CASE NO. S279578

IN THE SUPREME COURT OF THE STATE OF CALIFORNIA

CENTER FOR ENVIRONMENTAL HEALTH,

Plaintiff-Appellant,

v.

PERRIGO COMPANY, et al.,

Defendants-Respondents.

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

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

REPLY ON PETITION FOR REVIEW

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I. INTRODUCTION

Defendants do not dispute that their generic ranitidine-based antacid products contain significantly higher amounts of N-nitrosodimethylamine ("NDMA") than the brand name version, and therefore are not the same. Furthermore, Defendants knew for years that their products contained toxic levels of NDMA, but never bothered to disclose this fact to the U.S. Food and Drug Administration ("FDA") or to the consumers who unwittingly purchased and ingested these contaminated drugs. Nevertheless, applying the Court of Appeal's analysis, Defendants contend that the federally-imposed "duty of sameness" insulates generic drug makers from liability for ***knowingly and intentionally withholding such consumer warnings*** unless users can prove that they developed cancer directly from taking these drugs. Not so. Congress explicitly determined that Proposition 65 should act as a backstop to the Food, Drug, and Cosmetic Act ("FDCA") to reduce or eliminate the presence of harmful contaminants in over-the-counter ("OTC") drugs. Here, the significant civil penalties allowed by Proposition 65 would serve as a powerful deterrent to ensure that generic drug manufacturers will not use shoddy manufacturing practices, inferior storage methods, or second-rate ingredients, all of which led to the formation of NDMA in the drugs at issue. Alternatively, civil penalties would ensure that the cancer warnings required by Proposition 65 are properly given, such that consumers can choose to avoid the risk. This remedy will be wholly unavailable in this and all future Proposition 65 cases involving contaminated OTC generic drugs unless this Court grants review and reverses the Court of Appeal's decision. Thus, contrary to Defendants' assertion, the issues at play here are hardly "hypothetical." Answer to Petition for Review ("Answer") at 7.

The problems in the Court of Appeal's ruling could have been solved, first and foremost, by adopting the correct interpretation of the "duty of sameness" imposed by the FDCA. As the two seminal U.S. Supreme Court cases cited by Defendants hold, this duty requires identity between ***three and only three*** aspects of brand name and generic drugs: (1) active ingredient, route of administration, dosage form, and strength, (2) rate and extent of absorption, and (3) safety labeling. *See Mutual Pharm. Co. v. Bartlett* (2013) 570 U.S. 472, 477. In all other regards – including as to undisclosed contaminants in those drugs – the drugs and their labeling may be entirely different. Despite Defendants' claim that this case involves an "unremarkable" application of the *Mensing* and *Bartlett* cases (Answer at 7), the Court of Appeal's decision is in fact the first ever to broadly apply the limited holding of these cases beyond these three enumerated aspects. This includes this Court's ruling in *T.H. v. Novartis Pharmaceuticals Corp.* (2017) 4 Cal.5th 145, which (like *Mensing* and *Bartlett*) involved active ingredients, not contaminants. The Court of Appeal's decision will allow generic drug manufacturers to hide behind this "duty of sameness" to conceal known contaminants from the public – even though the levels of these contaminants and risks they pose are ***not the same*** as in the brand name version. This Court should intervene to prevent this anomalous result.

The Court of Appeal's overextension of this "sameness" rationale violates a different aspect of federal drug law: the express savings provision for Proposition 65 in the FDCA itself. As this Court held in *Dowhal*, this provision disallows preemption of Proposition 65 in the OTC drug context on the specific ground of ensuring federal "uniformity." Yet, the duty of sameness is precisely such a rationale. Defendants attempt to play up the

purported public health benefits of exempting generic drugs from regulation by Proposition 65, but this does not alter the fundamental character of this doctrine as one seeking uniformity. Defendants also gloss over the Congressional intent in exempting this protective California law from preemption as to OTC drugs: the Proposition 65 warning requirement is designed to incentivize drug manufacturers to "reduce[] toxic contaminants" in their products, thereby complementing federal law. The imposition of Proposition 65 liability on the generic manufacturers here would serve such a complementary role by providing an effective deterrence against future malfeasance.

