APPEAL NO. A163682

IN THE COURT OF APPEAL
of the
STATE OF CALIFORNIA

FIRST APPELLATE DISTRICT, DIVISION ONE

CENTER FOR ENVIRONMENTAL HEALTH
Plaintiff and Appellant,

v.

PERRIGO COMPANY, et al.
Defendants and Respondents.

Appeal from the Alameda County Superior Court
The Honorable Winifred Y. Smith
Alameda County Superior Court Case No. RG 20-054985

RESPONDENTS' ANSWER TO AMICUS CURIAE BRIEF OF THE ATTORNEY GENERAL

STEPTOE & JOHNSON LLP

DENNIS RAGLIN, SBN 179261
633 WEST FIFTH STREET,
SUITE 1900
LOS ANGELES, CA 90071
TELEPHONE: 213.439.9433
FACSIMILE: 213.438.7033
draglin@steptoe.com

GOODELL, DEVRIES, LEECH & DANN LLP

RICHARD M. BARNES (*PRO HAC VICE*)
DEREK M. STIKELEATHER (*PRO HAC VICE*)
*SEAN L. GUGERTY (*PRO HAC VICE*)
ONE SOUTH STREET, 20TH FLOOR
BALTIMORE, MD 21202
TELEPHONE: 410.783.4000
FACSIMILE: 410.783.4040
rmb@gdldlaw.com
dstikeleather@gdldlaw.com
sgugerty@gdldlaw.com

ATTORNEYS FOR DEFENDANT AND RESPONDENT
PERRIGO COMPANY

NORTON ROSE FULBRIGHT US LLP
JEFFREY B. MARGULIES (BAR NO. 126002)
LAUREN A. SHOOR (BAR NO. 280788)
555 SOUTH FLOWER STREET, 41ST FLOOR
LOS ANGELES, CALIFORNIA 90071
(213) 892-9200 • FAX: (213) 892-9494
jeff.margulies@nortonrosefulbright.com
lauren.shoor@nortonrosefulbright.com

ATTORNEYS FOR DEFENDANT AND RESPONDENT
TARGET CORPORATION

LEWIS BRISBOIS BISGAARD & SMITH LLP
PAUL A. DESROCHERS (BAR NO. 214855)
333 BUSH STREET, SUITE 1100
SAN FRANCISCO, CALIFORNIA 94104
(415) 362-2580 • FAX: (415) 434-0882
Paul.Desrochers@lewisbrisbois.com

ATTORNEYS FOR DEFENDANT AND RESPONDENT
GRANULES USA, INC.

ARNOLD & PORTER KAYE SCHOLER LLP
TRENTON H. NORRIS (BAR NO. 164781)
WILLIS M. WAGNER (BAR NO. 310900)
THREE EMBARCADERO CENTER 10TH FLOOR
SAN FRANCISCO, CALIFORNIA 94111
(415) 471-3303 • FAX: (415) 471-3400
trent.norris@arnoldporter.com
will.wagner@arnoldporter.com

ATTORNEYS FOR DEFENDANT AND RESPONDENT
7-ELEVEN, INC.

BLANK ROME LLP
CHERYL S. CHANG (BAR NO. 237098)
JESSICA A. MCELROY (BAR NO. 299919)
2029 CENTURY PARK EAST, 6TH FLOOR
LOS ANGELES, CALIFORNIA 90067
(424) 239-3400 • FAX: (424) 239-3434
Chang@BlankRome.com
JMcElroy@BlankRome.com

BLANK ROME LLP
TERRY M. HENRY (*PRO HAC VICE*)
ONE LOGAN SQUARE, 130
PHILADELPHIA, PENNSYLVANIA 19103
(215) 569-5500 • FAX: (215) 569-5555
THenry@BlankRome.com

ATTORNEYS FOR DEFENDANT AND RESPONDENT
APOTEX CORP.

GORDON REES SCULLY MANSUKHANI LLP
BRIAN M. LEDGER (BAR NO. 156942)
101 W. BROADWAY, SUITE 2000
SAN DIEGO, CALIFORNIA 92101
(619) 696-6700 • FAX: (619) 696-7124
bledger@grsm.com

ATTORNEYS FOR DEFENDANTS AND RESPONDENTS
DR. REDDY'S LABORATORIES, INC. &
DR. REDDY'S LABORATORIES LOUISIANA, LLC

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INTRODUCTION

In *Dowhal v. SmithKline Beecham Consumer Healthcare* (2004) 32 Cal.4th 910 (*Dowhal*), the California Supreme Court addressed *obstacle* preemption in the context of a Proposition 65 claim brought against the manufacturer of a brand name drug product. *Dowhal* did not create a bright line rule applicable to *all* categories of conflict preemption of a Proposition 65 claim, as the Attorney General incorrectly claims. Further, *Dowhal* did not address whether the 21 U.S.C. § 379r(d)(2) savings clause (section 379r) saves Proposition 65 claims from a separate category of conflict preemption, namely, generic-drug *impossibility* preemption under the United States Supreme Court's landmark rulings in *Mensing* and *Bartlett*.[1] That is a question of first impression for this Court.

