No. S109306

IN THE SUPREME COURT OF THE STATE OF CALIFORNIA

PAUL DOWHAL,
Plaintiff and Respondent,

v.

SMITHKLINE BEECHAM CONSUMER HEALTHCARE, LP; McNEIL CONSUMER PRODUCTS COMPANY, A DIVISION OF McNEIL-PPC, INC., PHARMACIA & UPJOHN, INC., ALZA CORPORATION; AVENTIS PHARMACEUTICALS, INC., COSTCO COMPANIES, INC., LUCKY STORES, INC., RITE AID CORPORATION; SAFEWAY, INC., and WALGREEN COMPANY,
Defendants and Petitioners.

Appeal from a Judgment Based
On an Order Granting a Motion for
Summary Judgment and Denying a
Cross Motion for Summary Adjudication

Court of Appeal, First Appellate District, Division Five, No. A094460
Superior Court of the State of California
for the County of San Francisco
Honorable David A. Garcia, Judge Presiding

Unfair Competition Case
(*See* Bus. & Prof. Code § 17209 and Cal. Rule of Court 16(d))

APPLICATION FOR LEAVE TO FILE BRIEF AMICUS CURIAE AND BRIEF AMICUS CURIAE OF PUBLIC CITIZEN IN SUPPORT OF RESPONDENT DOWHAL

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APPLICATION FOR LEAVE TO FILE BRIEF AMICUS CURIAE

TO THE JUSTICES OF THE SUPREME COURT OF THE STATE OF CALIFORNIA:

Pursuant to California Rule of Court 14(b), applicant Public Citizen requests leave to file a brief amicus curiae in support of plaintiff-respondent Paul Dowhal. The issue in this case is whether Food and Drug Administration ("FDA") regulation of over-the-counter ("OTC") drugs under the Food, Drug, and Cosmetic Act, 21 U.S.C. § 321 *et seq*. ("FDCA"), preempts application of the California statute commonly known as Proposition 65 to OTC drugs. In particular, the question is whether FDA regulation of the warnings on OTC nicotine replacement products preempts the State from requiring manufacturers of those products to warn that nicotine is known to the State of California to cause reproductive harm. Public Citizen has reviewed the submissions of the parties and believes that the additional argument in the accompanying brief will assist the Court in resolving this case.

The amicus brief first examines the relevance of 21 U.S.C. § 379r, which contains a clause explicitly saving Proposition 65 from an express preemption provision that applies to state regulation that imposes requirements on OTC drugs that are "different from or in addition to" federal requirements. Defendants' argument that a Proposition 65 warning would frustrate Congress's objectives flies in the face of Congress's own unambiguous

decision to preserve Proposition 65 warnings that are "different from" or "in addition to" federal requirements for OTC drugs.

Next, the brief explains why Proposition 65 does not frustrate the purposes of the agency's regulation of nicotine replacement products, in light of *Sprietsma v. Mercury Marine* (2002) 123 S. Ct. 518, and the role delegated to the FDA by Congress.

Finally, drawing on Public Citizen's expertise in the area of federal drug regulation, this brief discusses Defendants' assertion that a Proposition 65 warning is preempted because such a warning would render their products misbranded. This argument is belied by the FDCA provisions that address misbranding and undisputed evidence about the effects of nicotine on fetuses.

Public Citizen is a national non-profit consumer advocacy organization founded in 1971. It is based in Washington, DC, and has an office in Oakland, California. On behalf of its 125,000 members, including more than 25,000 members in California, Public Citizen engages in research, education, lobbying, and litigation on a broad range of consumer issues. Of particular relevance here, Public Citizen, through its Health Research Group, monitors the safety of drugs and FDA regulation of them. Public Citizen therefore is very familiar with the federal requirements applicable to drugs. In addition, Public Citizen lawyers have represented plaintiffs on appeal and have participated as counsel for amicus in many cases involving a question of preemption

of state law, including cases involving prescription drugs, *see Motus v. Pfizer* (9th Cir.) Nos. 02-55372, 02-55498 (pending); medical devices, *see*, *e.g.*, *Medtronic v. Lohr* (1996) 518 U.S. 470; pesticides, *see*, *e.g.*, *Taylor AG Industries v. Pure-Gro* (9th Cir. 1995) 54 F.3d 555; and hazardous substances, *see*, *e.g.*, *Jenkins v. James Day & Co*. (Ohio 1994) 634 N.E.2d 998.

