requires that the warning be delivered so "as to render [it] likely to be seen, read, and understood by an ordinary individual *under customary conditions of purchase or use*." (Regs., § 25601, subd. (c), italics added.) Unlike the safe-harbor methods of providing consumer-product warnings, which require that the warning be on the product's label, displayed at the point of sale, or "automatically provide[d] . . . to the purchaser prior to

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[18] CEH also identifies "postings on websites or over social media" as possible methods of conveying Proposition 65 warnings. Our discussion of "public advertising" includes such means of communicating with the general public.

or during the purchase" (Regs., § 25602, subd. (a)), advertising is not necessarily likely to be seen during purchase or use of the product.[19] But the parties do not address this issue, so we will assume for the sake of argument that public advertising could be a valid method of conveying a Proposition 65 warning about the generic-drug defendants' products.

The question, therefore, is whether a Proposition 65 warning transmitted through public advertising constitutes "labeling" under the FDCA. *Kordel* addressed the relationship between advertising and labeling, stating that advertising qualifies as labeling "where the advertising performs the function of labeling." (*Kordel*, *supra*, 335 U.S. at p. 350.) The Supreme Court recognized that the Federal Trade Commission (FTC) had responsibility for false advertising of drugs under legislation that created the commission.[20] (*Kordel*, at p. 351; 52 Stat. 111 (1938).) But the Court found nothing in the legislative history suggesting that Congress thereby "had the

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[19] We recognize that *Dowhal* referred to advertising as a permissible method of giving a Proposition 65 warning. (See *Dowhal*, *supra*, 32 Cal.4th at p. 918.) But when *Dowhal* was decided, former California Code of Regulations, title 22, section 12601, subdivision (b)(1)(C), provided that a Proposition 65 warning could be given through "[a] system of signs, public advertising identifying the system and toll-free information services, or any other system that provides clear and reasonable warnings." Now, the regulations no longer identify advertising as part of a suitable method of conveying a warning and focus on whether a consumer will see the warning before or during purchase or use. Thus, CEH is simply incorrect that "almost any form of public communication can serve as [a] proper warning method under Proposition 65."

[20] Under the Federal Trade Commission Act, it is "unlawful for any person, partnership, or corporation to disseminate, or cause to be disseminated, any false advertisement" meant to "induc[e] . . . the purchase . . . of foods, drugs, devices, services, or cosmetics." (15 U.S.C. § 52(a).) "The term 'false advertisement' means an advertisement, other than labeling, which is misleading in a material respect." (*Id.*, § 55(a)(1).)

purpose to eliminate from the [FDCA] advertising [that] performs the function of labeling. Every labeling is in a sense an advertisement. The advertising which we have here performs the same function as it would if it were on the article or on the containers or wrappers." (*Kordel*, at p. 351.)

In 1971, "[t]o resolve issues of enforcement resulting from [the] concurrent jurisdiction" of the FDA and the FTC over the marketing of OTC drugs, the agencies "agreed to a division of regulatory authority: the FDA regulates the labeling of OTC drugs while the FTC monitors the advertising for these drugs." (*Sandoz Pharmaceuticals Corp. v. Richardson-Vicks, Inc.* (3d Cir. 1990) 902 F.2d 222, 226–227.) Under the agencies' memorandum of understanding, the FTC "has primary responsibility with respect to the regulation of the truth or falsity of all advertising (other than labeling)" of OTC drugs, whereas the FDA "has primary responsibility for preventing misbranding" of OTC drugs and "will exercise primary jurisdiction over all matters regulating [their] labeling." (36 Fed. Reg. 18539 (1971).) In contrast, the FDA retains primary responsibility for regulating the advertising of prescription drugs. (*Ibid.*; see 21 U.S.C. § 352(n); 21 C.F.R. § 202.1.)

As both *Kordel* and the 1971 memorandum of understanding demonstrate, there is no firm dividing line between "labeling" and "advertising," and materials normally thought of as advertising can constitute "labeling" under the FDCA. Under *Kordel*, the touchstone is whether the material is "designed for use in the distribution and sale of the drug" and "part[] of an integrated distribution program."[21] (*Kordel*, *supra*,

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[21] We reject CEH's claim that *Kordel* held that the "function of labeling" is providing "directions for drug use." The material at issue in *Kordel* related to the drugs' usage (*Kordel*, *supra*, 335 U.S. at p. 348), but the Supreme Court never suggested that the *only* function of drug labeling is to provide directions for use. Clearly, it is not.

335 U.S. at p. 350.) In our view, any public advertising containing a Proposition 65 warning that is "likely to be seen, read, and understood by an ordinary individual under customary conditions of purchase or use" (Regs., § 25601, subd. (c)) would qualify as "advertising [that] performs the function of labeling" under *Kordel*. (*Kordel*, at p. 351.)

CEH focuses on disproving the notion that "any and all warning statements are 'labeling.' " Again, even if some advertising that contains warnings does not constitute "labeling" under federal law, CEH's claim is still preempted if all advertising *that would comply with Proposition 65* qualifies as "labeling." Thus, CEH's arguments based on (1) the differentiation between "advertising" and "labeling" in the FDCA and its regulations and (2) cases involving the FDCA's preemptive effect on other state laws miss the mark. Likewise, CEH's observation that some of the generic-drug defendants issued press releases warning about NDMA in their products without first obtaining FDA approval is irrelevant. Even assuming such press releases complied with federal law, CEH does not argue that the generic-drug defendants could lawfully issue Proposition 65 warnings by the same method.

In short, CEH fails to demonstrate that the generic-drug defendants could give Proposition 65 warnings by any method that would not constitute "labeling" under the FDCA. Accordingly, it would be impossible for the generic-drug defendants to give such warnings without violating the federal duty of sameness, and CEH's claim is preempted.

III.
DISPOSITION

The judgment is affirmed. Respondents are awarded their costs on appeal.

Humes, P.J.

WE CONCUR:

Banke, J.

Swope, J.*

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

Center For Environmental Health v. Perrigo Company et al., A163682

Trial Court:

Superior Court of the County of Alameda

Trial Judge:

Hon. Winifred Y. Smith

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Center For Environmental Health v. Perrigo Company et al., A163682

PROOF OF SERVICE

I, Sam Litt, declare:

I am a citizen of the United States and employed in the County of San Francisco, State of California. I am over the age of eighteen (18) years and not a party to this action. My business address is 503 Divisadero Street, San Francisco, CA 94117 and my email address is slitt@lexlawgroup.com.

On April 18, 2023, I served the following document(s) on all interested parties in this action by placing a true copy thereof in the manner and at the addresses indicated below:

PLAINTIFF-APPELLANT'S PETITION FOR REVIEW

☒ **BY THE TRUFILING SYSTEM**: I transmitted a PDF version of the document(s) listed above electronically to the email address(es) indicated on the attached service list [or noted above] before 5 p.m. on the date executed.

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Please also see attached service list

I declare under penalty of perjury under the laws of the State of California that the foregoing is true and correct.

Executed on April 18, 2023 at San Francisco, California.

Sam Litt

SERVICE LIST
CEH v. Perrigo Company, et al.
Court of Appeal Case No: A163682

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