Dowhal does provide helpful guidance, however. *Dowhal* stressed that savings clauses must be construed narrowly and ordinarily do *not* save state-law claims from conflict preemption. And *Dowhal* concluded that the legislative history of the section 379r(d)(2) savings clause suggests that Congress intended it to have only a limited impact on conflict preemption,

[1] *PLIVA, Inc. v. Mensing* (2011) 564 U.S. 604 [131 S.Ct. 2567, 180 L.Ed.2d 580] (*Mensing*); *Mutual Pharmaceutical Co., Inc. v. Bartlett* (2013) 570 U.S. 472 [133 S.Ct. 2466, 186 L.Ed.2d 607] (*Bartlett*).

saving Proposition 65 claims only from "conflict preemption in pursuit of national uniform labeling." (*Dowhal*, *supra*, 32 Cal.4th at p. 926.)

Consistent with those principles, section 379r(d)(2)'s savings clause does not save CEH's Proposition 65 claim here. Generic-drug impossibility preemption is premised on Congress's enactment of a binding statutory requirement that generic-drug manufacturers use the same warning labels as the equivalent brand name drug product, the "duty of sameness." But as the Supreme Court held in *Mensing*, Congress's intent in enacting the duty of sameness was not to push for uniformity in drug labeling, but rather to provide consumers with widespread access to inexpensive drugs. Thus, the savings clause is inapplicable, and CEH's Proposition 65 is preempted under the ordinary application of generic-drug impossibility preemption.

The Attorney General is similarly incorrect to claim that warnings through advertising and other types of communications are not "labeling" under federal law. CEH made this same argument in prior briefing, and Respondents have previously explained that any form of public communication of warning statements constitutes "labeling," and are therefore subject to the federal duty of sameness. Thus, advertising and other types of communications are not an exception to generic-drug preemption.

Finally, the Attorney General is correct that if federal law preempted issuing a warning, non-warning actions Respondents could have taken are irrelevant.

Therefore, and for the reasons given below and in Respondents' prior briefing to this court, the trial court's preemption ruling should be affirmed.

ARGUMENT

I. THE 21 U.S.C. § 379R(D)(2) SAVINGS CLAUSE DOES NOT SAVE CEH'S PROPOSITION 65 CLAIM FROM GENERIC-DRUG IMPOSSIBILITY PREEMPTION.

A. *Dowhal* addressed only a specific category of conflict preemption that is not at issue in this appeal—obstacle preemption for a brand name drug.

The Attorney General (AG) misreads *Dowhal* as establishing "the governing test for California courts to claims of conflict between Proposition 65 and the [Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. § 301 et seq.,] as applied to [over-the-counter] drugs" for *all* categories of federal conflict preemption for *all* pharmaceutical drugs. (ACB 8, 12–16.) To the contrary, *Dowhal* addressed only one specific category of conflict preemption of a Proposition 65 claim: *obstacle* preemption for a brand name drug product.

Dowhal involved a Proposition 65 claim against the manufacturers of over-the-counter brand name gums and patches that aimed to help people quit smoking through nicotine replacement therapy. (*Dowhal*, *supra*, 32

Cal.4th at pp. 917, 919.)[2] The brand name drug manufacturer had not included a Proposition 65 warning that the products contained a chemical known to the state of California to cause reproductive harm. (*Dowhal*, at p. 918.) But that was because the FDA "never permitted defendants to use the Proposition 65 warning." (*Id.* at pp. 918–919.) The FDA rejected requests from the brand name drug manufacturers to add a Proposition 65-compliant warning and instructed them to use only the FDA-approved warning labeling, or else the FDA would deem the products misbranded under federal law. (*Id.* at pp. 919–921.) In response to a citizen's petition filed by plaintiff, the FDA explained that it did not want the Proposition 65 warning to appear on the products' label out of a concern that its phrasing might lead pregnant women, concerned over the risks of the nicotine replacement therapy products, to avoid using those products and instead continue smoking cigarettes. (*Id.* at pp. 922, 934–935.)

In this context, the Supreme Court analyzed whether the Proposition 65 claim was preempted under conflict preemption. The Court began by

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[2] *Dowhal* noted that the nicotine replacement therapy products were approved pursuant to a new drug application (NDA). (*Dowhal*, *supra*, 32 Cal.4th at pp. 919–920.) A product approved under an NDA is synonymous with a brand name drug product. (RB 26–27, 66.) In contrast, generic drugs are approved under a distinct and materially different regulatory process through an *abbreviated* new drug application. (RB 19–20.)

recognizing that there are two distinct categories of conflict preemption: (1) *impossibility* preemption, "where it is impossible for a private party to comply with both state and federal requirements," and (2) *obstacle* preemption, "where state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." (*Dowhal*, *supra*, 32 Cal.4th at pp. 923–924, internal quotation marks omitted.) These two categories of preemption are separate and distinct, with each requiring a fundamentally different legal analysis.[3]

In *Dowhal*, the Court focused its analysis exclusively on *obstacle* preemption. *Dowhal* held that the Proposition 65 claim was obstacle preempted, i.e., that there was a direct conflict between the warning required by Proposition 65 and the *FDA's policy* that the brand manufacturers must use only the FDA-approved warning. (*Dowhal*, *supra*, 32 Cal.4th at p. 929

[3] Indeed, since *Dowhal* was issued, the California Supreme Court has explained that conflict preemption based on impossibility and obstacle preemption are "analytically distinct and may rest on wholly different sources of constitutional authority" and should be treated as "separate categories" of preemption. (*Viva! Internat. Voice for Animals v. Adidas Promotional Retail Operations, Inc.* (2007) 41 Cal. 4th 929, 935–936 & fn.3; accord *Solus Industrial Innovations, LLC v. Superior Court* (2018) 4 Cal.5th 316, 332; *Friends of the Eel River v. North Coast Railroad Authority* (2017) 3 Cal.5th 677, 705; *Quesada v. Herb Thyme Farms, Inc.* (2015) 62 Cal.4th 298, 308; *People ex rel. Harris v. Pac Anchor Transportation, Inc.* (2014) 59 Cal.4th 772, 777–778; *Parks v. MBNA America Bank, N.A.* (2012) 54 Cal.4th 376, 383.)