Public Citizen is concerned about a trend, particularly apparent in the federal courts, of immunizing defendants from tort liability by holding that federal statutes preempt the claims of tort plaintiffs. These holdings have been repeatedly rejected by the United States Supreme Court. *See*, *e.g.*, *Sprietsma*, 123 S. Ct. 518; *Medtronic,* 518 U.S. 470; *Freightliner Corp. v . Myrick* (1995) 514 U.S. 280. Nonetheless, defendants' attempts to assert a preemption defense to evade duties imposed under state law make this appeal critically important, even beyond the bounds of Proposition 65.

Accordingly, Public Citizen requests leave to file the attached brief.

Dated: July 11, 2003

Respectfully submitted,

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No. S109306

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BRIEF AMICUS CURIAE OF PUBLIC CITIZEN IN SUPPORT OF RESPONDENT DOWHAL

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INTEREST OF AMICUS CURIAE

Founded in 1971, Public Citizen is a consumer advocacy organization with offices in Washington, DC, California, and Texas. On behalf of its 125,000 members nationwide, including more than 25,000 in California, Public Citizen educates consumers about drug safety, advocates for effective regulation of consumer products, and works to protect consumers' access to state-law remedies for injuries caused by defective products, among other things. Public Citizen is concerned that, if adopted by this Court, the position taken by Defendants in this case will hamper the ability of states to maintain and enforce laws intended to protect the health and safety of their citizens. Public Citizen therefore urges this Court to affirm the decision of the court of appeal.

STATEMENT OF THE CASE

1. Under the Food, Drug, and Cosmetic Act ("FDCA"), a manufacturer must obtain the approval of the Food and Drug Administration ("FDA") before marketing a new drug. During the approval process, the FDA considers the results of clinical trials, proposed labeling, and other information to determine whether the drug would be safe and effective for the uses stated in the proposed labeling. *See* 21 U.S.C. §§ 355(b)(1)(A), (b)(1)(F), (d), (e). FDA marketing approval includes approval of the labeling. After approval, the manufacturer cannot make certain labeling changes without first obtaining

FDA approval, but it may make other labeling changes without approval. 21 C.F.R. §§ 314.70(b), (c). Among the changes in the latter category are changes "[t]o add or strengthen a contra-indication, warning, precaution, or adverse reaction." *Id.* at § 314.70(c)(2)(i).

2. California's Safe Drinking Water and Toxic Enforcement Act, commonly known as Proposition 65, requires any person doing business in California to give a clear and reasonable warning before exposing any individual to a chemical known to the State to cause cancer or reproductive toxicity. Cal. Health & Safety Code § 25249.5; *see* 22 Cal. Code of Regs. § 12601(a) ("CCR"). The regulations implementing Proposition 65 set forth certain "safe harbor" warnings that are deemed to be clear and reasonable. *Id*. § 12601(b). For example, the statement "WARNING: This product contains a chemical that is known to the State of California to cause birth defects or other reproductive harm" is a safe harbor warning. *Id*. § 12601(b)(4)(B). Proposition 65 warnings may be given on a product's label, via store signs, or through advertising. *Id*. § 12601(b)(1)(A)-(C). Nicotine is one of the chemicals listed under Proposition 65 as a chemical known to the State to cause reproductive toxicity. *Id*. § 12000(c).

In addition, Proposition 65 does not convey an implicit disagreement with the FDA's findings: "This article establishes exposure levels solely for purposes of Section 25249.10(c) of the Act. Nothing in this article shall be

construed to establish exposure levels for other regulatory purposes." 22 C.C.R. § 12801(e); *see also id.* at § 12701(d).

3. This action was brought by Paul Dowhal to enforce Proposition 65 with respect to over-the-counter ("OTC") nicotine replacement products, which are intended to help people to quit smoking. The FDA requires that the labels of those products include the following language:

> If you are pregnant or breast-feeding, only use this medicine on the advice of your health care provider. Smoking can seriously harm your child. Try to stop smoking without using any nicotine replacement medicine. This medicine is believed to be safer than smoking. However, the risks to your child from this medicine are not fully known.

