CASE NO. A163682

IN THE COURT OF APPEAL
OF THE STATE OF CALIFORNIA

FIRST APPELLATE DISTRICT, DIVISION 1

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

Superior Court of the State of California for the County of Alameda
Case No. RG 20-054985
The Honorable Winifred Y. Smith, Presiding

APPELLANT'S OPENING BRIEF

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TO BE FILED IN THE COURT OF APPEAL **APP-008**

COURT OF APPEAL First **APPELLATE DISTRICT, DIVISION** 1	COURT OF APPEAL CASE NUMBER: A163682
ATTORNEY OR PARTY WITHOUT ATTORNEY: STATE BAR NUMBER: NAME: Mark N. Todzo; Joseph Mann FIRM NAME: LEXINGTON LAW GROUP STREET ADDRESS: 503 Divisadero Street CITY: San Francisco STATE: CA ZIP CODE: 94117 TELEPHONE NO.: (415) 913-7800 FAX NO.: (415) 759-4112 E-MAIL ADDRESS: mtodzo@lexlawgroup.com; jmann@lexlawgroup.com ATTORNEY FOR (*name*): Plaintiff and Appellant Center for Environmental Health	SUPERIOR COURT CASE NUMBER: RG 20-054985
APPELLANT/ PETITIONER: CENTER FOR ENVIRONMENTAL HEALTH RESPONDENT/ REAL PARTY IN INTEREST: PERRIGO COMPANY, et al.	
CERTIFICATE OF INTERESTED ENTITIES OR PERSONS *(Check one):* ☑ INITIAL CERTIFICATE ☐ SUPPLEMENTAL CERTIFICATE	

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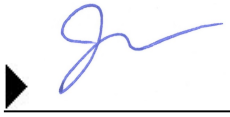

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I. QUESTIONS PRESENTED

1. Does federal implied impossibility preemption apply where compliance with both federal and state requirements is indisputably possible?
2. Does Health & Safety Code §25249.10(a) operate to expand the preemptive effect of federal law such that, where one possible method of compliance with Proposition 65 conflicts with federal law, Proposition 65 is entirely preempted?

II. INTRODUCTION AND SUMMARY OF ARGUMENT

N-nitrosodimethylamine ("NDMA") is a potent carcinogen and also an undisclosed contaminant in Respondents' over-the-counter ("OTC") acid reducing medications containing ranitidine (the "Products").[1] Because the NDMA results from poor manufacturing and storage of the Products and is not a listed ingredient, it was never mentioned by Respondents or any other manufacturer during the federal drug approval process. Accordingly, the U.S. Food and Drug Administration ("FDA") was not aware of it and never had an opportunity to review, consider, or approve any warning relating to NDMA in the Products – even though ordinary use of the Products by consumers resulted in significant exposures to the cancer-causing chemical. California's Proposition 65 requires a clear and reasonable cancer warning for NDMA exposures, and it is undisputed that Respondents failed to provide such warnings to any of the millions of Californians who purchased and ingested Products containing NDMA. The underlying case and this appeal seek to hold Respondent drug-makers and sellers responsible for their violations of Proposition 65.

The trial court dismissed Appellant Center for Environmental Health's ("CEH") claims against Respondents, agreeing with Respondents that compliance with both the federal Food, Drug, and Cosmetic Act ("FDCA") and Proposition 65 was impossible, and therefore that CEH's

[1] Ranitidine has historically been sold in the United States under the brand name "Zantac," one of the most popular and best-selling OTC drug products ever to hit the market, as well as under generic names. The Respondents in this action are either manufacturers of Products sold under generic brands ("Generic Manufacturers") or retailers that sell such Products under their own in-store "private label" brands ("Private Label Retailers").

claims were preempted. This is an untenable result because compliance with both Proposition 65 and the FDCA by Respondents was clearly possible. The trial court essentially acknowledged a number of the possible means by which Respondents could have dually complied, yet utilized unprecedented and flawed reasoning to find CEH's claims preempted under the doctrine of impossibility preemption.

Proposition 65 requires companies such as Respondents that cause exposures to toxic chemicals to provide warnings prior to the exposures. *See* Health and Safety Code §25249.6. Companies may thus comply by either providing a "clear and reasonable" warning or eliminating the exposure. *Id*. Companies are given broad authority with regard to the provision of warnings; almost any form of public communication can serve as proper warning method under Proposition 65. *See Dowhal v. SmithKline Beecham Consumer Healthcare* (2004) 32 Cal.4th 910, 918.

The FDCA serves a similar protective purpose as Proposition 65 by, in part, broadly regulating OTC drugs. Congress intended federal law to regulate OTC drugs almost exclusively and, to that end, included an expansive express preemption provision barring states from imposing any requirements concerning any aspect of OTC drugs generally, and public communications concerning warnings specifically. *See* 21 U.S.C. §379r(a) & (c). However, Congress also enacted a provision expressly carving Proposition 65 out of the preemptive reach of the statute. *See id.* §379r(d)(2). Therefore, Proposition 65 requirements concerning OTC drugs, including public communications regarding warnings, are saved from FDCA preemption. Since Congressional intent is the touchstone of preemption analysis, the express carve-out of Proposition 65 from FDCA preemption could easily end the inquiry, except for a narrow judicial

exception to the coexistence of Proposition 65 and the FDCA with regard to OTC drugs. Where the FDA expressly rejects a Proposition 65 warning for a particular OTC drug or class of OTC drugs, Proposition 65 has been held to conflict with federal law and therefore be preempted. *See Dowhal*, 32 Cal.4th at 927.

This narrow exception does not apply here. Unlike the situation in *Dowhal*, the lone instance in which Proposition 65 was found preempted by the FDCA regarding OTC drugs, the FDA has never considered – let alone rejected – a Proposition 65 warning for the Products. Nor has the FDA determined that providing a cancer warning regarding the NDMA in the Products frustrates some federal purpose. Nevertheless, the trial court wrongly determined that CEH's claims were impliedly preempted by the FDCA under the doctrine of impossibility preemption.

In order for federal law to preempt state law under the impossibility prong of implied conflict preemption, compliance with both federal and state law must be a "physical impossibility." *Wyeth v. Levine* (2009) 555 U.S. 555, 589. The analysis here is both logical and uncomplicated – that which is possible is not impossible. Because there are a number of ways by which Respondents could have complied with both Proposition 65 and the FDCA, dual compliance was possible so CEH's claims are not preempted. For example, Respondents could have provided Proposition 65-compliant warnings regarding the carcinogenicity of the NDMA in the Products by means of public advertising that would not have conflicted with the FDCA. While public advertising is an approved method of Proposition 65 compliance, it is not even regulated by the FDCA as to OTC drug products. Respondents could also have complied with both laws by reducing or removing the NDMA from the Products. Under Proposition 65, no warning

is required where there is no significant exposure to a listed chemical, and the FDCA does not regulate the undisclosed contamination of the Products with NDMA.

The trial court nevertheless held that it was impossible for Respondents to comply with both statutory schemes because Respondents, as manufacturers of generic Products, are bound under the "duty of sameness" to follow whatever the brand name manufacturer does with regard to the Products. Because the brand name manufacturers also sold Products in California with NDMA and did not provide Proposition 65 warnings, the trial court reasoned Respondents were not allowed to anything differently. The trial court was mistaken.

The "duty of sameness" is a doctrine derived from the drug approval process where the manufacturer of a generic drug must show that its product is identical in terms of ingredients and labeling to the brand name drug. It is entirely a creature of the FDCA. The concept is that where the FDA has fully reviewed the name brand drug's safety profile and approved it for consumer use, a generic drug that has identical ingredients and labeling will have the same safety profile and is therefore subject to an abbreviated approval process. However, this duty of sameness does not extend to matters that are not regulated by the FDA. This makes sense. For instance, the FDA does not regulate worker wages, so a manufacturer of generic drugs is not bound by the duty of sameness to pay its workers the same as those of the brand name manufacturers. So too here. Since the FDA does not regulate OTC drug advertising, and had no knowledge of or oversight of the undisclosed contamination of the drugs with NDMA, the duty of sameness does not bind Respondents to have the same advertising

as the brand name manufacturers or to include the same amount of an undisclosed contaminant in the Products.

The facts at issue in this case bear this out. Once Respondents were outed by an independent laboratory for their contamination of the Products with NDMA, certain Respondents took action in an attempt to head off severe FDA repercussions and provided some, albeit understated, warnings regarding NDMA in the Products. These communications were directed to the public by means of press releases and were neither approved by the FDA nor identical to public communications sent out by the brand name manufacturers. Respondents did so without violating any provision of the FDCA and the FDA did not penalize them in any way. Thus, when Respondents chose to provide warning statements to the public regarding NDMA in the Products, they were able to do so. Because public communications regarding NDMA warnings for the Products are possible and actually occurred, the trial court's determination that public communication of a Proposition 65 warning here is impossible cannot stand.

The trial court rejected this logic, finding that while Respondents were free to voluntarily provide warnings for the Products, a statutorily required warning for the Products was impossible. There is simply no support for this conclusion. The trial court also found that any form of public communication that contains a warning statement is "labeling" within the definition of the FDCA, and therefore falls within the duty of sameness. This conclusion is counter-factual, since Respondents included warning statements in unapproved and non-identical communications, and is also contradicted by the language of the FDCA and its implementing

regulations, which address advertising and labeling separately, and provide for warning statements in both.