As a final matter, neither the Court of Appeal nor Defendants address the various ways in which the FDCA's definition of "labeling" has been modified in the 80 years since the *Kordel* decision, including several ways that would allow a valid Proposition 65 warning. Both also fail to counter the various factors that distinguish the *Leeman* action from the present case.

To redress these various errors of law and thereby to preserve the important voter-enacted rights conferred by Proposition 65, this Court should grant review of the Court of Appeal's decision.

II. ARGUMENT IN SUPPORT OF REVIEW

Defendants' Answer provides no reason to deny further review. To the contrary, Defendants concede many points that indicate why this Court's examination of the legal questions at hand would be especially appropriate.

A. This Case Presents Issues of Statewide Importance that Should Be Decided by This Court.

Defendants do not dispute that resolving this appeal will require a

sober analysis of Congressional intent as applied to the regulation of OTC drugs under concurrent federal-state authority. Defendants also concede that questions of federal preemption should generally be resolved by this Court in light of its unique institutional competence. *See Southern Cal. Chapter of Assoc'd Builders v. California Apprenticeship Council* (1992) 4 Cal.4th 422, 431 n.3. Because the Court of Appeal decision effectively invalidates Proposition 65 as to the vast majority of OTC drugs sold in California, this Court's review of that decision plainly implicates issues of statewide concern. Moreover, the specific issue of whether the duty of sameness extends to any matters outside of the three things specified by the FDCA (such as contaminants) has never been addressed by ***any*** court prior to the Court of Appeal's decision.[1] The Court of Appeal's mishandling of this novel issue only underscores the necessity of this Court's review.

Nonetheless, Defendants attempt to characterize this appeal as raising only "theoretical" or "illusory" issues that will have "no practical significance" to any California consumers because "the products at issue in this case are no longer being sold in California." Answer at 7-8, 10. These assertions ignore the importance of Proposition 65 in securing the protective public health objectives that both California's voters and Congress sought. Ranitidine is not presently being sold in California only because Defendants earlier adopted inferior drug manufacturing and storage practices and utilized cheap, low-grade ingredients that rendered the drug

[1] Defendants cite to a series of preemption rulings in the pending Zantac MDL, but fail to counter that these lower court opinions (1) were addressing a different issue involving "design defect" claims (which Petitioner Center for Environmental Health ("CEH") does not raise here), and (2) are still subject to reversal on appeal. *Compare* Answer at 18-19, *with* Petition for Review ("Petition") at 24.

so contaminated with NDMA as to be unfit for public consumption. (1AA:0165-66; 1AA:0071 (¶24).) Defendants both knew and intended that users of these products would be exposed to these contaminants. (1AA:0073-74 (¶¶32-36, 43).) It is not "hypothetical" to say that the substantial civil penalties available under Proposition 65 – in the amount of $2,500 per day per unwarned exposure (Health & Safety Code §25249.7(b)(1)) – would have a significant impact on future decisions to cut corners by these same Defendants, all of which continue to manufacture drugs for sale in California. As the U.S. Supreme Court has noted, civil penalties "do more than promote immediate compliance[.] … [T]hey also deter future violations." *Friends of the Earth, Inc. v. Laidlaw Envtl. Servs. (TOC), Inc.* (2000) 528 U.S. 167, 185; *see also DiPirro v. Bondo Corp.* (2007) 153 Cal.App.4th 150, 183 ("An award of civil penalties under [Proposition 65] is … designed to deter misconduct and harm[.]"). Thus, even if the drug is never reintroduced, Proposition 65 provides remedies that will have real-world impacts on Defendants' conduct and, thus, public health.

The necessity of these remedies could not be more obvious here. Defendants historically failed to warn about a cancer risk of which they knew full well (but never disclosed to the FDA) and also eschewed good manufacturing practices (of which they were also aware) that would have halted these dangerous exposures altogether. Even now, their position essentially boils down to: "We already got away with it, so there is nothing more to be done." This arrogant perspective ignores the instrumental role of civil penalties in preventing future violations. *E.g.*, *Laidlaw*, 528 U.S. at 186 ((("[A] defendant once hit in its pocketbook will surely think twice before [violating the law] again.").