Jt. Req. Jud. Notice, Exh. 1 at 8. However, the FDA does not require that the labeling include a statement that complies with Proposition 65, such as "This product contains a chemical known to the State of California to cause birth defects," or "Nicotine, whether from smoking or medication, can harm your baby."

The superior court dismissed the action on the ground that the FDCA impliedly preempts Proposition 65 with respect to OTC drugs. The court of appeal reversed, finding that Defendants could comply with both federal requirements and Proposition 65's requirements and that compliance with Proposition 65 would not frustrate Congress's purpose in enacting the FDCA and relevant provisions thereof.

ARGUMENT

I. THE PRESUMPTION AGAINST PREEMPTION APPLIES IN THIS CASE.

The federal preemption doctrine has its origin in the Supremacy Clause, article VI, clause 2 of the Constitution of the United States, which states:

> This Constitution, and the Laws of the United States which shall be made in Pursuance thereof; and all Treaties made, or which shall be made, under the Authority of the United States, shall be the supreme Law of the Land; and the Judges in every State shall be bound thereby, and any Thing in the Constitution or Laws of any State to the Contrary notwithstanding.

The Supremacy Clause provides the constitutional authority for the proposition that conflicts between federal and state law are resolved in favor of federal law. *See McCulloch v. Maryland* (1819) 4 Wheat. 316, 427, 4 L. Ed. 579; *Cipollone v. Liggett Group, Inc.* (1992) 505 U.S. 504, 516. Preemption is said to be "express" if a federal statute explicitly addresses the domain of state law that is or is not preempted, and "implied" if the structure and purpose of federal law, but not its actual words, preempt state law. *See id*. The implied preemption doctrine is itself divided into two types: field preemption and conflict preemption. Conflict preemption is further subdivided into two types, one based on the impossibility of simultaneously complying with both federal and state law, and the other triggered if state law frustrates the purposes of federal law.

However, in light of the constitutional imperative of federalism embodied, among other places, in the Tenth Amendment, "[c]onsideration under the Supremacy Clause starts with the basic assumption that Congress did not intend to displace state law." *Maryland v. Louisiana* (1981) 451 U.S. 725, 746. A party seeking preemption of state law thus bears a heavy burden, for "[p]reemption of state law by federal . . . regulation is not favored 'in the absence of persuasive reasons—either that the nature of the regulated subject matter permits no other conclusion, or that Congress has unmistakably so ordained.'" *Chicago & North Western Transp. Co. v. Kalo Brick & Tile Co.* (1981) 450 U.S. 311, 317 (quoting *Florida Lime & Avocado Growers, Inc. v. Paul* (1963) 373 U.S. 132, 142).

Moreover, the presumption against preemption is even stronger where "Congress [has] legislated . . . in a field which the States have traditionally occupied, [involving] the historic police powers of the States." *Rice v. Santa Fe Elevator Corp.* (1947) 331 U.S. 218, 230. In other words, the presumption is "that state and local regulation of health and safety matters can constitutionally coexist with federal regulation" because "the regulation of health and safety matters is primarily, and historically, a matter of local concern." *Hillsborough County v. Automated Med. Labs., Inc.* (1985) 471 U.S. 707, 716, 719; *Chemical Specialties Manufacturers Ass'n v. Allenby* (9th Cir. 1992) 958 F.2d 941, 943. This presumption applies here because

preemption would displace the historic power of the State of California to protect the health and safety of its citizens. *See, e.g., Medtronic, Inc. v. Lohr* (1996) 518 U.S. 518 U.S. 470, 484-86.

The foregoing anti-preemption principles are deeply embedded in the "federal-state balance" that is fundamental to the nation's constitutional plan. *Hillsborough County*, 471 U.S. 707; *Jones v. Rath Packing Co.* (1977) 430 U.S. 519, 525; *see also* Corboy & Smith, *Federal Preemption of Product Liability Law: Federalism and the Theory of Implied Preemption* (1992) 15 Am. J. Trial Advoc. 435, 444-57 (discussing presumption against preemption in context of Tenth Amendment and federalist principles). Thus, the Supreme Court's Supremacy Clause jurisprudence reflects "an acknowledgment that the States retain substantial sovereign powers under our constitutional scheme, powers with which Congress does not readily interfere." *Gregory v. Ashcroft* (1991) 501 U.S. 452, 461; *see also Jones*, 430 U.S. at 525 (presumption against preemption "provides assurance that the 'federal-state balance' will not be disturbed unintentionally by Congress or unnecessarily by the courts") (quoting *United States v. Bass* (1971) 404 U.S. 336, 349).