The facts further demonstrate that the duty of sameness does not apply to the Respondents' undisclosed contamination of the Products with NDMA. Once the FDA was informed by an independent third-party that the Products contained NDMA, it undertook testing of the Products. That testing demonstrates that the NDMA content of the Products varies substantially – from almost non-detectable amounts to very significant amounts. This is in contrast to ingredients named in OTC drug products, which must appear in identical amounts between the brand name and generic versions of the drug. Because the duty of sameness requires all of the FDA-regulated aspects of the brand name and generic versions of the same OTC drugs to be identical, the hundred-fold differences in NDMA content of the Products must necessarily fall outside the FDA's purview.

Faced with the fact that different manufacturers have different amounts of NDMA in their Products notwithstanding the "duty of sameness," the trial court erected a new ground for preemption – one that has never been recognized by any other court – in order to find CEH's claims preempted. The trial court held that Proposition 65 contains a "self-exception" that requires preemption of Proposition 65's application to a particular exposure in its entirety once the court finds that any method of Proposition 65 compliance conflicts with federal law. The trial court's finding of a "self-exception" is based on Health and Safety Code §25249.10(a), which provides that Proposition 65's exposure provision shall not apply to "[a]n exposure for which federal law governs in a manner that preempts state authority." The trial court interpreted this to mean that where federal law preempts ***any*** aspect of state authority under Proposition

65, Proposition 65 is wholly preempted. This ruling does not comport with a plain reading of the statute, and undermines the broad remedial purpose intended by the millions of California voters who passed Proposition 65 by referendum. Moreover, the ruling runs contrary to every published appellate case (including the principal case on which the lower court's opinion relies), which universally hold that the usual federal impossibility preemption test applies in Proposition 65 cases notwithstanding Health and Safety Code §25249.10(a).

Because the ruling of the lower court is legally flawed and wrong, it must be overturned. Doing so will serve an important purpose that furthers the goals of both Proposition 65 and the FDCA. Drug companies like Respondents must be held accountable for exposing Californians to dangerous carcinogens without warning. Where, as here, the carcinogen is never disclosed to the FDA, Proposition 65 serves as a backstop to ensure that Californians are nevertheless provided with the warnings they deemed necessary, or that drugs are made more safely such that they are free from toxic contaminants. Congress recognized these protective purposes of Proposition 65 when it expressly exempted it from the preemptive reach of the FDCA. Allowing the trial court's ruling to stand allows 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.

III. STATEMENT OF THE CASE

A. STATEMENT OF APPEALABILITY

The present appeal is taken from the trial court's final Judgment of Dismissal with respect to Respondents, based on the trial court's Order

Sustaining Demurrers to Second Amended Complaint Without Leave to Amend. (3AA:1007-08.)[2] That Judgment fully resolved CEH's claims below as to Respondents, but did not address CEH's claims as to Defendants Sanofi-Aventis U.S. LLC and Chattem, Inc. (hereinafter, the "Brand Name Manufacturers"), which are proceeding in the trial court. However, "where, as here, there is a judgment resolving all issues between a plaintiff and one defendant, then either party may appeal from an adverse judgment, even though the action remains pending between the plaintiff and other defendants." *BGJ Assoc., LLC v. Wilson* (2003) 113 Cal.App.4th 1217, 1225 n.3 (citation omitted); *see also Justus v. Atchison* (1977) 19 Cal.3d 564, 568 (applying exception to "one judgment rule" where demurrer granted without leave to amend as to portion of plaintiff's claims). Accordingly, CEH's challenge of the adverse judgment as to Respondents is properly appealable.

B. LEGAL BACKGROUND

1. Proposition 65

The California Safe Drinking Water and Toxic Enforcement Act of 1986, Health & Safety Code §25249.5 *et seq.* – commonly known as Proposition 65 – was passed in a 1986 referendum by nearly two-thirds of California's voters to protect themselves from toxic chemicals. (3AA:0717-20.) As its formal name implies, the law governs two activities: (1) discharges of toxicants to drinking water (*see* Health & Safety Code §25249.5) ("Section 25249.5"),[3] and (2) exposures of

[2] 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. 3, pp. 1007-08 of the AA.

[3] The discharge provisions in Section 25249.5 are not at issue in this appeal.

individuals to toxicants (*see id.* §25249.6) ("Health & Safety Code §25249.6"). By enacting Proposition 65, the voters of California determined that "hazardous chemicals pose a serious potential threat to their health and well-being," and expressly "declare[d] their rights … to protect themselves and the water they drink against chemicals that cause cancer, birth defects, and other reproductive harm." (3AA:0718 (Proposed Proposition 65, §1).) Thus, preventing exposures to toxic chemicals is the common thread among these two central provisions of Proposition 65. (3AA:0717 (Proposition 65, Analysis by the Legislative Analyst, Background) (statute was intended to improve "state … programs designed to protect people against possible exposures to harmful chemicals").)

Section 25249.6 states that "No 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." 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). exemption allows a defendant to:

> show that the exposure poses no significant risk assuming lifetime exposure at the level in question for substances known to the state to cause cancer, and that the exposure will have no observable effect assuming exposure at one thousand (1000) times the level in question for substances known to the state to cause reproductive toxicity, based on evidence and standards of comparable scientific validity to the evidence and standards which form the scientific basis for the listing[.]

Id. 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. *Cf.* 11 Cal. Code Regs. ("C.C.R.") §3201(b)(1)-(2) ("public benefit" conferred by Proposition 65 settlements is presumptively established either by "the giving of a clear and reasonable warning" or "[r]eformulation of a product … or other changes in the defendant's practices that reduce or eliminate the exposure to a listed chemical").

Once liability is established, a court may award appropriate remedies including an injunction to halt or ameliorate ongoing violations and an assessment of civil penalties to deter future violations. Health & Safety Code §25249.7(a)-(b). Where warnings are the chosen method of Proposition 65 compliance, the statute provides that:

> '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.

Health & Safety Code §25249.11(f). Thus, 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. There are extensive regulations that elaborate on Proposition 65's clear and reasonable warning requirement and provide examples of "safe harbor" warnings – exemplary warnings already deemed to be "clear and reasonable." 27 C.C.R. §25600 *et seq.* These warnings are not mandatory, *i.e.*, an entity is free to provide other warnings so long as they satisfy Proposition 65. *See Dowhal*, 32 Cal.4th at 918 (safe harbor warnings are

"optional"). The regulations provide safe harbor warnings for consumer products generally that include warnings provided on signs, shelf tags, shelf signs, and via any electronic device or process. 27 C.C.R. §25602. In any event, 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").

Proposition 65 provides for two additional statutory exemptions, one of which lies at the heart of the dispute on this appeal. Health & Safety Code §25249.10(a) ("Section 25249.10(a)") provides that the liability provision in Section 25249.6 "shall not apply" to "an exposure for which federal law governs warning in a manner that preempts state authority." Many courts have ruled on Proposition 65 preemption issues; none of them have applied anything other than the usual test for federal preemption under the Constitution's Supremacy Clause. *E.g., Physicians Comm. for Responsible Med.* ("*PCRM*") *v. McDonald's Corp.* (2010) 187 Cal.App.4th 554, 565.

2. Federal OTC Drug Regulation

a. Initial Drug Approval and Post-Approval Changes

Consistent with Proposition 65's protective purpose, the FDCA's primary objective is "to protect consumers from dangerous products." *U.S. v. Sullivan* (1948) 332 U.S. 689, 696. To do so, the FDCA prohibits the sale of unapproved drugs. *See* 21 U.S.C. §355(a).

There are two methods by which the FDA approves OTC drugs: (1) the OTC drug monograph process, and (2) a new drug application ("NDA"). *See* 21 U.S.C. §§355(b), 355h. All of the Products at issue in this appeal were approved under the derivative equivalent of the NDA

process for generic drugs – an abbreviated new drug application ("ANDA") – applicable to ranitidine specifically. *See id.* §355(j).

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." *PLIVA, Inc. v. Mensing* (2011) 564 U.S. 604, 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 (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." *Mutual Pharm. Co. v. Bartlett* (2013) 570 U.S. 472, 477 (internal quotations and brackets removed); *see also Mensing*, 564 U.S. at 613 (referring to this as the "duty of sameness"). However, this "duty of sameness" does not extend to matters that not approved by the FDA in the NDA/ANDA process, such as undisclosed contaminants that may be present in the drug. *See* 21 U.S.C. §355(j)(1)(A). Furthermore, there is no "duty of sameness" regarding certain aspects of drug labeling where federal law allows the ANDA holder to use different labeling. *See, e.g.*, 21 C.F.R. §314.94(a)(8)(iv) (generic version of federally regulated drug may use expiration date that is different from the brand name counterpart).