Defendants attempt to deemphasize this by pointing to the availability of traditional tort remedies. Their view is that Californians should be exposed to readily preventable carcinogens in drug products, become afflicted with cancer, and then sue for damages. Answer at 13-14. But this is exactly what California voters sought to prevent when they enacted Proposition 65 as a "self-protection" measure – the warning is supposed to precede the exposure, such that individuals have a meaningful opportunity to avoid the hazard altogether. (3AA:0717-18; 3AA:0721-22.) It is also what Congress sought to prevent in carving out Proposition 65 from federal preemption in the OTC drug context. *See* 143 Cong. Rec. S9811, S9843-44 (Sept. 24, 1997). Defendants' belief that their own profits should take precedence over public safety suggests that substantial civil penalties are very much needed here. Unless this Court grants review, these remedies will be forever lost to California's citizens.

B. It Makes No Sense to Apply a Federal Duty of Sameness to Unwanted Contaminants in OTC Drug Products.

Faced with the glaring flaws in the Court of Appeal's ruling that the duty of sameness encompasses harmful contaminants in federally regulated drugs, Defendants' Answer admits many central aspects of CEH's argument that counsel in ***favor*** of this Court's review.

First, Defendants do not contest that NDMA is present in radically different levels in brand name versus generic ranitidine, with levels trending much higher in generic products. (3AA:0778-80.) This is critical, as it conclusively shows that the FDA imposes no "duty" that levels of contaminants in brand and generic products should be identical – indeed, as Defendants and the Court of Appeal elsewhere admit, NDMA "is not supposed to be in [these drugs] at all." Answer at 11 (citing panel's

opinion). Oddly, both Defendants and the Court of Appeal believe that this fact somehow absolves Defendants of liability. Yet, Defendants knew for years that the drugs were contaminated with NDMA and did nothing. Thus, the fact that NDMA should not be in the drugs weighs heavily in favor of imposing significant penalties, not absolution.

Defendants' repeated finger-pointing at the brand name manufacturer is inapposite where, as here, there is a hundred-fold difference in NDMA levels between ranitidine products made by different manufacturers. *Id.* at 13-14. Even if there were no Proposition 65 claim against the brand name manufacturers, the higher NDMA levels in the generic versions would remain actionable under Proposition 65.

Defendants also concede that the duty of sameness is not all-inclusive, *i.e.*, for certain aspects of generic drugs, there is no such duty at all. *See* Respondents' Brief (Case No. A163682) (filed Apr. 21, 2022) at 31 (citing to the same three aspects articulated by CEH, and no others). One example is inactive ingredients, which need not be the same in the generic version and in fact may require different warnings based on different risks posed by such constituents. Petition at 21 (citing *Zeneca, Inc. v. Shalala* (4th Cir. 2000) 213 F.3d 161, 169). The only analytical difference between inactive ingredients and undisclosed contaminants is that inactive ingredients – though not subject to the duty of sameness – are at least vetted by the FDA during the federal drug approval process. *See* 21 U.S.C. §355(j)(4)(H). Undisclosed contaminants are not vetted by the FDA at all – thus, the duty of sameness is even less applicable. (*E.g.*, 3AA:0733-3 ("extraneous contaminants" such as NDMA are addressed by everyday "good management practices" outside of drug approval process);

3AA:0751-53 (same).)[2]

Rather than grapple with these issues, Defendants cite to the *Mensing* and *Bartlett* cases as if they were directly controlling. Answer at 17-18. But these cases are not on point because they did not involve unwanted contaminants. Rather, the health risks at issue in either case were presented by the ***active ingredient*** of the drug, which all parties agree ***are*** vetted during drug approval and ***are*** one of the three aspects expressly subject to a federal duty of sameness. *See* Petition at 15. Furthermore, in each case, the risks presented by the active ingredient were the same regardless of whether the brand name or generic version of the drug was ingested. This is not at all like the present case, where the levels of NDMA in generic ranitidine are orders of magnitude higher. And, because the risk here is presented by contamination issues that depend on the variable practices of each manufacturer, no amount of safety testing by the brand name manufacturer would or could ensure the safety of the generic version.