["We conclude that the FDA's August 17, 2001, letter established a *federal policy* prohibiting defendants from giving consumers any warning other than the one approved by the FDA in that letter, and that the use of a Proposition 65 warning would *conflict with that policy*" (emphasis added)]; see *id.* at pp. 934–935 ["Here, however, the FDA warning serves a nuanced goal—to inform pregnant women of the risks of NRT products, but in a way that will not lead some women, overly concerned about those risks, to continue smoking. This creates a conflict with the state's more single-minded goal of informing the consumer of the risks. *That policy conflict* justifies federal preemption here." (Emphasis added.)].) As explained in greater detail below, *Dowhal* also held the section 379r(d)(2) savings clause did *not* bar obstacle preemption of the plaintiff's Proposition 65 claim under the circumstances before it. (*Id.* at p. 926.)

Respondents do not dispute that *Dowhal*'s specific holding—regarding policy-based *obstacle* preemption of a Proposition 65 warning for a brand name drug product—is binding on this court. But that holding is irrelevant because *Dowhal* did not address the sole category of preemption at issue here: *impossibility* preemption for the manufacturers and sellers of a generic drug product.

B. *Dowhal* did not hold that section 379r(d)(2) saves Proposition 65 claims from impossibility preemption.

The AG wrongly cites *Dowhal* for the broad proposition that Congress' enactment of the section 379r(d)(2) savings clause saves Proposition 65 claims from virtually *all* instances of implied conflict preemption, including generic-drug impossibility preemption, aside from one narrow set of circumstances: "where the state warning conflicts with federal requirements, purposes or concerns 'on a basis *relevant to consumer health*.' " (ACB 12–13, quoting *Dowhal*, *supra*, 32 Cal.4th at p. 926.) The AG's warped reading of *Dowhal* is directly contrary to analysis and holdings of *Dowhal* itself, and should be rejected by this Court

Dowhal began its analysis by placing the section 379r(d)(2) savings clause in context of the overall statutory scheme. The Food and Drug Administration Modernization Act of 1997 (Modernization Act) (Pub.L. No. 105-115 (Nov. 21, 1997) 111 Stat. 2296) included express preemption provisions for over-the-counter drugs. Specifically, 21 U.S.C. § 379r(a) provides that "no State or political subdivision of a State may establish or continue in effect any requirement— [¶] (1) that relates to the regulation of [an over-the-counter drug]; and [¶] (2) that is different from or in addition to, or that is otherwise not identical with, a requirement under [the FDCA]." And 21 U.S.C. § 379r(c)(2) provides that "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."

Thus, Congress's adoption of the Modernization Act imposed a new national uniformity in over-the-counter drug labeling. Because the Act prohibits states from requiring manufacturers or sellers of over-the-counter drugs to issue warnings that are different from, in addition to, or not identical with the warnings required by federal law, the result is that over-the-counter drugs sold across the 50 states generally bear only the warnings that federal law requires.

But as explained in *Dowhal*, the Modernization Act also "contained a savings clause designed specifically to preserve Proposition 65" from the express preemption in 21 U.S.C. § 379r(a). (*Dowhal*, *supra*, 32 Cal.4th at pp. 919; *id*. at p. 924.) That savings clause, section 379r(d)(2), provides: "This section shall not apply to a State requirement adopted by a State public initiative or referendum enacted prior to September 1, 1997." Proposition 65 is "the only state enactment that falls within the savings clause." (*Dowhal*, at p. 919.)

Dowhal recognized that *Geier v. American Honda Motor Co., Inc.* (2000) 529 U.S. 861 [120 S.Ct. 1913, 146 L.Ed.2d 914] (*Geier*) "established a strong

presumption" that when Congress enacts a savings clause it "does not ordinarily intend to bar conflict preemption." (*Dowhal*, *supra*, 32 Cal.4th at p. 924.) *Geier* and later cases "established a general rule upholding conflict preemption even if the applicable federal law contains a savings clause." (*Id.* at p. 925–926, citing *Sprietsma v. Mercury Marine, a Div. of Brunswick Corp.* (2002) 537 U.S. 51, 63 [123 S.Ct. 518, 154 L.Ed.2d 466] (*Sprietsma*) & *Buckman Co. v. Plaintiffs' Legal Committee* (2001) 531 U.S. 341, 352 [121 S.Ct. 1012, 148 L.Ed.2d 854].) Thus, *Dowhal* concluded that "In light of that language, history, and the principles established by [*Geier*], and other United States Supreme Court decisions, . . . the savings clause of 21 United States Code section 379r(d)(2), does not entirely exclude conflict preemption." (*Id.* at p. 926.)