II. ENFORCING PROPOSITION 65 WITH RESPECT TO NICOTINE REPLACEMENT PRODUCTS WOULD NOT FRUSTRATE THE PURPOSES OF FEDERAL REGULATION.

A. Congress Has Made Explicit That Allowing Proposition 65 Warnings That Are "Different From, In Addition To, Or That [Are] Not Otherwise Identical With" Federal Warnings Does Not Frustrate The Purposes Of Federal Regulation.

The provision of the FDCA entitled "National Uniformity for Nonprescription Drugs," 21 U.S.C. § 379r, was added in 1997. Section 379r provides, in relevant part:

> (a) IN GENERAL.—Except as provided in subsection (b), (c)(1), (d), (e), or (f), no State or political subdivision of a State may establish or continue in effect any requirement—
>
> > (1) that relates to the regulation of a drug that is not subject to the requirements of section 503(b)(1) or 503(f)(1)(A); and
> >
> > (2) that is different from or in addition to, or that is not otherwise identical with, a requirement under this Act . . .
>
> . . . .
>
> (d) EXCEPTIONS.—
>
> > . . . .
> >
> > (2) STATE INITIATIVES.—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, approved by California voters as an initiative in 1986, is the only state law that falls within the exception of subsection (d)(2). Thus, as Defendants agree, Proposition 65 and actions brought to enforce its requirements are not *expressly* preempted.

1. Although section 379r is an express preemption provision, it is nonetheless relevant here because its terms are largely a codification of implied conflict preemption principles. Section 379r(a) was enacted out of concern that "[d]ifferent or additional requirements at the State or local level can work against our national marketplace, confuse consumers, raise prices, undermine public confidence in our regulatory system and in products important to the public health, and result in divergent public health protection throughout the country." S. Rep. 105-43 (1997) at 66. Stated differently, Congress was concerned that state and local laws could frustrate the purposes of the federal regulation.

Nonetheless, Congress chose explicitly to exclude Proposition 65 from the scope of preemption. It thus made a conscious decision to allow Proposition 65 to remain in effect, despite its potential to impose requirements that conflict with FDA requirements. As the Senate sponsor, Senator Jeffords, stated, discussing section 379r: "Well, to California we said, OK, you have that [Proposition 65] so we will carve you out. Go forward. . . . The Federal Government will not intervene, will not do away with that." 143 Cong. Rec. S8837, S8845 (daily ed. Sept. 5, 1997). Accordingly, Senator Boxer thanked the Senate sponsors for excluding Proposition 65 from the scope of section 379r's preemption: "I want to thank Senators Gregg and Jeffords for working with me to ensure that California's proposition 65 will not be preempted by the

uniformity provisions of this bill." 143 Cong. Rec. S9842, S9844 (daily ed. Sept. 24, 1997). Senator Feinstein echoed those comments, stating: "I am pleased that the Senate agreed with my request to explicitly exempt Proposition 65, preserving this important California law, and I thank my colleagues for their support." *Id.*

"The case for federal preemption is particularly weak where Congress has indicated its awareness of the operation of state law in a field of interest and has nonetheless decided to 'stand by both concepts and to tolerate whatever tension there [is] between them.'" *Bonito Boats v. Thunder Craft Boats* (1989) 489 U.S. 141, 167 (quoting *Silkwood v. Kerr-McGee Corp.* (1984) 464 U.S. 238, 256). Thus, to the extent that Defendants are arguing that Proposition 65 is preempted because it frustrates the objectives of Congress, Congress has explicitly stated that Proposition 65 does not do so and that any conflicts between the federal law and Proposition 65 must be tolerated.

2. Pointing to the regulatory history of nicotine replacement products, Defendants and the FDA have tried to distinguish Congress's objectives generally from the FDA's objectives specifically with regard to these products. Thus, they have argued that a Proposition 65 warning would frustrate FDA's purpose of encouraging their use to help people stop smoking. This frustration of *agency* purpose claim runs directly counter to section 379r(d), which indicates that Congress intended to tolerate such "conflicts."