Once a drug has been approved for sale by the FDA, changes to the NDA or ANDA can only be made in accordance with FDA regulations. *See* 21 C.F.R. §§314.70, 314.97. Whether FDA approval is required for such changes depends on whether the manufacturer seeks to make a "major," "moderate," or "minor" change to the drug. *Id.* §314.70(b)(1),

(c)(1), (d)(1). "Major" changes require FDA approval prior to implementation; "moderate" and "minor" changes do not. *Id.* §314.70(b)(3), (c)(3), (d)(3). However, for operational changes that were never part of the NDA or ANDA to begin with, such as those to address undisclosed contaminants in a drug product, 21 C.F.R. §§314.70 and 314.97 are facially inapplicable.

b. OTC Drug Labeling and the FDCA's Exclusive Savings Provision for Proposition 65

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). Under its FDCA authority, the FDA has also promulgated a regulation on "[f]ormat and content requirements for over-the-counter (OTC) drug product labeling," which sets forth the requirements for the familiar "Drug Facts" section of OTC drug labels. 21 C.F.R. §201.66(b)(10). The "content" requirements relate to components such as ingredients, drug use, and intended purposes, as well as specific sorts of "warnings" that may appear in the "Drug Facts" section. *Id.* §201.66(c). However, nothing in 21 C.F.R. §201.66 states that all warnings are "labeling," nor do its content restrictions purport to regulate statements other than those made on "[t]he outside container or wrapper of the retail package, or the immediate container label if there is no outside container or wrapper." *Id.*

In 1997, Congress added an express preemption provision to the FDCA. That section, entitled "National Uniformity for Nonprescription Drugs," 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." 21 U.S.C. §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 – whether relating to product warnings, safety, or reformulation – are in most instances precluded by the operation of federal law. It is undisputed by the parties that CEH's claims under Proposition 65 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). As U.S. Senator Barbara Boxer noted during the passage of this provision, "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." *Id.* at 926 n.6

(quoting 143 Cong. Rec. S9811, S9843 (Sept. 24, 1997)).[4] Senator Boxer's statement confirms that Congress believed that concurrent regulation of OTC drugs under Proposition 65 and the FDCA would ***improve*** – not impede – federal purposes regarding OTC drugs. It also highlights the vital role of Proposition 65 in actually ***reducing*** toxic exposures, above and beyond simply warning about these risks.

Following the passage of 21 U.S.C. §379r(d)(2), the FDA ***removed*** an express preemption provision from 21 C.F.R. §201.66 that it had earlier proposed.[5] As the FDA then stated: "This amendment to the [FDCA] ***supersedes the agency's proposed regulation*** preempting State and local labeling requirements. The agency, therefore, has removed the preemption provision from this final rule and will, at this time, rely on ***the terms of the statute*** in addressing preemption issues." *See* 64 Fed. Reg. 13,254, 13,272 (Mar. 17, 1999) (emphases added). Thus, both Congress ***and*** the FDA have acknowledged that Proposition 65 stands alone as a state law provision that, in effect, overrides federal law when it comes to warnings on OTC drug labeling.[6]

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[4] As the *Dowhal* court noted, "[s]uch statements … can provide evidence of Congress' intent." 32 Cal.4th at 926 n.6 (citing *Brock v. Pierce Cnty.* (1986) 476 U.S. 253, 263).

[5] That provision read: "No State or local governing entity may establish or continue in effect any law, rule, regulation, or requirement for OTC drug product labeling format or content that is different from, or in addition to, that required by FDA." 62 Fed. Reg. 9024, 9052 (Feb. 27, 1997).

[6] As a factual matter, many OTC drugs regulated by the FDA contain Proposition 65 warnings on their labels or their labeling, without objection from the FDA. (3AA:0941 (¶29).) Proposition 65 cancer warnings are also readily provided on third-party retailer websites selling FDA-regulated OTC drugs, also without objection from the FDA. (*Id.*)

c. OTC Drug Advertising

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).[7] Conspicuously, nothing in the FDCA or the FDA's NDA or ANDA regulations contemplate the FDA's pre-approval of advertisements respecting ***any*** federally-regulated drugs. *See* 21 U.S.C. §355; 21 C.F.R. §§314.50, 314.94.

The FDA has promulgated regulations relating to the "advertising" of ***prescription*** drugs alone. *See* 21 C.F.R. §202.1. These regulations contain certain restrictions on the contents of "contraindications" or "warnings" that may or must be in ***prescription*** drug advertisements, including that such warnings must be the same as that "contained in required, approved, or permitted labeling for the advertised drug dosage form." 21 C.F.R. §202.1(e)(3)(iii). However, the FDCA does not in any way regulate ***OTC*** drug advertisements. *See*, *e.g.*, 21 U.S.C. §352(n) (setting forth restrictions on "prescription drug advertising," but not OTC drugs); *id.* §352(x) (setting forth restrictions on "nonprescription drugs" without mentioning "advertising"). The FDA itself has confirmed this fact.

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[7] *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").

(*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.").)[8] 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.

C. FACTUAL BACKGROUND

Ranitidine is a popular OTC medication for the treatment of heartburn. (1AA:0071 (¶27).) NDMA is a nitrosamine, which is a class of chemical compounds that form when nitrates and amino acids combine. (*Id.* (¶23).) NDMA has been officially listed under Proposition 65 as a chemical known to the State of California to cause cancer for over 30 years. (1AA:0070 (¶22).) NDMA has no function in Products or any other medications – indeed, its principal use is to induce tumors in experimental animals during laboratory research. (1AA:0071 (¶23).) Thus, NDMA is found in Products not as an intentionally added ingredient, but as an unwanted contaminant. (*Id.* (¶24); *see also* 1AA:0165 (FDA characterizes NDMA in Products as "contaminant" and "impurity").) According to the FDA, NDMA can form in ranitidine through the use of contaminated

[8] The absence of any FDA regulation on OTC drug advertising is further confirmed by voluminous case law. *E.g.*, *Mylan Pharms., Inc. v. Procter & Gamble Co.* (S.D.N.Y. 2006) 443 F.Supp.2d 453, 460 (citing *Sandoz Pharm. Corp. v. Richardson-Vicks, Inc.* (3rd Cir. 1990) 902 F.2d 222, 227, and *Bristol-Myers Co. v. FTC* (2nd Cir. 1984) 738 F.2d 554, 559-60); *Terry v. McNeil-PPC, Inc.* (E.D. Pa. Nov. 13, 2015) 2015 U.S. Dist. LEXIS 153970, at *8.

materials and ingredients, the application of inferior drug manufacturing processes, and improper drug storage after manufacture. (1AA:0071 (¶24).)

In the summer of 2019, an independent laboratory reported to the FDA that it had found high levels of NDMA in a set of drug products (including the Products at issue here) that had already been made available for sale and consumption to individuals. (1AA:0073 (¶36).) Given the mechanisms by which NDMA forms in ranitidine (and the fact that a third-party lab was able to unearth this problem), Respondents knew or should have known about this problem 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).) In withdrawing their Products, several Respondents issued "voluntary" press releases on the FDA's public website that expressly included warnings that NDMA is a "probable human carcinogen" that had been found in their Products. (3AA:0942 (¶32).) These included press releases both by Brand Name Manufacturers and Generic Manufacturers, which contained statements regarding NDMA in Products that differed from one another in various ways. (*Compare* 1AA:0135-38; *with* 3AA:0782-84.)

In November 2019, the FDA published the results of preliminary testing it performed on a number of rantidine products, including Products sold by some of the Respondents. (3AA:0778-80.) Although NDMA was found in every product tested, the levels were highly variable across different Products as well as different vendors. (*Id.*) Specifically, the FDA found more than a 100-fold difference in NDMA levels – from 2.85 parts

per million ("ppm") down to 0.02 ppm. (*Id.*) None of the NDMA results for generic ranitidine products matched the NDMA levels found in brand name Zantac. (*Id.*)

In April 2020, the FDA issued a formal request that all manufacturers of prescription and OTC ranitidine immediately withdraw these drugs from the U.S. market. (1AA:0165.) The FDA's request was spurred by newer findings that NDMA levels increase in ranitidine over time, especially when stored at higher than room temperatures, which "may result in consumer exposures to unacceptable levels of this impurity." (1AA:0166.) Because its studies "show [a] risk to public health" – specifically, a risk of developing cancer in persons who ingest contaminated ranitidine – the FDA announced that it was "advising consumers taking OTC ranitidine to stop taking any tablets or liquid they currently have, dispose of them properly and not buy more; for those who wish to continue treating their condition, they should consider using other approved OTC products." (1AA:0165-66.)

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); *see also* 3AA:0941 (¶31) ("When the FDA does not agree that a Proposition 65 warning on an OTC drug is appropriate, it clearly and publicly states its position.").) 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.)

D. PROCEDURAL HISTORY

1. Early Proceedings

In the fall of 2019, CEH began serving manufacturers and retailer sellers of ranitidine with "60-Day Notices of Violation" regarding NDMA in Products, alleging violations of Proposition 65 for exposing Californians to known carcinogens without a warning. (1AA:0072 (¶29).) On February 19, 2020, CEH filed its original Complaint against Respondents Perrigo Company ("Perrigo") (a Generic Manufacturer) and Target Corporation ("Target") (a Private Label Retailer). (1AA:0025; 2AA:0553; 1AA:0275.) On May 26, 2020, both Perrigo and Target filed Answers. (1AA:0035; 1AA:0047.)

On November 6, 2020, CEH filed a First Amended Complaint to add Respondents Granules USA, Inc. ("Granules"), Apotex Corp. ("Apotex"), and 7-Eleven, Inc. ("7-Eleven") as named defendants. (1AA:0056.) Granules and Apotex are Generic Manufacturers; 7-Eleven is a Private Label Retailer. (1AA:0086; 2AA:0553; 1AA:0275.)

On January 4, 2021, CEH filed a Second Amended Complaint ("SAC") to add affiliated entities Dr. Reddy's Laboratories, Inc. and Dr. Reddy's Laboratories Louisiana, LLC (together, "Dr. Reddy's") (a Generic Manufacturer) as a named defendant, along with the Brand Name Manufacturers. (1AA:0066; 2AA:0553; 2AA:0333.)

On February 19, 2021, the Respondents filed demurrers to CEH's SAC, followed by the Brand Name Manufacturers' own demurrer on February 25, 2021. (1AA:0077; 1AA:0244; 1AA:0263; 2AA:0325; 2AA:0526; 2AA:0625; 2AA:0643.) After full briefing and submission of certain judicially noticeable materials, the trial court, Hon. Winifred Y. Smith presiding, held a hearing and entertained oral argument on the

demurrers on May 5, 2021. (3AA:1106.)