Still, *Dowhal* found that the section 379r(d)(2) savings clause does place *some* restrictions on conflict preemption of Proposition 65 claims—albeit only in limited circumstances, which were not present for the brand name drug product at issue in *Dowhal*, and likewise are not present for the generic ranitidine products at issue this appeal. Specifically, the Modernization Act's "legislative history suggests an intent to preclude conflict preemption in pursuit of national uniform labeling" on the part of the FDA. (*Dowhal*, *supra*, 32 Cal.4th at p. 926.) The *Dowhal* court therefore held that

"If the FDA's directive here prohibiting nonidentical labels is to be sustained, it must be on a basis relevant to consumer health, and not because the Proposition 65 label would frustrate the FDA's policy favoring national uniformity." (*Ibid.*)

This holding makes intuitive sense in cases where a defendant argues that a Proposition 65 claim is *obstacle* preempted because it frustrates the purpose of an FDA policy. In passing the Modernization Act, Congress enacted express preemption provisions aimed at achieving national uniformity in over-the-counter drug labeling. Yet, at the same time, Congress also enacted a savings clause preserving Proposition 65 warnings from that new express preemption. If the FDA tried to sidestep that statutory scheme and adopt a policy barring the defendant from adding Proposition 65 warnings based *solely* on a goal of uniformity of labeling, it would thwart Congress's intent. Thus, the *Dowhal* court sensibly insisted on evidence showing that the FDA had some *other* basis relevant to consumer health for barring a Proposition 65 warning before an FDA directive is given preemptive effect via obstacle preemption.

But *Dowhal* did not address the entirely different preemption category facing this court here: impossibility preemption for a generic drug product. For generic drugs, a federal *statute*, the FDCA, mandates a "duty of

sameness" in generic-drug labeling (i.e., a binding duty that the generic-drug's warning labeling match that of the equivalent brand name drug) and drug design (i.e., a binding duty that a generic drug must have the same molecular active ingredient as the brand name drug). (RB 26–31.) That federal *statutory* requirement directly conflicts with Proposition 65's requirement to add a warning for NDMA that does not appear on the brand name drug's label. And the United States Supreme Court has twice held that since it is impossible for generic-drug defendants to comply with both a state-law warning requirements and the federal duty of sameness for generic drug warning labeling, state-law warning claims are preempted under the doctrine of impossibility preemption and must be dismissed. (See *Mensing*, *supra*, 564 U.S. at pp. 618, 624; *Bartlett*, *supra*, 570 U.S. at pp. 484–486.)

Thus, the AG is plainly incorrect in framing *Dowhal* as providing a "governing test" that this court can simply straightforwardly apply in this appeal. *Dowhal* dealt only with the impact of the section 379r(d)(2) savings clause on obstacle preemption from an FDA policy. It did not consider whether the savings clause also impacts impossibility preemption stemming from a federal statute, the basis for the trial court's preemption ruling here.

C. The section 379r(d)(2) savings clause does not limit generic-drug impossibility preemption of Proposition 65 claims.

Because *Dowhal* did not decide whether the section 379r(d)(2) savings clause has any impact on generic-drug impossibility preemption, and there is no other appellate decision squarely on point, it is a question of first impression for this court. The court can and should hold that the savings clause does not bar or restrict preemption of Proposition 65 claims based on generic-drug impossibility preemption, and affirm the trial court's preemption ruling, for three reasons.

1. *Dowhal* recognized a strong presumption in favor of upholding conflict preemption even if the federal statute contains a savings clause.

While *Dowhal's* specific holding is not dispositive here, its underlying analysis shows that savings clauses *ordinarily* do not bar or restrict conflict preemption. *Dowhal* recognized "a strong presumption" that when Congress enacts a savings clause it "does not ordinarily intend to bar conflict preemption," and that there is "a general rule upholding conflict preemption even if the applicable federal law contains a savings clause." (*Dowhal*, *supra*, 32 Cal.4th at pp. 924–926.)

Moreover, *Dowhal* recognized that the United States Supreme Court has *never* interpreted a savings clause in a manner that would preserve a state-law requirement from preemption when that state law directly conflicts

with a federal *statutory scheme* enacted by Congress. (*Dowhal*, *supra*, 32 Cal.4th at p. 926 [holding that "the United States Supreme Court has never interpreted a savings clause so broadly as to permit a state enactment to conflict with a federal regulation scheme"]; see *Geier*, *supra*, 529 U.S. at p. 869–870 [noting that the United States Supreme Court has " 'repeatedly decline[d] to give broad effect to saving clauses where doing so would upset the careful regulatory scheme established by federal law,' " and holding that express preemption clause and saving clause in the National Traffic and Motor Vehicle Safety Act, "does not foreclose . . . 'any possibility of implied [conflict] pre-emption,' " and that "Nothing in the language of the saving clause suggests an intent to save state-law tort actions that conflict with federal regulations"].)[4] Other federal courts, including the Court of Appeals for the Ninth Circuit, have held similarly.[5] Thus, were this court to hold that

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[4] Accord, *Sprietsma*, *supra*, 537 U.S. at pp. 64–65 (express preemption and saving clause in the Federal Boat Safety Act did not " 'bar the ordinary working of conflict pre-emption principles' [citation], that find implied pre-emption 'where it is impossible for a private party to comply with both state and federal requirements' "); see *Williamson v. Mazda Motor of America, Inc.* (2011) 562 U.S. 323, 329–330 [131 S.Ct. 1131, 179 L.Ed.2d 75] (same).