Both the statutory language and the legislative history of section 379r(d), quoted above, make clear that this savings clause was enacted specifically to allow Proposition 65 to operate even in instances in which it posed an obstacle to federal regulation. The FDA's authority to regulate derives solely from Congress, and its purposes are defined by Congress. Because Congress has expressly provided that the purposes of federal regulation are not frustrated by Proposition 65, the claim that the FDA's own purposes are frustrated has no merit.

The decision in *Geier v. American Honda Motor Co.* (2000) 529 U.S. 861, is not to the contrary. In *Geier*, the United States Supreme Court analyzed a savings clause that provided that "compliance with" a federal safety standard "does not exempt any person from any liability under common law." 15 U.S.C. § 1397(k). The Court held that the clause did not evince congressional intent to save tort claims from implied conflict preemption, as the words used "sound as if they simply bar a special kind of defense." 529 U.S. at 869. Although the Court further held that the savings clause there had *no* bearing on the question of conflict preemption, *id.* at 870, it also made clear that Congress could save state law from conflict preemption if it wanted to do so. *Id.* at 872.

In section 379r(d), Congress did just that; it saved Proposition 65 from implied conflict preemption. Unlike the savings clause in *Geier*, which

referred *generally* to common law claims, the savings clause here refers to the *specific* state law at issue. This distinction is significant because section 379r(d) evinces Congress's intent to permit Proposition 65 in particular to co-exist with FDA requirements, even to the extent that Proposition 65 conflicts with federal law by requiring warnings that are "different from," "in addition to," or "not otherwise identical with" federal regulations. In other words, the savings clause was enacted specifically to allow Proposition 65 to operate even where it might pose an obstacle to federal regulation.

B. Even Putting Aside Section 379r(d), The Frustration Of Agency Purpose Argument Lacks Merit.

Even if section 379r(d) did not foreclose the possibility of preemption under a frustration of agency purpose theory, Defendants' argument would fail for two reasons.

First, the agency's statement of purpose—to encourage use of the products—has no preemptive effect because it appears in an amicus brief and other informal statements, not in a formal agency pronouncement. In *Sprietsma v. Mercury Marine* (2002) 123 S. Ct. 518, the Supreme Court considered whether the Coast Guard's decision not to require propeller guards on motor boats impliedly preempted a state-law damages action that alleged that the manufacturer's motor boat was unreasonably dangerous because the motor was not protected by a propeller guard. Rejecting the manufacturer's

preemption argument, the Court explained that "[i]t is quite wrong" to view a decision declining to impose a requirement as the "functional equivalent" of a prohibition against state regulation of the subject matter. Rather, a decision not to take regulatory action leaves the applicable law "exactly the same" as it was before the agency's consideration of the matter. *Id.* at 527; *accord Freightliner Corp. v. Myrick* (1995) 514 U.S. 280, 289 (where agency had no standard either requiring or prohibiting antilock brakes, state common law as applied to antilock brakes not preempted); *Puerto Rico Dept. of Consumer Affairs v. Isla Petroleum Corp*. (1988) 485 U.S. 495, 501, 503 (absent explicit statement of intent, federal inaction has no preemptive effect).

The FDA's decision not to require a Proposition 65 warning mirrors the situation presented in *Sprietsma*. In both cases, the defendants premised the conflict preemption argument on agency action *not* taken, as opposed to the agency's imposition of a requirement or prohibition. With regard to OTC nicotine delivery products, the FDA has rejected the Proposition 65 warning, *see* Jt. Req. Jud. Notice, Ex. 1 at 8, but it has not taken any formal action to prohibit Defendants from adding one. Just as in *Sprietsma*, where the agency had considered whether to impose a requirement and decided not to do so, here the FDA considered a Proposition 65 warning in response to Dowhal's citizen petition and denied his request that the manufacturers be *required* to add such a warning. *See id.* However, the FDA never prohibited Defendants from

including one. As the United States recently explained to the United States Supreme Court, "the mere fact that the agency has made a considered decision to forgo federal regulation does not, in and of itself, give rise to an inference that all state law on the subject—including state tort law—is meant to be preempted." US Br. in *Sprietsma v. Mercury Marine* (filed Mar. 29, 2002) S. Ct. No. 01-706, 2002 WL 500643 at *18.