2. The Demurrer Order Underlying the Appeal

On May 7, 2021, the trial court issued the order that underlies the judgment presently on appeal ("Order"). (3AA:0899.) The analysis in the Order runs as follows.

The court began by noting that there are potential methods of compliance with Proposition 65 beyond the mere provision of a warning, such as "order[ing] a defendant to manufacture the products free of contaminants, to take greater care in storing the products, and to set expiration dates to require sale before the degradation of the products." (3AA:0902-03.) Nonetheless, the court held that these options were irrelevant in light of Health & Safety Code §25249.10(a), which the court held to create a "self-exception" that operates more broadly that the usual federal test for implied preemption. (3AA:0903-04.)

As for Proposition 65 compliance by way of warnings, the court held that since the FDA approves drug "labeling" and since "labeling" under the FDCA "includes all means of transmitting warnings," then federal law must "govern warning" so as to preempt the application of Proposition 65 under Section 25249.10(a). (3AA:0910-12.) To reach this broad conclusion, the court relied on the FDA's regulation on OTC drug labeling (which characterizes "warnings" as part of the "content" of such "labeling"), as well as case law that it believed to support the notion that any drug-related statement in any form is "labeling" where it "performs the function of labeling." (3AA:0911 (citing 21 C.F.R. §201.66); 3AA:0913-14 (citing *Kordel v. United States* (1948) 335 U.S. 345).) Despite recognizing that "[t]he FDCA does not regulate the advertising of OTC drugs" (3AA:0911), the court read the FDA's regulations to govern OTC drug advertisements

more comprehensively than prescription drug advertisements. (3AA:0915 (citing 21 C.F.R. §202.1(l)(2)).) Likewise, despite noting that "[t]here are no FDA regulations about point of sale or shelf disclosures for OTC drugs" (3AA:0911), the court held that Proposition 65 warnings by means of "point of sale" sign are precluded by a California appellate case interpreting preemption under a different federal statute. (3AA:0913-14 (citing *American Meat Inst. v. Leeman* (2009) 180 Cal.App.4th 728).) The court also cited to a series of federal cases allegedly holding "claims regarding any failure to transmit warnings through any communication channel" to be preempted by the FDCA. (3AA:0915-17.)

The court made a further ruling *sua sponte* that "as soon as a regulatory authority (or Proposition 65 plaintiff) asserts that a warning is mandated then the warning is no longer voluntary 'advertising'" but "labeling." (3AA:0918-20.) Thus, although the Court noted that a Proposition 65 warning ***could*** be included in voluntary advertising, the fact that federal law regulates ***other*** types of warnings (*i.e.*, on labels or in labeling) triggers Section 25249.10(a) so as to fully extinguish CEH's claims. (3AA:0920-21 (ruling as to Brand Name Manufacturers); 3AA:0925 (Generic Manufacturers); 3AA:0926-27 (Private Label Retailers).) Remarkably, the court's holding on this point is even broader than the rule that the Respondents urged the court to adopt in their initial moving papers. These entities first argued that Section 25249.10(a) means that if all possible Proposition 65 warnings are preempted by federal law, then the Court need not look to the possibility of reformulation or other means of reducing NDMA in Products. (1AA:0276-77; 2AA:0557.) However, on reply, Respondents argued more expansively that Section 25249.10(a) "clearly" means that preemption of even a single method of

Proposition 65 warning results in preemption of CEH's Proposition 65 claims in their entirety. (3AA:0824; 3AA:0840.)

Applying these principles to the Generic Manufacturers, the court concluded that the "duty of sameness" requiring them to use the same OTC drug labels and labelling as the brand name counterpart precluded their ability to add Proposition 65 warnings to their own Products via any means. (3AA:0921-23 (citing *Mensing*, 564 U.S. 604; *Bartlett*, 570 U.S. 472).)[9] As for the Private Label Retailers (which do not hold NDAs or ANDAs for Products and thus are not subject to the "duty of sameness"), the Court held that CEH's claims were nonetheless precluded because any mandatory Proposition 65 warning is "labeling." (3AA:0926-27.)

The lower court adopted a different ruling as to the Brand Name Manufacturers.[10] Unlike the Generic Manufacturers, the court noted, the Brand Name Manufacturers may avail themselves of the FDA's regulations allowing "moderate" changes to Product labeling to add warnings. (3AA:0907-08 (citing *Levine*, 555 U.S. at 572-73).) However, the court concluded that CEH's SAC was deficient for failing to plead a labeling deficiency that the Brand Name Manufacturers could have corrected using the pertinent FDA regulations. (3AA:0908-10.)

Based on the reasoning detailed above, the lower court sustained the

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[9] The court recognized that this "duty of sameness" does ***not*** apply to the expiration dates listed on Product labels and labeling, but determined this to be legally irrelevant given the "self-exception" in Section 25249.10(a). (3AA:0924-25 (citing 21 C.F.R. 314.94(a)(8)(iv)).)

[10] Although the correctness *vel non* of the lower court's ruling as to the Brand Name Manufacturers is not before this Court on appeal, CEH provides a brief recitation in the interest of completeness, and also to provide context for where the lower court proceedings now stand.

demurrer of the Generic Manufacturers and Private Label Retailers without leave to amend. (3AA:0921-22; 3AA:0925.) As to the Brand Name Manufacturers, the court sustained the demurrer but allowed leave to amend to address whether the FDA regulations would allow a labeling change without FDA approval. (3AA:0907.)

3. Later Proceedings

On June 4, 2021, CEH filed the now-operative Third Amended Complaint ("TAC") as to the Brand Name Manufacturers. (3AA:0934.)[11] In response to the lower court's instructions, the TAC contains further allegations that the Brand Name Manufacturers could have provided a valid Proposition 65 warning as to the carcinogenic hazards of NDMA in Products without seeking FDA approval. (3AA:0940-41 (¶28).)

The Brand Name Manufacturers filed a second demurrer on July 21, 2021. (3AA:0951.) On December 8, 2021, after full briefing by the parties and an oral argument, the court issued an order overruling this second demurrer.[12] (3AA:1195.)

IV. STANDARD OF REVIEW ON APPEAL

A trial court ruling granting a demurrer on grounds of federal preemption is subject to the appellate court's de novo review. *Hood v. Santa Barbara Bank & Trust* (2006) 143 Cal.App.4th 526, 535-36. The proper interpretation of a state statute is likewise "a pure question of law" that the appellate court reviews de novo. *People ex rel. Lockyer v.*

[11] CEH served all Respondents, which at the time were still parties to the underlying action, with the TAC. (3AA:0948-49.)

[12] The second demurrer order was issued by Judge Evelio Grillo, who took over the proceedings below from Judge Winifred Y. Smith upon her retirement from the bench at the end of July 2021. (3AA:1195.)

Shamrock Foods Co. (2000) 24 Cal.4th 415, 432. Under the de novo standard of review, the appellate court gives no deference to the trial court's ruling or the reasons cited for its ruling, but instead decides the matter anew. *Heredia v. Farmers Ins. Exch.* (1991) 228 Cal.App.3d 1345, 1353-54.

V. DISCUSSION

A. CEH'S PROPOSITION 65 CLAIMS ARE NOT PREEMPTED UNDER THE FEDERAL "PHYSICAL IMPOSSIBILITY" STANDARD.

The U.S. Supreme Court has held that impossibility preemption applies only where compliance with both federal and state regimes is a "physical impossibility." *Levine*, 555 U.S. at 589. The record here reflects that there are many means available by which any of the Respondents could have complied with Proposition 65 while fully complying with their obligations under the FDCA. Because the trial court ruled that compliance with both laws was impossible despite numerous possible means of dual compliance, the decision should be reversed.

1. Implied Impossibility Preemption Is a "Demanding Defense" That Has Never Been Held to Preclude Any Application of Proposition 65.

"The 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. There are two general classes of preemption: express and implied. "Congress's express intent in this regard will be found when Congress explicitly states that it is preempting state authority." *Id.* at 955. Implied preemption is subdivided into three types: (1) field ("when it is clear that Congress intended, by comprehensive legislation, to occupy the entire field of regulation, leaving no room for the

states to supplement federal law"); (2) obstacle ("when state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress"); and (3) impossibility ("when compliance with both federal and state regulations is an impossibility"). *Id.* (citations omitted). Only "impossibility" preemption is at issue in the present appeal.[13]

In assessing claims of implied preemption, the Court's task is guided by a "presumption against preemption" of state law – one that is especially strong where "federal law touches a field that has been traditionally occupied by the States." *Solus Indus. Innovs., LLC v. Sup. Ct.* (2018) 4 Cal.5th 316, 332; *see also Chemical Specialties Mfrs. Ass'n, Inc. v. Allenby* (9th Cir. 1992) 958 F.2d 941, 943 (applying such presumption as to Proposition 65). An even further presumption against implied preemption applies when 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. As noted above, Congress has gone even further by expressly – and uniquely – ***saving*** Proposition 65 from preemption as to OTC drugs in 21 U.S.C. 379r(d)(2).

In order to find impossibility preemption, ***all*** manners of compliance with state law effectively must be forbidden by federal law. *See Florida Lime & Avocado Growers, Inc. v. Paul* (1963) 373 U.S. 132, 142-43

[13] Respondent Apotex argued below that Proposition 65 is further impliedly preempted under the "field" prong. That proposition was correctly rejected by the lower court, and that decision is not before this Court on appeal. (3AA:0927-28.) Likewise, Apotex was the only defendant to argue that CEH's claims were moot, which was rejected and not appealed. (3AA:0928-30.)