[5] See *Nexus Pharmaceuticals, Inc. v. Central Admixture Pharmacy Services, Inc.* (9th Cir., Sept. 13, 2022, No. 20-56227) __ F.4d __ [2022 WL 4175106, at p. *5, fn. 47] (affirming FDCA implied preemption of claim brought by manufacturer against compounding facility for allegedly copying manufacturer's drug product and holding that general savings clause in FDCA " 'does *not* bar the ordinary working of conflict pre-emption principles,' " quoting *Geier*, *supra*, 529 U.S. at p. 869]); *National Federation of*

CEH's Proposition 65 claim is saved from impossibility preemption stemming from a conflict with the federal *statutory scheme* for generic drugs—which includes the duty of sameness in generic-drug warning labeling—that would be contrary to settled United States Supreme Court precedent and persuasive law from the Ninth Circuit.

In sum, *Dowhal* recognized that (1) savings clauses do not ordinarily restrict the ordinary working of conflict preemption, and (2) that the highest court has *never* interpreted a savings clause to save a state-law claim from conflict with a federal statutory scheme. This reasoning, standing alone, is sufficient for this court to find that the section 379r(d)(2) savings clause does not restrict the ordinary working of generic-drug conflict preemption and, consequently, to affirm the trial court's preemption ruling.

2. The federal duty of sameness underlying generic-drug impossibility preemption was enacted based on a policy goal of making inexpensive drugs widely available to consumers, not uniformity in labeling.

Even if the court goes further and considers *Dowhal's* statements regarding the Congressional intent behind the section 379r(d)(2) savings

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the Blind v. United Airlines, Inc. (9th Cir. 2016) 813 F.3d 718, 731–732 (express preemption provisions of the Federal Aviation Act did not "foreclose the application of ordinarily implied preemption principles"); *Marentette v. Abbott Laboratories, Inc.* (2d Cir. 2018) 886 F.3d 112, 120 (express preemption provisions in the Organic Foods Production Act did not bar finding of conflict preemption).

clause, it should still affirm the trial court's preemption ruling. As previously noted, *Dowhal* found that the Modernization Act's "legislative history suggests an intent to preclude conflict preemption in pursuit of national uniform labeling." (*Dowhal*, *supra*, 32 Cal.4th at p. 926.) But, contrary to the AG's arguments, the statutory scheme establishing the federal duty of sameness in generic-drug warning labeling—the source of generic-drug impossibility preemption—was *not* based on a pursuit of national uniform labeling. Rather, Congress had a very different policy goal of providing consumers with widespread access to inexpensive generic drugs.

As *Mensing* explained, "under the 1962 Drug Amendments to the Federal Food, Drug, and Cosmetic Act, 76 Stat. 780, 21 U.S.C. § 301 et seq., a manufacturer seeking federal approval to market a new drug must prove that it is safe and effective and that the proposed label is accurate and adequate." (*Mensing*, *supra*, 564 U.S. at p. 612.) For manufacturers to meet those requirements "involves costly and lengthy clinical testing," which naturally results in more expensive drugs for consumers. (*Ibid.*) Originally, the requirements for extensive and costly testing applied to any drug being brought on the market. (*Ibid.*) But in 1984, "Congress passed the Drug Price Competition and Patent Term Restoration Act, [Pub.L. No. 98-417 (Sept. 24, 1984)] 98 Stat. 1585, commonly called the Hatch-Waxman Amendments,"

which permitted generic drugs to gain FDA approval by showing (1) "equivalence to a [brand name] reference listed drug that has already been approved by the FDA" and (2) " 'that the [safety and efficacy] labeling proposed . . . is the same as the labeling approved for the [brand-name] drug.' " (*Id.* at pp. 612–613, citing 21 U.S.C. § 355(j)(2)(A), (2)(A)(v), & (4)(G).) "This allows manufacturers to develop generic drugs inexpensively, without duplicating the clinical trials already performed on the equivalent brand-name drug." (*Id.* at p. 612.) Thus, Congress's intent in adopting the Hatch-Waxman Amendments was to encourage "the generic drug market to expand, bringing more drugs more quickly and cheaply to the public." (*Id.* at p. 626.)

The Congressional record from the debate over the Hatch-Waxman Amendments also show Congress's policy intent to reduce drug prices for consumers, and particularly for senior citizens who spend a significant share of their income on pharmaceutical drugs. The bill's lead sponsor in the House of Representatives, Congressman Henry Waxman, noted that the Amendments "will reduce the cost of drugs for all consumers" and that "Older Americans, in particular, will benefit from the legislation because they are the largest consumers of medicines." (Remarks of Rep. Waxman, 130 Cong. Rec. H8701, H8706 (1984), at <https://bit.ly/3qUnadU> [as of Sept. 21, 2022].) Similarly, Senator Orrin Hatch, the leading proponent in the Senate,

explained that with the changes in the bill, "The public receives the best of both worlds—cheaper drugs today and better drugs tomorrow. The proliferation of new generics for some of the most important drugs on the market will save consumers an estimated $1 billion or more over the next decade." (Remarks of Sen. Hatch, 130 Cong. Rec. S10503, S10504 (1984), at <https://bit.ly/3f7d6vA> [as of Sept. 21, 2022].)[6]

In summary, *Dowhal* found that the legislative history of the section 379r(d)(2) savings clause suggests a Congressional intent to save conflict