This Court's opinion in *T.H. v. Novartis Pharmaceuticals Corp.* (2017) 4 Cal.5th 145 (which Defendant cite in support) aptly demonstrates why their position is wrong, and why this Court should intercede to set matters right. *T.H.* involved two infant plaintiffs who suffered birth defects after their pregnant mother took a drug containing an active ingredient that presented reproductive risks known to the brand name manufacturer but that were withheld from the FDA. *Id.* at 161. *T.H.* is a particularly instructive case in that the mother there did ***not*** take the brand name version

[2] These guidance documents purport to provide the FDA's "current thinking" on the topic of "impurities in drug substances used in generic drug products." (3AA:0751.) The FDA has maintained this consistent position on contaminants for decades.

of the drug – the only drug she took was the generic version. *Id.* at 155. Nonetheless, because the duty of sameness ensured that the generic version of drugs presented identical risks as the brand name version, and because the duty of sameness in labeling indisputably applies to active ingredients, the plaintiff's "failure to warn" claims against the brand name manufacturer were upheld as viable. *Id.* at 166-75.

This Court's analysis in *T.H.* shows why the Court of Appeal's ruling cannot stand. The Court there imposed a duty to warn on the brand name manufacturer only because "federal regulations granted the brand-name drug manufacturer – and no other manufacturer – control over the active ingredients in the generic drug and the content of the warnings included in the generic's label" respecting such ingredients. 4 Cal.5th at 168-69. Here, the brand name manufacturer of Zantac had no control over the levels of NDMA found in the generic version because ***this contamination is caused exclusively by the conduct of the generic manufacturer***. We know this because the two versions contain vastly different amounts of NDMA – this is based on the ***generic manufacturer's*** use of inferior manufacturing methods, storage practices, and drug constituents, not the brand name manufacturer's.

This Court in *T.H.* also emphasized that state failure to warn claims serve "as a complementary form of drug regulation with respect to drug labeling" by "provid[ing] incentives for drug manufacturers to disclose safety risks promptly." 4 Cal.5th at 169. Here, the imposition of Proposition 65 liability would "complement" federal drug regulation by taking the generic manufacturers to task for their failure to apprise the public (or the FDA) of the known NDMA contamination issue. Thus, far from supporting Defendants' position, this Court's analysis in *T.H.*

eviscerates it.

In sum, review by this Court is needed to secure a proper interpretation of the "duty of sameness" under the FDCA, thereby settling a vital question of law.

C. Congress Has Expressly Forbidden the Preemption of Proposition 65 Claims Based on Uniformity Considerations Such as the Duty of Sameness.

The Court of Appeal committed further, independent error in failing to give proper effect to the FDCA's express savings provision in 21 U.S.C. 379r(d)(2). Neither the Court of Appeal nor Defendants counter that Congress specifically expressed an intent to preserve Proposition 65 as to ***contaminants in antacids*** – the precise regulatory case here – with no indication that this should depend on whether the drug at issue was sold under a generic or a brand name. *See* Petition at 28-29. Both the Court of Appeal and Defendants also sidestep the fact that this Court in *Dowhal* concluded that conflict preemption of Proposition 65 presented "an unusual case," and not – as the ruling below suggests – a typical case. *Id.* at 27-28. These concessions highlight the infirmities in the Court of Appeal's decision, and indicate why review by this Court should be granted.

Defendants' Answer invites this Court to further misconstrue the central holding in *Dowhal*. According to Defendants, "the savings clause bars only implied preemption of FDA policy actions that are based ***solely*** on a desire to enforce uniformity in labeling, without any basis relevant to consumer health." Answer at 23 (emphasis in original). This is not correct. As Defendants note, many (if not ***all***) Congressional enactments in the drug context implicate in some way the goal of "advancing public health." *Id.* If it were enough that there was ***any*** health goal involved, then implied

preemption would entirely swallow the express exemption from preemption in Section 379r(d)(2). What *Dowhal* held is that uniformity rationales can ***never*** be the basis of implied Proposition 65 preemption as to OTC drugs. *See* 32 Cal.4th at 926 ("The legislative history suggests an intent to preclude conflict preemption in pursuit of national uniform labeling."). The "duty of sameness" ***is*** such a rationale, and simply because a call for uniformity implicates public health issues does not transform it into something ***other*** than a uniformity rationale. Thus, *Dowhal* compels reversal.