("compliance with both federal and state regulations" must be "a physical impossibility"). For this reason, the U.S. Supreme Court has observed that "[i]mpossibility pre-emption is a demanding defense." *Levine*, 555 U.S. at 573.

In the Proposition 65 context, courts have recognized that the "proper approach" to impossibility preemption is to "reconcile the operation of both statutory schemes with one another rather than holding that one has been completely ousted." *Allenby*, 958 F.2d at 949 (citation and internal brackets omitted). Thus, where clear and reasonable warnings are at issue, "[t]o find that Proposition 65 is preempted [by a federal law], we must determine that ***all*** possible consumer product warnings that would satisfy Proposition 65 conflict with provisions of [that law]." *Committee of Dental Amalgam Mfrs. & Distribs. v. Stratton* (9th Cir. 1996) 92 F.3d 807, 810 (emphasis in original). CEH is unaware of a single case where impossibility preemption specifically was held to preclude Proposition 65 claims, and Respondents cited none below.

The *Dowhal* case provides a helpful illustration of how these preemption principles play out in the Proposition 65 context. There, the FDA had expressly held (in formal response to a citizen petition) that a reproductive warning for nicotine – a Proposition 65-listed reproductive toxicant – on smoking-cessation patches would conflict with the federal policy of discouraging smoking. 32 Cal.4th at 919-22. According to highly specific guidance provided by the FDA, there was no way to provide a reproductive warning that complied with Proposition 65 but would not encourage smoking by making women believe that nicotine patches were essentially as dangerous. *See id.* at 929. Moreover, since nicotine was the active ingredient in these products (and since smokers need this chemical to

satisfy their addiction), there was no way to reformulate the products to not contain nicotine. Thus, the case presented a "lesser of two evils" situation: exposure to toxicants would occur either via smoking or by a nicotine patch designed to assist in smoking cessation – the FDA determined that the latter was preferable to the former. *See id.* at 922. In ruling that the plaintiff's claims were "obstacle" preempted, the California Supreme Court observed that "this is 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." *Id.* at 934. *Dowhal* is very much an outlier among Proposition 65 preemption cases, as it involved direct agency statements confirming the unavoidable conflict between state and federal law.

2. Respondents Cannot Satisfy the Strictures of the Implied Impossibility Preemption Test as to CEH's Claims.

The present case is nothing like *Dowhal*. Not only has the FDA never stated that Proposition 65 cancer warnings would violate the FDCA or its own regulations, but it actually agrees that the Products present a significant cancer risk. Accordingly, Respondents could have complied with both Proposition 65 and the FDCA in a number of different ways. This includes several methods by which Respondents could have provided valid Proposition 65 warnings without FDA approval, as well as several ways by which Respondents could have ensured that NDMA levels in the Products were low enough that no Proposition 65 warning were required. If any ***one*** of these methods is viable, then impossibility preemption is inapplicable.

a. The FDA Has Never Stated That a Proposition 65 Warning on Products Would Conflict with Any Federal Policy.

Unlike *Dowhal*, the FDA has never considered – let alone considered and rejected – whether a Proposition 65 warning could be given with respect to NDMA in the Products. Nor has the FDA opined that a warning regarding the carcinogenicity of NDMA in the Products would undermine any federal policy promoting the use of OTC heartburn medications, as was the case in *Dowhal* as to smoking cessation. Instead, the FDA here determined the opposite: that consumers can avoid both the cancer risk from consuming Products containing NDMA ***and*** the risk of heartburn. (1AA:0165 (advising that consumers stop taking ranitidine and use other OTC heartburn drugs instead); 1AA:0071 (¶27 (OTC alternatives to ranitidine that do not contain NDMA are readily available)).) Thus, the situation at bar is not at all like the "lesser of two evils" presented by *Dowhal*, nor does it present an "unusual case" demanding conflict preemption where federal and state interests stand in opposition.[14] 32 Cal.4th at 934. Rather, the federal and California regulatory interests are in perfect alignment.

It is telling that Respondents have been unable to point to a single FDA pronouncement that compliance with the FDCA and Proposition 65 would be impossible here. Not only did *Dowhal* involve such direct agency statements of an unavoidable conflict, but as a general matter, when the FDA does not agree that a warning on an OTC drug is appropriate, it clearly and publicly states its position. (3AA:0941 (¶31).) The FDA's

[14] To be sure, it is not "unusual" that the case happens to involve generic drugs rather than brand name ones.

silence on this point in the present case speaks volumes. (3AA:0940-41 (¶28).)

b. Respondents Could Have Provided Warnings Via Advertisements, Websites, or Other "General Methods" Without Violating Any Provision of the FDCA.

One prominent method by which Respondents could have provided compliant Proposition 65 warnings is by public advertising, which is an approved warning method under Proposition 65. Health & Safety Code §25249.11(f) (warnings may be provided by "general methods" including "placing notices in public news media, and the like.").[15] As the lower court correctly observed, "the FDCA does not regulate the advertising of OTC drugs." (3AA:0911; *see also* 3AA:0912 ("The FDCA regulation of 'warnings' … is non-existent regarding advertising.").) The trial court nonetheless found the FDCA to wholly preempt Proposition 65 because, in its view, ***any and all*** communications involving a warning are properly characterized as "labeling" that require FDA approval. For a number of reasons, the court was wrong.

In the first place, nothing in the FDCA or its implementing regulations state that any and all warning statements are "labeling," or that an "advertisement" becomes "labeling" the moment it includes a warning statement. As noted above, the FDCA consistently distinguishes between "advertisements" and "labeling," with no indication that the inclusion of a

[15] Other "general methods" by which any of the Respondents could have provided valid Proposition 65 warnings include postings on websites or over social media. As with advertisements, there are no FDCA provisions or regulations that purport to disallow such communications, and such communications are just as broadly permitted by the Congressional savings of Proposition 65 from preemption under 21 U.S.C. §379r(d)(2).

warning makes the two equivalent.[16] *See* discussion *supra* Section III.B.2.c. To the contrary, the FDCA's provision on prescription drug advertising refers to certain types of warnings regarding "side effects" and "contraindications" that ***must*** be included in such "advertisements," but specifies that such warnings are ***not*** "labeling." 21 U.S.C. §352(n); *see also* 21 C.F.R. §202.1(l)(1) (this includes "advertisements" that are "published [in] journals, magazines, other periodicals, and newspapers" or "broadcast through media such as radio, television, and telephone communication systems"). To hold otherwise, as the lower court did, effectively nullifies these provisions.

Puzzlingly, the trial court cited to 21 C.F.R. §202.1(l)(2) – which defines "labeling" in the prescription drug context – as "support[ing] a reading of 'labeling' to include any information transmitted to the person who makes the decision whether the drug is appropriate." (3AA:0915.) But as applied to OTC advertisements – which the court believed to be transmitted to the broader "target audience" of "the general public" (*id.*) – this would yield ***greater*** regulation of OTC drug advertising than prescription drugs. This in an odd result where there is no federal regulation to this effect, and where FDA itself emphatically confirms that it "does not oversee the advertising of over-the-counter (OTC) drugs." (3AA:0769.)[17]

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[16] The California Supreme Court in *Dowhal* likewise referred to "product labeling" and "public advertising" as separate concepts. 32 Cal.4th at 918.

[17] Even in the prescription drug context, courts hold that not all "advertising" is "labeling." *E.g.*, *In re Lipitor Atorvastatin Calcium Mktg., Sales Practices, & Prods. Liab. Litig.* (D.S.C. 2016) 185 F.Supp.3d 761, 772 ("[A]dvertising to the general public, as opposed to materials for use

21 U.S.C. §379r(c)(2) further underscores this point. This provision confirms that Congress believed "public communication relating to a warning of any kind" to be ***broader*** than "labeling" – if it had not, Congress would have simply used the term "labeling" in Section 379r(c)(2). "Ordinarily, where the Legislature uses a different word or phrase in one part of a statute than it does in other sections or in a similar statute concerning a related subject, it must be presumed that the Legislature intended a different meaning." *Roy v. Sup. Ct.* (2011) 198 Cal.App.4th 1337, 1352 (citation omitted). Especially given the prevalence of this distinction throughout the FDCA, Congress appears to have chosen these terms with particularity, and to have intended a different meaning for each.

The lower court's reliance on the OTC labeling requirements in 21 C.F.R. §201.66 as support for its holding was also erroneous. The court reached its central conclusion that any "warning" required by state law necessarily becomes "labeling" by crediting that "[t]he FDCA regulations state that 'warning' is part of 'content.'" (3AA:0911 (citing 21 C.F.R. §201.66(c)(5)).) But, as explained above, ***the FDA itself*** has confirmed that 21 C.F.R. §201.66 does not govern all warnings for OTC drugs. In fact, it specifically determined this in light of the express Congressional exemption for Proposition 65 from preemption in 21 U.S.C. §379r(d)(2). *See* 64 Fed. Reg. at 13,272. It is anomalous to say that a provision that is inapplicable to Proposition 65 warnings on OTC drug labels nevertheless precludes Proposition 65 warnings on OTC drug labels. It is even more anomalous to then extend this notion beyond labels and to say that any

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by medical professionals, is not considered labeling and, thus, can be changed without the need to invoke [21 C.F.R. §314.70(b)-(c)].").