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[6] In fact, Hatch-Waxman has proven more successful in reducing drug prices for consumers than Congress initially anticipated. The FDA has found that introduction of a single generic competitor leads to price reductions of more than 30 percent, and more than four generic competitors competing for market share leads to drops in prices of over 70 percent. (Conrad & Lutter, U.S. Food & Drug Admin., Generic Competition and Drug Prices: New Evidence Linking Greater Generic Competition and Lower Generic Drug Prices (Dec. 2019) pp. 2–3, at <https://www.fda.gov/media/133509/download> [as of Sept. 21, 2022].) The Congressional Budget Office (CBO) estimates that "by substituting generic for brand-name drugs, purchasers saved roughly $8 billion to $10 billion in 1994 (at retail prices)." (Cong. Budget Off., How Increased Competition From Generic Drugs Has Affected Prices And Returns In The Pharmaceutical Industry (July 1998) p. ix, at <https://www.cbo.gov/sites/default/files/105th-congress-1997-1998/reports/pharm.pdf> [as of Sept. 21, 2022].) The CBO report specifically identified the Hatch-Waxman Amendments as the leading factor "behind the dramatic rise in sales of generic drugs that has made those savings possible." (*Ibid.*) The FDA has found similar cost savings in more recent years, estimating annual savings from newly approved generics drugs to be $17.8 billion in 2018, $24.8 billion in 2019, and $10.7 billion in 2020. (Conrad et al., U.S. Food & Drug Admin., Estimating Cost Savings from New Generic Drug Approvals in 2018, 2019, and 2020 (Aug. 2022), at <https://www.fda.gov/media/161540/download> [as of Sept. 21, 2022].)

preemption "in pursuit of national uniform labeling," but *not* to "entirely exclude conflict preemption" for Proposition 65 claims. (*Dowhal*, *supra*, 32 Cal.4th at p. 926.) *Mensing* and the Congressional record of the Hatch-Waxman Amendments establish that Congress's intent in enacting the generic-drug duty of sameness was to ensure the provision of widespread and inexpensive drugs to consumers, and not to pursue national uniformity in drug labeling. Thus, the savings clause does not save Proposition 65 claims from impossibility preemption for generic drugs.[7]

3. Enforcing the preemptive effect of the federal duty of sameness for generic drugs does not render section 379r(d)(2) a "nullity."

Contrary to the AG's arguments, the trial court did not render the section 379r(d)(2) savings clause a "nullity" by holding that CEH's

[7] The AG also argues that the savings clause saves Proposition 65 claims from any form of conflict preemption except for federal enactments issued "on a basis relevant to consumer health." (ACB 8–10, 12–16.) It is true that, as part *Dowhal's* obstacle preemption ruling, it held that "*If the FDA's directive here* prohibiting nonidentical labels is to be sustained, it must be on a basis relevant to consumer health, and not because the Proposition 65 label would frustrate the FDA's policy favoring national uniformity." (*Dowhal*, *supra*, 32 Cal.4th at p. 926, emphasis added.) But *Dowhal* did not hold that Proposition 65 claims are saved from *impossibility* preemption unless a court finds that the federal statute was enacted "on a basis relevant to consumer health." Regardless, the Hatch-Waxman Amendments and the generic-drug duty of sameness were enacted to provide consumers with greater access to inexpensive drugs, a goal that is plainly relevant to consumer health.

Proposition 65 warning claim was preempted based on *Mensing*, *Bartlett*, and the duty of sameness. (ACB 19.)

The AG misconstrues the trial court's ruling. The trial court did not hold that "Proposition 65 simply does not apply to exposures in OTC drugs because, in its view, warnings not approved by the FDA cannot be added to such products." (ACB 19.) To the contrary, the trial court recognized that manufacturers of brand name over-the-counter drugs can unilaterally add Proposition 65 warnings to drug labeling, without waiting for FDA approval, through the so-called "Changes Being Effected" (CBE) federal regulatory process. (3 AA 907–909; see *Mensing*, *supra*, 564 U.S. at p. 614 ["When making labeling changes using the CBE process, [brand name] drug manufacturers need not wait for preapproval by the FDA, which ordinarily is necessary to change a label. [Citation.] They need only simultaneously file a supplemental application with the FDA."].)

The court thus permitted CEH to amend its complaint to state such a claim against the manufacturers of brand name over-the-counter Zantac. (3 AA 907–909.) And CEH ultimately did so; the action is currently proceeding before the trial court as to the brand name defendants based on CEH's third amended complaint. (See 3 AA 934–936.) Consequently, affirming the trial court's ruling would not prevent enforcement of Proposition 65's warning

requirements as to brand name over-the-counter drug products that fail to add a Proposition 65-compliant warning to their existing drug labeling.

Moreover, affirming the trial court's ruling at issue here would not mean that generic over-the-counter drugs sold in California would never bear Proposition 65 warnings. As *Dowhal* recognized, "in most cases" a manufacturer of a brand name over-the-counter drug can add a Proposition 65 warning to its label without that warning being precluded under obstacle preemption. (*Dowhal*, *supra*, 32 Cal.4th at p. 934.) And as soon as a brand name manufacturer adds a Proposition 65 warning to its label, generic-drug manufacturers *must* follow suit and change their own warning labeling in compliance with the federal duty of sameness. (See *Mensing*, *supra*, 564 U.S. at p. 618 ["Federal law . . . demanded that generic drug labels be the same *at all times* as the corresponding brand-name drug labels" so long as the generic drug was on the market (emphasis added)].)