In this regard, Defendants' reliance on *Geier* is misplaced. In *Geier*, the Court found that the plaintiff's state-law claims seeking to hold Honda liable for not installing an air bag in her car would conflict with the agency's implementation of a regulation requiring passive restraints in passenger cars. The finding of a conflict was based on the agency's "own contemporaneous explanation" of the objectives of the regulation, which included giving auto manufacturers flexibility in their choice of passive restraint systems. 529 U.S. at 877-80; *see also* US Br. in *Sprietsma, supra*, at *19 ("*Geier* does not suggest that common-law suits will be preempted whenever the federal agency has focused its attention upon the particular aspect of motor vehicle performance that forms the basis of the plaintiff's claim.").

In contrast, neither Defendants nor the FDA ground their argument in any prior FDA statement about implementation of the FDCA or the functioning of the labeling and misbranding regulations. To the contrary, in one of its few statements about the scope of preemption made outside of

litigation, the FDA has expressed the view that state labeling requirements that impose additional requirements, on top of those required by the FDA, are *not* preempted. In 1998, the FDA issued regulations addressing pharmacists' provision of written patient information in the form of "Medication Guides" for certain types of prescription drugs. 63 Fed. Reg. 66378 (1998). Manufacturers are required to obtain FDA approval of the Medication Guides (21 C.F.R. § 208.24(a)), and the FDA has prescribed numerous specific requirements as to both form and content. *See id*. § 208.20. Nonetheless, when issuing the final rule, the FDA rejected comments calling for the FDA to express an intent to preempt State regulation of labeling requirements:

> FDA regulations establish minimal standards necessary, but were not intended to preclude states from imposing additional labeling requirements. States may authorize additional labeling but they cannot reduce, alter, or eliminate FDA-required labeling.

63 Fed. Reg. at 66383-84.

Here, the State of California, through Proposition 65, has "authorize[d]" "additional labeling" that does not "reduce, alter, or eliminate FDA-required labeling." The provision of Medication Guides parallels the situation here: Medication Guides are distributed at the pharmacy, and Proposition 65 can be satisfied by posting warnings at the point of sale, without altering the product labeling itself. Accordingly, the FDA's view prior to this litigation supports the continued viability of Proposition 65 as applied to drugs. *See also United*

States v. Mead Corp. (2001) 533 U.S. 218, 228 (degree of deference due to government depends on, among other things, consistency and formality).

Second, Defendants cannot rely on the FDA's reasoning that allowing a stronger pregnancy warning might discourage use of OTC nicotine replacement products for two reasons. To begin with, because the FDA has approved warnings for the prescription products that satisfy Proposition 65 (*see infra* pp. 19-20), the suggestion that a Proposition 65 warning would be counter-productive to the goal of encouraging pregnant women to quit smoking seems disingenuous at best. To our knowledge, the FDA has never stated that it prefers OTC to prescription nicotine delivery products. Tellingly, neither Defendants nor the FDA offered evidence in this litigation that the warnings on the prescription products adversely affected product use.

Moreover, the FDA's mission is neither to encourage nor to discourage use of particular drugs. Whereas the Office of the Surgeon General and the Centers for Disease Control, for example, work to promote public health by, among other things, educating the public in the hope of affecting people's choices, the FDA's "mission" is to "promote the public health by promptly and efficiently reviewing clinical research and taking appropriate action on the marketing of regulated products in a timely manner" and to "protect the public health by ensuring that human . . . drugs are safe and effective." 21 U.S.C. § 393. That is, the FDA's role is to ensure that manufacturers provide

physicians and consumers with adequate information with which to make their own decisions about which products to use. Accordingly, whether or not a Proposition 65 warning would make pregnant women think twice before using OTC nicotine delivery products, such a warning would not interfere with any FDA objective within the scope of its statutory authority.

III. A PROPOSITION 65 WARNING WOULD NOT RENDER THE PRODUCTS MISBRANDED.

Defendants do not claim that it is physically impossible to give the warnings approved by the FDA and the Proposition 65 warning. Rather, relying on FDA amicus briefs filed in the court of appeal and in support of the petition to this Court, Defendants argue that providing a Proposition 65 warning is impliedly preempted because such a warning would render their products misbranded. The FDCA, however, as well as United States Supreme Court case law and briefs filed by the United States Department of Justice in other cases, do not support Defendants' theory.