Proposition 65 warning regarding an OTC drug product ***in any form*** is disallowed by the FCDA (especially since Congress specified in 21 U.S.C. §379r(c)(2) that the Proposition 65 saving clause as to OTC drugs extends to "public information or any other form of public communication relating to a warning of any kind"). And yet this is precisely what the court's order below did. This ruling cannot stand.

The trial court was also wrong to rely on federal case law for the proposition that the FDCA categorically preempts any state law claim based on "any failure to transmit warnings through any communication channel." (3AA:0915.)[18] In the first place, all of these cases involved ***prescription*** drug advertisements, which (unlike OTC drug advertisements) the FDCA actually regulates. Furthermore, none of the cases involved Proposition 65, which has been expressly and singularly carved out of the FDA's regulatory scheme for "labeling" of OTC drugs. Lastly, none of the cases involved a hazard caused by a contaminant that was never disclosed during the NDA or ANDA process (as was the case with NDMA), and which the FDA agrees should not be present in the drug under any circumstances. Thus, these cases are readily distinguishable.

Lastly, the lower court's distinction between "voluntary" and "involuntary" advertising as the touchstone for what is "labeling" or "warning" does not hold water. (3AA:0918-20.) Again, the FDCA

[18] In support, the court cited *Strayhorn v. Wyeth Pharms., Inc.* (6th Cir. 2013) 737 F.3d 378, 394; *Guarino v. Wyeth* (11th Cir. 2013) 719 F.3d 1245, 1249; *Montero v. Teva Pharms. USA Inc.* (S.D.N.Y. Apr. 14, 2020) [2020 U.S. Dist. LEXIS 65304, at *7]; *In re Fosamax Prods. Liab. Litig.* (S.D.N.Y 2013) 965 F.Supp.2d 413, 419; *In re Yasmin and Yaz (Drospirenone) Mktg., Sales Practices & Prods. Liab. Litig.* (S.D. Ill. Nov. 18, 2015) [2015 U.S. Dist. LEXIS 156489, at *14]. (3AA:0916-17.)

suggests the precise opposite: a compelled warning in a prescription drug "advertisement" is ***not*** "labeling." 21 U.S.C. §352(n). The case law is in accord: for instance, the *Terry* case involved compelled state law warnings through "advertising," yet that court ruled that such claims were not preempted by the FDCA. 2015 U.S. Dist. LEXIS 153970, at *8. State law can readily compel advertisements to report purely factual and uncontroversial information (such as the fact that the Products contain NDMA) or to prevent consumer deception (such as might be fomented by consumers unwittingly ingesting a known carcinogen). *See National Ass'n of Mfrs. v. S.E.C.* (D.C. Cir. 2015) 800 F.3d 518, 519, 532; *Consumers Union of U.S., Inc. v. Alta-Dena Certified Dairy* (1992) 4 Cal.App.4th 963, 972-75.[19] The latter would be particularly appropriate for any Respondents that earlier made statements of a false or misleading nature as to the "safety" of their Products, or simply neglected to mention that these Products contain NDMA. (*E.g.*, 3AA:0938 (¶21), 3AA:0941 (¶30) (CEH's operative pleading makes such allegations as to the Brand Name Manufacturers).) Thus, a court could order that any of the Respondents undertake corrective advertising to counteract these false or misleading claims without running afoul of preemption concerns.

[19] The lower court attempted to distinguish *Alta-Dena* by claiming that the court there used the term "warning" rather than "advertising" to refer to this remedy. (3AA:0919 (citing 4 Cal.App.4th at 974-75 & n.6).) This is not accurate: the *Alta-Dena* court squarely referred to the future corrective "warning" mandate as "advertising." *See* 4 Cal.App.4th at 971, 973. Other courts have required advertising to rectify earlier marketing statements regarding FDA-regulated OTC drugs, even where the FDA had made certain findings supporting the earlier claims. *E.g.*, *Warner-Lambert Co. v. FTC* (D.C. Cir. 1977) 562 F.2d 749.

To the extent there is any lingering doubt on the question, the conduct of certain Respondents themselves following the third-party NDMA findings reveals that they can and did undertake remedial advertising without running afoul of FDA regulations. Respondent Apotex claims that it issued a "voluntary" recall in September 2019 without FDA urging or approval, yet overlooks that the press release it issued states that NDMA is a "probable human carcinogen" and that this chemical had been found in its ranitidine. (1AA:0086-87; 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.[20] 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.

c. Respondents Could Have Provided "Point-of-Sale" Warnings Without Violating Any Provision of the FDCA.

Another means by which any of the Respondents could have provided valid Proposition 65 warnings is via in-store displays. Again, these sorts of warnings are allowed by Proposition 65's implementing regulations (*see* 27 C.C.R. §25602) and, as the lower court conceded, "[t]here are no FDA regulations about point of sale or shelf disclosures for OTC drugs." (3AA:0911.) Nonetheless, the court found that the FDCA's

[20] It is doubtful that these representations satisfied Proposition 65, given the cagey language employed by Apotex in an effort to downplay the risks. Nonetheless, it is meaningful that public statements explicitly addressing the carcinogenic hazards associated with the Products were allowed by the FDA at all.

definition of "labeling" in 21 U.S.C. 321(m) – which includes label text and graphics as well as materials "accompanying" such labels – compels the conclusion that off-label warnings can only be altered with prior FDA approval. (3AA:0913-18.)

The chief case it cited in support – *American Meat Institute v. Leeman* (2009) 180 Cal.App.4th 728 – was decided under a different statute (the federal Meat Inspection Act ("MIA")) that 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 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. Here, in contrast, 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 in 21 U.S.C. §379r(d)(2). And, *Leeman* failed to note the California Supreme Court's observation in *Dowhal* that "point-of-sale signs" are ***not*** "product labeling." 32 Cal.4th at 918.

The other primary authority cited by the lower court (and the *Leeman* court) was *Kordel v. United States* (1948) 335 U.S. 345. That case held, in interpreting the FDCA's misbranding provision, that "accompanying" drug labeling does not require "physical attachment" to a corresponding drug label. *Id.* at 350. To the extent that *Kordel* further suggested that "labeling" includes advertising that "performs the function of labeling" (*id.*), it bears noting that the case was decided nearly 40 years before Congress amended the FDCA to distinguish between labeling and

advertisements as applied to prescription versus OTC drugs,[21] and nearly 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." Moreover, the "function of labeling" being performed in *Kordel* was that the literature in question explained how to use the drug (335 U.S. at 348) – the case did not hold or imply that any warning on a federally regulated drug is "labeling."

Notably, the broad reading of *Kordel* adopted by the *Leeman* court was rejected by the Ninth Circuit in the context of the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"). *Allenby*, 958 F.2d 941. There, the court analyzed the viability of Proposition 65 warnings on point-of-sale signs given FIFRA's "uniformity" provision, which forbids states from imposing any requirements on pesticide "labeling" that are different from the federal requirements. *Id.* at 944 (citing 7 U.S.C. §136v(b)). Like the FDCA, FIFRA defines "labeling" to mean text and graphics on the label as well as materials "accompanying" such labels. *Id.* at 945-46 (citing 7 U.S.C. §136(p)(2)). The defendants in *Allenby* argued that *Kordel*'s expansive reading of "labeling" in the FDCA supported their contention that Proposition 65 point-of-sale warnings were preempted by federal law. However, despite the fact that "the manufacturer may not change the label without the EPA's prior approval" under FIFRA, the *Allenby* court rejected preemption, holding that "[m]anufacturers only become liable for misbranding when their labels are insufficient, not for posting additional warning signs as dictated by state law." *Id.* at 944, 947. In so finding (and

[21] Accordingly, in prescription drug cases, court cite to *Kordel* yet nonetheless hold that "labeling" does not encompass all "advertising." *E.g.*, *In re Lipitor*, 185 F.Supp.3d at 771-72.

in distinguishing *Kordel*), the court noted that the issuance of Proposition 65 warnings would not "circumvent" compliance with federal law. *Id.* at 947.

The same analysis is proper here. *See also Cotter*, 53 Cal.App.4th at 1387-88 (making same finding as *Allenby* in context of Federal Hazardous Substances Act). The FDCA does not purport to preclude Proposition 65 from requiring additional warnings beyond those found on an OTC drug label – indeed, as noted above, Congress believes that Proposition 65 warnings are perfectly consonant with federal regulation.[22] Providing such warnings with respect to NDMA specifically would not "circumvent" federal law, but would convey the same message that the FDA already believes should be conveyed, *i.e.*, that the Products contain NDMA, a known carcinogen.

Finally, it is revealing that FDA's regulations interpreting 21 U.S.C. §321(m) do not mention in-store signs or displays. *E.g.*, 21 C.F.R. §202.1(l)(2) (as applied to prescription drugs, "labeling" is "[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"). 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. None of the federal cases cited by the lower court's

[22] Moreover, *Allenby* found no federal preemption even though FIFRA, unlike the FDCA, contains no express savings clause for Proposition 65.

Order applied this interpretive principle, or specifically referred to point-of-sale warnings. (3AA:0916-17.)

For all of these reasons, the Court should reject any argument that Proposition 65 point-of-sale warnings are precluded by federal law here.

d. Respondents Could Have Taken Steps to Reduce or Eliminate NDMA Exposures Without Violating Any Provision of the FDCA.