II. THE ATTORNEY GENERAL ADDS NO NEW ANALYSIS REGARDING WHETHER COMMUNICATIONS CONVEYING A WARNING ARE "LABELING" UNDER FEDERAL LAW.

The parties' briefing in the trial court and on appeal has extensively addressed whether warnings conveyed through point-of-sale shelf signs, public advertising, websites, or other similar means constitute "labeling" under federal law. Respondents have explained that all forms of

communications that issue a warning to consumers about a generic-drug product are "labeling" and therefore subject to the federal duty of sameness in generic-drug labeling and are preempted under *Mensing* and *Bartlett*. (RB 34–46.) CEH asserts that these forms of communications are not labeling, or at least not with respect to over-the-counter drug products, and are exceptions to generic-drug impossibility preemption. (AOB 31–40.)

While the AG agrees with CEH on this issue, it notably does not advance CEH's argument. Instead, the AG relies solely on the same points and cases already raised by CEH, all of which were addressed in the Respondents' brief. California and persuasive federal authorities have consistently held that communicating a warning through advertising or other mediums is "labeling" under federal law and, therefore, subject to generic-drug impossibility preemption. (RB 34–40.) The trial court did not err in following this body of well-settled law.

III. THE ATTORNEY GENERAL CORRECTLY EXPLAINS THAT NON-WARNING ACTIONS ARE IRRELEVANT TO PREEMPTION OF THE PROPOSITION 65 CLAIM.

CEH has argued that Health and Safety Code section 25249.6 "plainly contemplates two methods of compliance: providing a clear and reasonable warning ***or*** not exposing persons to listed chemicals." (ARB 26.) The AG's brief correctly rejects this dual compliance argument. Instead, the AG

interprets Proposition 65 to mean that the *only* duty or requirement for a company doing business in California is "to provide 'clear and reasonable warning' before exposing any individual to a chemical known to the state to cause cancer or reproductive toxicity." (ACB 28, quoting Health & Saf. Code, § 25249.6; see RB 60–61 [making similar argument].) The AG flatly states that CEH's "alternative interpretation of Proposition 65 to include a duty to reformulate . . . is incorrect." (ACB 30.)

CEH will no doubt protest that the AG has misconstrued CEH's position. In its most recent filing in this appeal, CEH maintains there is a distinction between actions that would *comply* with Proposition 65 and actions that would satisfy a *duty or requirement* imposed by Proposition 65. (RJN Reply 13–14.) And CEH insists that because it has alleged Respondents could have reformulated their ranitidine products or taken other actions to reduce or eliminate NDMA in ranitidine, those methods of "compliance" foreclose preemption here. (ARB 24–29; RJN Reply 13–14.)

This argument misses the point. The Supremacy Clause preempts state law claims when "It was not lawful under federal law for [defendant manufacturers] to do what state law required of them." (*Mensing*, *supra*, 564 U.S. at p. 618.) Actions that a manufacturer could possibly have undertaken but that are not *required* by state law are irrelevant to the analysis. Thus, as

the AG correctly explains, because "it is clear that reformulation is not a statutory duty or requirement, the 'possibility' of reformulation is not relevant to the preemption analysis in this case." (ACB 30.)

Accordingly, if this court determines that federal law preempted Respondents from issuing a Proposition 65-compliant warning, that is enough to affirm the trial court's demurrer ruling for two separate and independent reasons:

First, Health and Safety Code section 25249.10, subdivision (a), provides that the Proposition 65 warning requirement "shall not apply to . . . [¶] (a) An exposure for which federal law governs warning in a manner that preempts state authority." The lower court correctly read that provision to mean that federal law preempting Respondents from issuing a warning for their ranitidine products suffices to dispose of the claim. (RB 54–59.)

Second, irrespective of Health and Safety Code section 25249.10, subdivision (a), the AG is correct that reformulation or other alleged actions that might have reduced levels of NDMA in the products are irrelevant to and cannot avoid preemption. Simply put, because the only duty that Proposition 65 imposes is a duty to warn, a federal law that preempts warnings makes it unlawful to do what state law requires and thereby preempts the entire Proposition 65 claim.

CONCLUSION

For these reasons, this Court should affirm the judgment in Respondents' favor.

Respectfully submitted,

September 21, 2022

STEPTOE & JOHNSON LLP
DENNIS RAGLIN

GOODELL, DEVRIES, LEECH & DANN, LLP
RICHARD M. BARNES
DEREK M. STIKELEATHER
SEAN GUGERTY

By: */s/ Dennis Raglin*
Dennis Raglin

Attorneys for Defendant and Respondent
Perrigo Company

September 21, 2022 **NORTON ROSE FULBRIGHT US LLP**
Jeffrey B. Margulies
Lauren A. Shoor

By: */s/ Jeffrey B. Margulies*
Jeffrey B. Margulies

Attorneys for Defendant and Respondent
Target Corporation

September 21, 2022 **LEWIS BRISBOIS BISGAARD & SMITH LLP**
PAUL A. DESROCHERS

By: */s/ Paul A. Desrochers*
Paul A. Desrochers

Attorneys for Plaintiff and Appellant
Granules USA, Inc.

September 21, 2022 **ARNOLD & PORTER KAYE SCHOLER LLP**
TRENTON H. NORRIS
WILLIS M. WAGNER

By: */s/ Trenton H. Norris*
Trenton H. Norris

Attorneys for Defendant and Respondent
7-Eleven, Inc.