The FDCA prohibits the misbranding of drugs and provides that a drug is misbranded if "its labeling is false or misleading in any particular." 21 U.S.C. § 352(a). "Labeling" means the label on the product, its wrapper, or container, and also "other written, printed, or graphic matter" "accompanying" the product. *Id*. § 201(m). Misbranded drugs are subject to an enforcement action by the FDA. *Id*. §§ 334, 335. However, the determination that a drug

is misbranded is not the FDA's to make. Rather, if the FDA wants to pursue enforcement action for alleged misbranding, the agency must file suit against the manufacturer in a federal district court. *Id*. §§ 332 (injunctions), 333 (criminal penalties), 334 (seizure). And the manufacturer is entitled to a jury trial. *Id*. §§ 332(b), 333, 334(b). Because the filing of an enforcement action does not guarantee that the FDA will prevail, no conflict would exist until the FDA had won the action. As the Supreme Court has explained: "The existence of a hypothetical or potential conflict is insufficient to warrant the preemption of the state [law]." *Rice v. Norman Williams Co.* (1982) 458 U.S. 654, 659.

Moreover, "Proposition 65 neither expressly nor impliedly requires additional product labeling." *Chemical Manufacturers' Ass'n*, 941 F.2d at 947. Rather, it may be satisfied either through labeling or in-store signs. 22 CCR § 12601(b)(3). The latter method of compliance cannot render Defendants' products misbranded for the simple reason that signs posted by stores—such as defendants Costco, Lucky Stores, Rite Aid, Safeway, and Walgreen—do not fall within the FDCA's definition of labeling. *Cf. Chemical Manufacturers' Ass'n*, 941 F.2d at 946 (Proposition 65 not preempted by Federal Insecticide, Fungicide, and Rodenticide Act because point-of-sale signs do not constitute "labeling" within meaning of Act). Putting aside the question of whether Congress has granted the FDA any authority over the conduct of drugstores, the FDA—outside the context of litigation—has

recognized that its regulation does not "limit the information that can be given to the patient" by pharmacists. 63 Fed. Reg. at 66382. Thus, in issuing a regulation with respect to patient information sheets that are prepared by manufacturers but handed out by pharmacies, the FDA confirmed that the "*pharmacist may add to the information* and discuss any aspect of the product with the patient, thereby promoting better communication between health care professionals and their patients." *Id.* (emphasis added).

In any event, the Court owes no deference to the FDA's assertion in this litigation that the Proposition 65 warning would render Defendants' products misbranded. To be sure, like a federal statute, federal agency action having the force of law may preempt conflicting state requirements. *Sprietsma,* 123 S. Ct. at 527; *Fidelity Federal Savings & Loan Ass'n v. De La Cuesta* (1982) 458 U.S. 141, 153. But as the United States has argued in other cases, a statement in an amicus brief falls far short of the sort of final agency action necessary to evaluate the potential for conflict between state-law claims and federal action. *See* US Br. in *Sprietsma, supra*, at *23 ("as a general matter, state law is not preempted by a mere expression of an opinion or statement of policy by a federal agency, untethered to any agency action that has legal effect in its own right"); *see also Mead*, 533 U.S. at 228 (degree of deference due to government depends on, among other things, consistency, formality, and

thoroughness of government's position). Thus, threats of enforcement action in FDA amicus briefs are insufficient to create a conflict.

Defendants also rely on various correspondence with the FDA, in which the FDA stated that adding a Proposition 65 warning "may" render the products misbranded. *See* JA 2401, *see also* JA 1560 ("could possibly"). Notably, Defendants have not pointed to a single instance—outside of the FDA amicus briefs in this litigation—in which the FDA stated that a Proposition 65 warning "would" render the product misbranded. The agency's statements were not only tentative, they were never issued for public notice and comment or published in the Federal Register. The letters thus lack the power to preempt. *See Chrysler Corp. v Brown* (1979) 441 U.S. 281, 313 (agency rule "cannot be afforded the 'force and effect of law' if not promulgated pursuant to the statutory minimum found in" the Administrative Procedure Act); *cf. Mead*, 533 U.S. at 228.