Beyond the various ways that Respondents could have complied with Proposition 65 by warning, there are a number of ways that Respondents could have dispensed with the need for Proposition 65 warnings by taking reasonable steps to reduce or prevent the NDMA exposures caused by the Products. As explained above, no Proposition 65 warning is required where the listed chemical has either been removed from the product in question, or where the listed chemical is present at levels below that requiring a warning. Health and Safety Code §25249.10(c); 27 C.C.R. §25721(a), (b). Moreover, NDMA is not a named ingredient that was part of any NDA or ANDA review by the FDA, but an unwanted contaminant that was never disclosed to the FDA until a third-party laboratory did so. (1AA:0071, 0073 (¶¶24, 36); *see also* 3AA:0939 (¶¶22-23).) Thus, there are many steps that would not have required FDA approval before they could have been taken prior to the market withdrawal of ranitidine, or that could be taken in the future.

For instance:

- The Generic Manufacturers could adopt better manufacturing practices designed to reduce NDMA contamination (such as using cleaner ingredients with fewer contaminants), and the Private Label Retailers could take steps to ensure that upstream entities are doing

the same (such as issuing specifications to and requiring certifications from such entities);[23]

- Any of the Respondents could take steps to ensure that Products are stored at the low end of the temperature range already approved by the FDA on the label;[24]
- Any of the Respondents could simply test the Products (or specific constituents in Products) for NDMA, and then not sell those Products or use those constituents if high levels of NDMA are found;[25] and/or

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[23] This does not conflict with FDA regulations, which already require OTC drug manufacturers to comply with good manufacturing practices; a failure to do so may subject the manufacturer to FDA enforcement for marketing an adulterated or misbranded drug. *See* 21 C.F.R. §§210.1(b), 330.1(a). Requiring proactive steps from the Private Label Retailers comports with the principle that such retailers are essentially treated as "upstream" entities when it comes to compliance with Proposition 65. *See* 27 C.C.R. §25600.2(e)(1).

[24] The FDA notes that "NDMA has been found to increase significantly" when stored at higher than room temperatures, which includes "temperatures the product may be exposed to during distribution." (1AA:0166.) The FDA-approved labels of the Products presently specify a temperature range that essentially approximates room temperature. (2AA:0415-43; 2AA:0451-66.) Here, the high levels of NDMA could be caused by storing ranitidine at temperatures higher than the range specified on the label (*e.g.*, in the back of a hot truck). In such instances, compliance with Proposition 65 could have been achieved earlier (and could readily be achieved in the future upon reintroduction of the Products) by taking steps to eliminate such practices. This could be accomplished without any FDA approval, and would not conflict with FDA regulations. 21 C.F.R. §211.142(b) (requiring strict compliance with good manufacturing practices relating to "[s]torage of drug products under appropriate conditions of temperature, humidity, and light so that the identity, strength, quality, and purity of the drug products are not affected").

[25] The fact that a third-party laboratory was able to discover the NDMA contamination issue through basic testing shows that any of these entities could have done so on their own as well. (1AA:0073 (¶36).) The record

- The Generic Manufacturers could reduce the amount of time specified as an expiration date on the Products' labels, thereby leading to lower levels of NDMA in those Products at the relevant time that they are ingested by consumers.[26]

Significantly, none of these steps involve changing any FDA-approved ingredients of any Products, or require the sort of drug "redesign" contemplated in cases like *Bartlett*. *See* 570 U.S. at 484. Thus, none of these steps give rise to any federal impossibility concerns.

e. The Generic Manufacturers' Overbroad Interpretation of the "Duty of Sameness" Is Demonstrably Wrong.

The Generic Manufacturers offer a broad construction of the federal "duty of sameness" that, they claim, precludes them from either (1) changing their Product "labeling" (including all forms of public advertising) to be different from the "labeling" used by the Brand Name Manufacturers on Zantac; and (2) changing the product's "design" (which

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reflects that the FDA did not observe NDMA levels above its numeric "acceptable daily intake limit" in many of the samples tested (3AA:0778-80), so it appears that employing such a screening mechanism would not lead to a total cessation in all sales. Thus, this option would not run afoul of the U.S Supreme Court's holding in the *Bartlett* case that impossibility preemption cannot be circumvented by suggesting that a drug company could simply "cease acting altogether in order to avoid liability." 570 U.S. at 488-90. And, as CEH alleges, the FDA wants Defendants to perform additional testing for NDMA (1AA:0073 (¶36)), so this in no way contravenes the agency's goals.

[26] This step would address the FDA's finding that that NDMA levels in ranitidine products increase over time. (1AA:0165; 1AA:0169.) This can be accomplished without FDA approval as a "moderate" change under the FDA's regulations, especially since the Generic Manufacturers have no duty under federal regulations to use the same expiration date on their drugs as the brand name equivalent. *Compare* 21 C.F.R. §314.70(c)(1), *with id.* §314.94(a)(8)(iv); *see also* 3AA:0924 (lower court agreed with this).

they claim to include all means by which NDMA could be reduced). (1AA:0098-0101; 2AA:0556-57; 2AA:0560-61.) The facts of this case show this interpretation to be plainly incorrect.

With respect to Product "labeling," the record reflects that Respondent Apotex – a Generic Manufacturer – issued a press release about carcinogenic NDMA in its Products in September 2019 that was not identical to a later press release on the same topic issued by the Brand Name Manufacturers. (*Compare* 1AA:0135-38; *with* 3AA:0782-84.) This gives the lie to Respondents' construction of the so-called "duty of sameness." If there was any such duty as to advertisements or statements like them – or if any communication containing a warning was "labeling" – then the Apotex statement should have been released ***after*** that of the Brand Name Manufacturers and should have been ***exactly the same***. Plainly, it was not.

As for reformulation, the facts in the record further show that not all methods of reducing NDMA in Products run afoul of any "duty of sameness" binding the Generic Manufacturers. It is undisputed that NDMA is a contaminant that was not disclosed during any NDA or ANDA process; thus, steps to address contamination issues do not have to be part of a request to change an NDA or ANDA. Notably, the FDA agrees with this proposition. (*E.g.*, 3AA:0733-34 (FDA has published guidelines on "impurities in drug substances" in the NDA/ANDA context, but notes that "[e]xcluded from this document are … extraneous contaminants, which should not occur in drug substances and are more appropriately addressed as good manufacturing practice issues"); 3AA:0751-53 (same).) The FDA findings that there is great variability in NDMA levels even as to the same FDA-approved Products further 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. (3AA:0778-80.)[27] As a conceptual matter, there is no FDA policy encouraging that generic OTC drugs must contain the same undesirable contaminants as their brand name counterparts. If this were true, then any time contaminants 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 cannot possibly be the law.

As the FDA clearly believes, contaminants like NDMA are not supposed to be in ***any*** drug. Rectifying such problems could be as simple as switching vendors, undertaking a process audit, using clean intake water, or sweeping the floor more regularly, none of which require FDA approval. The "duty of sameness" plainly does not extend to such circumstances.

For all of these reasons, it should be clear that compliance with Proposition 65 and federal drug law is not "physically impossible," as federal preemption jurisprudence demands.

B. THE TRIAL COURT ERRED IN INTERPRETING PROPOSITION 65 TO CONTAIN A "SELF-EXCEPTION" THAT EXTENDS FURTHER THAN THE FEDERAL PREEMPTION STANDARD.

As set forth above, compliance with both Proposition 65 and the FDCA is clearly possible. The trial court even conceded as much. Nevertheless, the court found CEH's claims to be preempted on the basis of what it termed the Proposition 65 "self-exception." (3AA:0903-05.)

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[27] Not only does this show that the NDMA problem is not an inherent feature of the ranitidine molecule (as in cases like *Bartlett*), but it also suggests that some Product manufacturers may already be taking some of the remedial steps (evidently, without obtaining FDA approval) that CEH believes all of the manufacturers should be taking.

The lower court's Order is the first-ever to find that Health & Safety Code §25249.10(a) compels 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). This is not what Section 25249.10(a) says. Nor does the court's interpretation comport with the California Supreme Court's directive that Proposition 65 must be construed broadly. This surprising holding should be overturned.

Health & Safety Code §25249.10(a) provides that the prohibition on unwarned exposures in Health & Safety Code §25249.6 "shall not apply to … [an] exposure for which federal law governs warning in a manner that preempts state authority." There are three competing interpretations here:

- Section 25249.6 "shall not apply to … [an] exposure for which federal law governs warning in a manner that preempts [***all***] state authority" (CEH's interpretation);
- Section 25249.6 "shall not apply to … [an] exposure for which federal law governs warning in a manner that preempts state authority [***regarding warnings***]" (Respondent's initial interpretation); and
- Section 25249.6 "shall not apply to … [an] exposure for which federal law governs warning in a manner that preempts [***any***] state authority" (the lower court's interpretation).

Only one of these interpretations – CEH's – correctly construes Proposition 65 in furtherance of its protective purpose. Moreover, only CEH's interpretation gives meaning to every term in Section 25249.10(a). Accordingly, this interpretation should prevail.

1. Consistent with Federal Jurisprudence, Section 25249.10(a) Requires That All Avenues of Compliance Must Be Foreclosed Before Proposition 65 Is Preempted.