September 21, 2022 **BLANK ROME LLP**
TERRY M. HENRY
CHERYL S. CHANG
JESSICA A. MCELROY

By: */s/ Cheryl S. Chang*
Cheryl S. Chang

Attorneys for Defendant and Respondent
Apotex Corp.

September 21, 2022 **GORDON REES SCULLY MANSUKHANI LLP**
BRIAN M. LEDGER
ULMER & BERNE LLP

By: */s/ Brian M. Ledger*
Brian M. Ledger

Attorneys for Defendants and Respondents
Dr. Reddy's Laboratories, Inc. and
Dr. Reddy's Laboratories Louisiana, LLC

CERTIFICATE OF WORD COUNT

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September 21, 2022

STEPTOE & JOHNSON LLP
DENNIS RAGLIN

GOODELL, DEVRIES, LEECH & DANN, LLP
RICHARD M. BARNES
DEREK M. STIKELEATHER
SEAN GUGERTY

By: */s/ Dennis Raglin*
Dennis Raglin

Attorneys for Defendant and Respondent
Perrigo Company

PROOF OF SERVICE

CENTER FOR ENVIRONMENTAL HEALTH
v.
PERRIGO COMPANY, ET AL.
CASE NO. A163682

STATE OF CALIFORNIA, COUNTY OF LOS ANGELES

At the time of service, I was over 18 years of age and not a party to this action. I am employed in the County of Los Angeles, State of California. My business address is: 633 W. Fifth Street, Suite 1900, Los Angeles, CA 90071.

On **September 21, 2022,** I served true copies of the following document(s) described as **RESPONDENTS' ANSWER TO AMICUS CURIAE BRIEF OF THE ATTORNEY GENERAL** on the interested parties in this action as follows:

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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 **September 21, 2022**, at Los Angeles, California.

/s/ Inez Brown
INEZ BRONW

SERVICE LIST
CENTER FOR ENVIRONMENTAL HEALTH
v.
PERRIGO COMPANY, ET AL.
CASE NO. A163682

GOODELL, DEVRIES, LEECH & DANN, LLP Richard M. Barnes Derek M. Stikeleather Sean Gugerty One South Street, 20th Floor Baltimore, Maryland 21202 rmb@gdldlaw.com *dstikeleather@gdldlaw.com* *sgugerty@gdldlaw.com*	Attorneys for Defendant and Respondent **Perrigo Company** [***Via TrueFiling***]
NORTON ROSE FULBRIGHT US LLP Jeffrey B. Margulies Lauren A. Shoor 555 South Flower Street, 41st Floor Los Angeles, California 90071 *jeff.margulies@nortonrosefulbright.com* *lauren.shoor@nortonrosefulbright.com*	Attorneys for Defendant and Respondent **Target Corporation** [***Via TrueFiling***]
LEWIS BRISBOIS BISGAARD & SMITH LLP Paul A. Desrochers 333 Bush Street, suite 1100 San Francisco, California 94104 *Paul.Desrochers@lewisbrisbois.com*	Attorneys for Defendant and Respondent **Granules USA, Inc.** [***Via TrueFiling***]
ARNOLD & PORTER KAYE SCHOLER LLP Trenton H. Norris Willis M. Wagner Three Embarcadero Center 10th Floor San Francisco, California 94111 *trent.norris@arnoldporter.com* *will.wagner@arnoldporter.com*	Attorneys for Defendant and Respondent **7-Eleven, Inc.** [***Via TrueFiling***]

GORDON REES SCULLY MANSUKHANI LLP
Brian M. ledger
101 W. Broadway, Suite 2000
San Diego, California 92101
bledger@grsm.com

Attorneys for Defendants and Respondents **Dr. Reddy's Laboratories, Inc. and Dr. Reddy's Laboratories Louisiana, LLC**

[***Via TrueFiling***]

ULMER & BERNE LLP
Megan B. Gramke
312 Walnut Street
Suite 1400
Cincinnati, Ohio 45202
mgramke@ulmer.com

Attorneys for Defendants and Respondents **Dr. Reddy's Laboratories, Inc. and Dr. Reddy's Laboratories Louisiana, LLC**

[***Via TrueFiling***]

BLANK ROME LLP
Cheryl S. Chang
Jessica McElroy
2029 Century Park East, 6th floor
Los Angeles, California 90067
cchang@blankrome.com
jmcelroy@blankrome.com

Attorneys for Defendant and Respondent **Apotex Corp.**

[***Via TrueFiling***]

BLANK ROME LLP
Terry M. Henry
One Logan Square, 130
North 18th Street
Philadelphia, PA 19103
thenry@blankrome.com

Attorneys for Defendant and Respondent **Apotex Corp.**

[***Via TrueFiling***]

LEXINGTON LAW GROUP
Mark N. Todzo
Joseph Mann
503 Divisadero Street
San Francisco, California 94117
mtodzo@lexlawgroup.com
jmann@lexlawgroup.com

Attorneys for Plaintiff and Appellant **Center for Environmental Health**

[***Via TrueFiling***]

Rob Bonta
Edward H. Ochoa
Laura J. Zukerman
Raissa S. Lerner
Office of the Attorney General
1515 Clay Street, 20th Floor
P.O. Box 70550
Oakland, CA 94612-0550
Raissa.Lerner@doj.ca.gov

Attorneys for Amicus Curiae
Attorney General Rob Bonta