D. "Labeling" Under the FDCA Does Not Encompass All Means of Providing Valid Proposition 65 Warnings.

The Court of Appeal improperly held that all clear and reasonable Proposition 65 warnings are necessarily "labeling" under the FDCA. In attempting to defend the Court of Appeal's all-encompassing interpretation of labeling, Defendants attribute to CEH two "strawman" arguments.

The first is that CEH is arguing that the *Kordel* ruling "should be disregarded … because of its age." Answer at 25 (citing *Kordel v. U.S.* (1948) 335 U.S. 345). In fact, CEH's argument is not that *Kordel* is simply old; it is that both the FDCA and its implementing regulations have been modified since 1948 in ways that show that "labeling" does not extend to every means of providing a warning on a drug product. These include (1) the amendment of the FDCA to distinguish between "labeling" and advertisements as applied to prescription versus OTC drugs, *see* Petition at 17-18 & n.4 (citing 21 U.S.C. §§321(m) & (n), 352(n) & (x)); (2) the amendment of the FDCA to specify that "labeling" is narrower than "any … public communication relating to a warning of any kind," *id.* at 31 (citing 21 U.S.C. §379r(c)(2)); (3) the promulgation of regulations stating

that "warnings" in prescription drugs are not "labeling," *id.* at 18 (citing 21 C.F.R. §202.1(e)(3)(iii), (l)); and (4) the promulgation of regulations providing examples of "labeling" under *Kordel* that exclude in-store signs or displays, *id.* at 32 (citing 21 C.F.R. §202.1(l)(2)). Since Proposition 65 expressly allows valid warnings to be provided by "general methods" such as advertisements, point-of-sale displays, or even electronic means, *see* Health & Safety Code §25249.11(f), these authorities demonstrate that cancer warnings could have been provided by Defendants without running afoul of the FDCA. Indeed, this fact is confirmed by the conduct of Defendants themselves: some generic manufacturers provided attenuated public warnings as to the presence of carcinogenic NDMA in their ranitidine products in the fall of 2019 – a month prior to different warnings issued by the brand name manufacturer – and the FDA did not blink. (*Compare* 1AA:035-38, *with* 3AA:0782-84.)

Defendants' second strawman argument is that CEH contends the *Leeman* case "should be disregarded … because it construed a different preemption provision … under the federal Meat Inspection Act (MIA)." Answer at 25 (citing *American Meat Inst. v. Leeman* (2009) 180 Cal.App.4th 728). This simplistic characterization fails to note the various factors that additionally distinguish *Leeman*, including that (1) the MIA, unlike the FDCA, requires FDA pre-approval of all product "labeling," (2) the U.S. Department of Agriculture ("USDA") there, unlike the FDA here, has interpreted "labeling" to include point-of-sale materials, (3) the USDA there, unlike the FDA here, has stated that Proposition 65 warnings on the products at issue would be preempted, and (4) the MIA, unlike the FDCA, contains no savings clause for Proposition 65. Petition at 32-33. All of these factors – which were discussed by the Ninth Circuit in *Chemical*

Specialties Mfrs. Ass'n, Inc. v. Allenby (9th Cir. 1992) 958 F.2d 941 – show why *Leeman* is not controlling here.

III. CONCLUSION

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

Dated: June 1, 2023

Respectfully submitted,
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CERTIFICATE OF WORD COURT

I, Joseph Mann, hereby certify that this brief was produced on a computer, and that it contains 3,486 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 June 2, 2023, at San Francisco, California.

/s/ Joseph Mann
Joseph Mann

PROOF OF SERVICE

I, Sam Litt, declare:

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

On June 2, 2023, I served the following document(s) on all interested parties in this action by placing a true copy thereof in the manner and at the addresses indicated below:

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

Executed on June 2, 2023 at San Francisco, California.

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IN THE SUPREME COURT OF THE STATE OF CALIFORNIA
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