"In construing a statute, [the Court's] fundamental task is to ascertain the Legislature's intent so as to effectuate the purpose of the statute." *Smith v. Sup. Ct.* (2006) 39 Cal.4th 77, 83. In the case of voter-enacted initiatives like Proposition 65, the intent of the electorate is paramount to this analysis. *See Styrene Info. & Rsch. Ctr. v. Office of Envtl. Health Hazard Assessment* (2012) 210 Cal.App.4th 1082, 1098 (noting that "the spirit of the act" should guide competing interpretations as to its "literal construction"). In divining the intent of the voters who adopted Proposition 65, the language of the statute is the obvious starting point. *See DiPirro v. Bondo Corp.* (2007) 153 Cal.App.4th 150, 190-91. Even so, "the 'plain meaning' rule does not prohibit a court from determining whether the literal meaning of a measure comports with its purpose or whether such a construction of one provision is consistent with other provisions of the statute." *People v. Canty* (2004) 32 Cal.4th 1266, 1277. As the California Supreme Court has emphasized, Proposition 65 should be "construe[d] … broadly to accomplish [its] protective purpose." *People ex rel. Lungren v. Sup. Ct.* ("*Lungren II*") (1996) 14 Cal.4th 298, 314.

Applying these canons of construction, it is plain that Section 25249.10(a) – like the Supremacy Clause generally – requires that federal and state law be in total conflict. This is evidenced by the inclusion of the phrase "in a manner that preempts state authority." As is clear from the discussion on federal preemption jurisprudence above, the only "manner" by which "state authority" can be precluded is where compliance with Proposition 65 by ***any available means*** is precluded. There is no indication

or authority for the contrary proposition that ***all*** means of Proposition 65 compliance are preempted where solely the provision of a single method of a state-imposed ***warning*** is preempted. If that were the intent, Section 25249.10(a) would have ended right after "governs warning" or concluded with "state authority to require warnings," but it does not. Rather, by specifying that the federal law governing warning must do so "in a manner that preempts state authority," the provision signals that the usual federal test must be satisfied. *See generally Copley Press, Inc. v. Sup. Ct.* (2006) 39 Cal.4th 1272, 1284 (courts should "strive to give effect and significance to every word and phrase" in a statute).

In addition, only CEH's interpretation interprets the statute broadly by giving the preemptive effect of Section 25249.10(a) its most limited scope. As noted above, the fundamental purpose of Proposition 65 is to protect California's citizens from exposures to potentially dangerous chemicals (such as NDMA). An interpretation like CEH's that cabins the preclusive effect of federal law to those situations where Proposition 65 is either explicitly preempted or there is a direct conflict with federal law ensures that the intent of the California voters will be given its full effect. Indeed, CEH's proposed interpretation is the only one that follows the California Supreme Court's guidance to "construe the statute broadly to accomplish its protective purpose." *Lungren,* 14 Cal.4th at 314. As such, this interpretation should be favored.

To the extent there is any ambiguity regarding Section 25249.10(a), the ballot materials on which two-thirds of Californians relied in enacting Proposition 65 demonstrate the implausibility of the interpretation advanced by Respondents and the court below. "When the enactment follows voter approval, the ballot summary and arguments and analysis

presented to the electorate in connection with a particular measure may be helpful in determining the probable meaning of uncertain language." *Styrene*, 210 Cal.App.4th at 1098 (citation omitted). As stated in those materials, the voters proclaimed that their objective was to (1) "protect themselves" from toxic chemicals by reducing reliance on government agencies; (2) "secure strict enforcement of the laws controlling hazardous chemicals"; and (3) "deter actions that threaten public health and safety." (3AA:0718 (Proposed Proposition 65, §1(a), (c)).) As the California Supreme Court noted in *Lungren II*, "Proposition 65 purported to partially supersede existing environmental laws, which the proponents of the initiative argued were not 'tough enough.'" 14 Cal.4th at 311 n.7. It strains credulity to say that these same voters would want federal preemption to extend even ***further*** than demanded by the U.S. Constitution. Surely, there is no conceivable reason why these voters would want federal laws to extinguish their state rights to compel a prohibition on unwarned exposures when there are numerous ways to provide Proposition 65 warnings or to reduce the subject chemical that are ***allowed*** under federal law.[28]

Health & Safety Code §25249.10(a) simply recognizes that where the state's authority under Proposition 65 is preempted as to a particular exposure, Proposition 65 does not apply to that exposure. This provision

[28] In a similar vein, such an interpretation contradicts the policy objectives noted by Senator Boxer during the passage of 21 U.S.C. §379r(d)(2). If providing a federal warning can preclude reformulation or other ameliorative steps that are eminently achievable by the regulated entities, then there will be no "reduced toxic contaminants" in "consumer products sold in California." *Dowhal*, 32 Cal.4th at 926 n.6. And, if the FDA does not know what is possible in the way of reformulation (as a Proposition 65 enforcement suit might establish), it cannot adopt the "more stringent standards for some consumer products" that may be needed. *Id.*

was likely included because the drafters of Proposition 65 wanted to make sure that the statute as a whole would survive against a preemption challenge if any part of it was found to conflict with federal law.[29] Most of the California citizens who voted to adopt Proposition 65 had likely never heard of federal preemption. Under these circumstances, Section 25249.10(a) would serve to educate the electorate as to the legal framework under which Proposition 65 would operate (or ***not*** operate, in those instances where it was found to be precluded by federal law). *See generally People ex rel. Lungren v. Sup. Ct.* ("*Lungren I*") (1995) 48 Cal.App.4th 1452, 1460 ("in construing voter-approved measures, words must be understood, not as the words of the civil service commission, or the city council, or the mayor, or the city attorney, but as the words of the voters who adopted the amendment," with "technical" readings to be rejected in favor of "common popular" ones) (citation omitted), *rev'd on other grounds by Lungren II* (1996) 14 Cal.4th 298. Thus, despite restating the federal test on preemption, Section 25249.10(a) does perform a valuable semantic function in the overall statutory scheme.[30]

[29] Predictably, there were several facial challenges to Proposition 65 on federal preemption grounds – all unsuccessful – in the years directly following the law's enactment. *See, e.g.*, *Allenby*, 958 F.2d at 943; *Cotter*, 53 Cal.App.4th at 1379.

[30] Contrary to the lower court's assertion, it is not true that provisions mirroring the federal law on preemption are unique to Proposition 65 among California statutory enactments. *Compare* 3AA:0905, *with, e.g.*, Fin. Code §§101, 4803, 14001.5.

2. The Competing Interpretations of Section 25249.10(a) Advanced by Respondents and the Lower Court Are Untenable.

Neither of the two alternative constructions of Section 25249.10(a) make sense in light of Proposition 65's protective scheme. Both interpretations would ***diminish*** the scope of Proposition 65, thereby leading to ***more*** unwarned exposures to toxic chemicals – precisely the opposite of what the voters sought to achieve. Furthermore, Respondents' assertion that the lower court's interpretation of Section 25249.10(a) is compelled by its "clear" terms is contradicted by the fact that Respondents adopted a ***different*** interpretation of these terms in their initial demurrer papers. (*Compare* 1AA:0276-77; 2AA:0557; *with* 3AA:0824; 3AA:0840.) If the language plainly supported the interpretation set forth in the court's Order – *i.e.*, that the existence of federal regulation governing ***any*** type of Proposition 65 warning precludes ***all*** types of Proposition 65 warning – then this position should have been consistent throughout.

Neither the lower court nor Respondents below cited to a single case adopting their position – there are none. Rather, the published cases that discuss Section 25249.10(a) all perform the usual constitutional preemption analysis, without once indicating that Proposition 65 itself has in any way altered that analysis. *E.g.*, *PCRM*, 187 Cal.App.4th at 565 (holding, consistent with CEH's view, that "[c]onflict preemption of [Proposition 65] by federal law does not automatically and necessarily result in the complete displacement of state law by federal law in its entirety," but "only insofar … as there is conflict") (citation omitted). The case law even more squarely rejects the lower court's specific holding that Section 25249.10(a) demands complete preemption where ***any*** type of Proposition 65 warning is preempted. Every single appellate case at the state or federal level

interpreting the nature of federal preemption in the specific context of Proposition 65 holds that the reviewing court's role is to "determine that all possible consumer product warnings that would satisfy Proposition 65 conflict with provisions of the federal statute[]." *Allenby*, 958 F.2d at 943; *Stratton*, 92 F.3d at 810 (same); *Cotter*, 53 Cal.App.4th at 1379 (same). Notably, this includes the *Leeman* case on which the Order centrally relied. There, even where Proposition 65 label warnings were concededly preempted, the court went on to analyze whether shelf-tag warnings would also be preempted. *See Leeman*, 180 Cal.App.4th at 735 n.2, 749-61. If the lower court's interpretation of Section 25249.10(a) were correct, the *Leeman* court – as well as the appellate courts in *Allenby* and *Cotter* – would have stopped their inquiries after finding that warnings on product labels were precluded by federal law. They did not. Plainly, Section 25249.10(a) cannot be read as broadly as the lower court held.

VI. CONCLUSION

The trial court's ruling is illogical, counter-factual, and contrary to established law. For all of the reason stated herein, this ruling should be reversed.

Dated: December 22, 2021

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 14,000 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 December 22, 2021, at San Francisco, California.

/s/ Joseph Mann
Joseph Mann

PROOF OF SERVICE

I, Owen Sutter, 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 osutter@lexlawgroup.com.

On December 22, 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:

APPELLANT'S OPENING BRIEF

APPELLANT'S APPENDIX IN LIEU OF CLERK'S TRANSCRIPT VOLUME 1 (EXHIBITS 1-18)(AA0001-AA0383)

APPELLANT'S APPENDIX IN LIEU OF CLERK'S TRANSCRIPT VOLUME 2 (EXHIBITS 19-34)(AA0384-AA659)

APPELLANT'S APPENDIX IN LIEU OF CLERK'S TRANSCRIPT VOLUME 3 (EXHIBITS 35-66)(AA0660-AA1201)

☒ **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 December 22, 2021 at San Francisco, California.

Owen Sutter

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

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