Notably, the FDA does not disagree that nicotine is, in Proposition 65 terms, "known to . . . cause birth defects or other reproductive harm." In fact, FDA regulations require that the label of prescription nicotine replacement products warn that the products "can cause fetal harm when administered to a pregnant woman." 21 C.F.R. § 201.57(f)(6)(i)(d); JA 1055 (FDA memo); Jt. Req. Jud. Notice, Exh. 1 at 3; *see also* JA 1056 (FDA memo stating "nicotine is clearly hazardous"). Consistent with this regulation, the FDA has not taken

enforcement action against the manufacturer of any prescription nicotine replacement product for warning about the risk of fetal harm.

Furthermore, the statements on prescription products do not suggest that the risks associated with nicotine are somehow different when products are marketed over the counter. For example, the website for one of the prescription products states, under "When should I NOT use the Nicotrol Inhaler?": "Do not use if you are pregnant (or think you may be pregnant) or nursing, unless your doctor tells you to do so. *Nicotine in any form can harm your unborn baby*." *See* www.nicotrol.com/inhaler/safety.asp (emphasis added); *see also* Respondent's Br. at 9 (citing similar warnings at JA 951, 960, 973, 1003, 1023).[1] The labels of both the Nicotrol Inhaler and the Nasal Spray state: "Nicotine has been shown in animal studies to cause fetal harm." *Physicians' Desk Reference* at 2776, 2778 (57th ed. 2003). Those labels

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[1] The Nicotrol Inhaler also provides the following "pregnancy warning":

> [N]icotine has been shown in animal studies to cause fetal harm. It is therefore presumed that NICOTROL Inhaler can cause fetal harm when administered to a pregnant woman. The effect of nicotine delivery by NICOTROL Inhaler has not been examined in pregnancy (See Precautions). **Therefore, pregnant smokers should be encouraged to attempt cessation using educational and behavioral interventions before using pharmacological approaches**. If NICOTROL Inhaler is used during pregnancy, or if the patient becomes pregnant while using it, the patient should be apprised of the potential hazard to the fetus.

Physicians' Desk Reference at 2775 (57th ed. 2003) (emphasis in original).

further caution: "Spontaneous abortion during nicotine replacement therapy has been reported; as with smoking, nicotine as a contributing factor cannot be excluded." *Id.* As these warnings make clear, the potential for harm does not depend on the characterization of the product as prescription or OTC.

The FDA's prescription nicotine warnings reflect the body of research showing that nicotine can cause severe reproductive harm, including spontaneous abortion, disruption of lung development, disturbance in cardiovascular function, and reduction in the delivery of nutrients to the fetus. JA 1210-11 at ¶¶ 8-13. As demonstrated by these warnings, the FDA does not actually disagree with the State about the risks posed to pregnant women by use nicotine replacement products.

Likewise, according to the Surgeon General, who is charged with "protect[ing] and advanc[ing] the health of the Nation through educating the public; [and] advocating for effective disease prevention and health promotion programs and activities" (www.surgeongeneral.gov/sg/duties.htm):

> The risks associated with using the nicotine patch during pregnancy are largely unknown. Nicotine itself poses risks to the fetus, including neurotoxicity, and pregnant women should first be encouraged to quit without pharmacotherapy. Because exposure to nicotine through maternal use of the patch probably poses less danger to the fetus than does continued maternal smoking, however, nicotine replacement therapy may be indicated for pregnant women who are unable to quit smoking. However, if a decision is made to use nicotine replacement therapy during pregnancy, the physician should consider monitoring blood nicotine levels, using doses at the low end of

> the effective range, and choosing intermittent delivery systems (such as nicotine gum). The issue is under active investigation.

Reducing Tobacco Use, A Report of the Surgeon General at 118 (HHS Aug. 2000) (www.cdc.gov/tobacco/sgr_tobacco_use.htm) (citations omitted). A Proposition 65 safe harbor warning is fully consistent with this assessment of the risks of OTC nicotine replacement products.

Accordingly, even if the FDA initiated enforcement action against a manufacturer who included a Proposition 65 warning on its OTC nicotine replacement product, it seems improbable that the agency would be able to demonstrate that the warning rendered the labeling "false or misleading." Indeed, the agency would be putting itself in the awkward position of arguing against its own regulations with respect to prescription products and against the conclusions of the United States Surgeon General. And, most importantly, until the agency prevailed in an enforcement action, the question whether the products were misbranded would remain open and no conflict would exist.

CONCLUSION

For the foregoing reasons, the decision of the court of appeal should be affirmed.

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