

CASE NO. S109306

IN THE SUPREME COURT OF THE STATE OF CALIFORNIA

PAUL DOWHAL, an individual acting
in the Public Interest and on behalf
of the General Public,

Plaintiff

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 Motion For
Summary Judgment And Denying 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)).

PLAINTIFF'S OPPOSITION BRIEF ON THE MERITS

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TABLE OF CONTENTS

INTRODUCTION AND SUMMARY OF ARGUMENT.	1
STATEMENT OF THE CASE.	6
1. FACTUAL BACKGROUND.	6
A. Defendants Expose Individuals To Nicotine, A Chemical Known To Cause Reproductive Harm.	6
2. The FDA-Required Warnings For Prescription Nicotine Replacement Products Have Always Warned, And Continue To Warn, That Exposure To Nicotine Can Cause Reproductive Harm.	8
C. FDA Acquiesced To SmithKline’s Request To Use The Diluted “Increased Heart Rate” Pregnancy Warning On Its OTC Products.	9
D. FDA Approved The Proposition 65-Compliant “Harm Your Baby” Warning For The OTC Habitrol Nicotine Patch.	10
E. FDA’s Informal Correspondence With Defendants Never “Prohibited” Them From Complying With Proposition 65.	12
F. FDA’s August 17, 2001 Letter To Plaintiff’s Counsel Tentatively Rejected Both Of The Warnings It Had Previously Approved..	12
II. PROCEDURAL BACKGROUND	14
III. STATUTORY BACKGROUND	14
A. Proposition 65.	14
B. Federal Food, Drug And Cosmetic Act.	15
1. General Provisions.	15

2.	Preemption Of State OTC Drug Requirements Under The FDCA.	16
	ARGUMENT.	19
I.	THE COURT OF APPEAL CORRECTLY CONCLUDED THAT PLAINTIFF’S PROPOSITION 65 CLAIMS ARE EXPRESSLY EXEMPTED FROM PREEMPTION UNDER THE FDCA.	19
A.	The Plain Language Of FDAMA Evidences Congress’ Clear Intent To Exempt Proposition 65 From FDCA Preemption.	21
B.	The Legislative History Of FDAMA Further Demonstrates Congress’ Intent To Exempt Proposition 65 From <i>Any</i> Federal Preemption Under The FDCA.	24
C.	Under FDAMA, FDA Has No Authority To Preempt “Different or Additional” Warnings Required By Proposition 65.	26
D.	<i>Geier</i> Does Not Permit A Court To Ignore The Clear Intent Of Congress.	27
II.	EVEN IF THIS COURT UNDERTAKES AN IMPLIED CONFLICT PREEMPTION ANALYSIS, NO CONFLICT BETWEEN PROPOSITION 65 AND FEDERAL LAW EXISTS IN THIS CASE.	29
A.	Informal FDA “Directives” And “Objectives” Do Not Have The “Force Of Law” And May Not Preempt State Law Under The Supremacy Clause.	31
1.	The Informal FDA Letters Before The Trial Court Are Not Constitutionally Capable Of Creating A Preemptive Conflict With Plaintiff’s Claims.	33
2.	FDA’s August 17 Letter To Plaintiff’s Counsel Does Not Carry The Force Of Law.	37

3.	FDA’s Amicus Brief Is Not Capable Of Elevating Its Prior Informal Actions To The Status Of Law.	38
B.	FDA’s Litigation-Inspired Interpretations Of Its Informal Actions Are Not Entitled To Deference.	39
C.	The Application Of Proposition 65 To OTC Nicotine Products Does Not Conflict With Any Federal Requirement Or Purpose.	42
1.	The FDA Letters Do Not Prohibit Defendants From Complying With Proposition 65.	42
2.	The Alleged Federal Objective Defendants Cite In Support Of Their Frustration Of Purpose Argument Is Not Valid Under The FDCA.	46
3.	Defendants Can Comply With Both Proposition 65 And FDA’s Requirements And Objectives For The Products.	47
	CONCLUSION.	50

TABLE OF AUTHORITIES

CALIFORNIA CASES

<i>Carlin v. Superior Court</i> (1996) 13 Cal.4th 1104	47
<i>Comm. of Seven Thousand v. Sup.Ct.</i> (1988) 45 Cal.3d 491	23
<i>Kanter v. Warner Lambert Co.</i> (2002) 99 Cal.App.4th 780	9, 35, 36
<i>McCall v. PacifiCare of Cal.</i> (2001) 25 Cal.4th 412	37
<i>People v. American Standard</i> (1996) 14 Cal.4th 294	3, 14, 46
<i>People ex rel. Lungren v. Cotter & Co.</i> (1997) 53 Cal.App.4th 1373	<i>passim</i>
<i>Smiley v. Citibank</i> (1995) 11 Cal.4th 138	20
<i>Yamaha Corp. of America v. State Bd. of Equalization</i> (1998) 19 Cal.4th 1	24, 40
<i>Younger v. Jensen</i> (1980) 26 Cal.3d 397	30, 43

FEDERAL CASES

<i>American Deposit Corp. v. Schacht</i> (N.D. Ill. 1995) 887 F.Supp. 1066	30, 34
<i>Ass'n. of Int'l Auto Mfrs v. Mass. D.E.P.</i> (2 nd Cir. 2000) 208 F.3d 1	24

<i>Barclays Bank PLC v. Franchise Tax Bd. of California</i> (1994) 512 U.S. 298	38, 39
<i>Batterton v. Marshall</i> (D.C. Cir. 1980) 648 F.2d 694	32
<i>Biotics Research Corp. v. Heckler</i> (9 th Cir. 1983) 710 F.2d 1375	34
<i>Brock v. Cathedral Bluffs Shale Oil Co.</i> (D.C. Cir. 1986) 796 F.2d 533	34, 39
<i>Chemical Specialties Mfrs. Assn. v. Allenby</i> (9 th Cir. 1992) 958 F.2d 941	<i>passim</i>
<i>Christensen v. Harris County</i> (2000) 529 U.S. 576	30, 41
<i>Chrysler Corp. v. Brown</i> (1979) 441 U.S. 281	32
<i>Cipollone v. Liggett Group, Inc.</i> (1992) 505 U.S. 504	19, 21
<i>City of New York v. FCC</i> (1988) 486 U.S. 57	<i>passim</i>
<i>Comm. of Dental Amalgam Mfrs. & Distribs. v. Stratton</i> (9 th Cir. 1996) 92 F.3d 807	48
<i>English v. General Electric Co.</i> (1990) 496 U.S. 72	19, 21
<i>FDA v. Brown & Williamson Tobacco Corporation, et al.</i> (2000) 529 U.S. 120	16, 42, 47
<i>Federal Energy Administration v. Algonquin</i> (1976) 426 U.S. 548	24
<i>Fidelity Fed. Savings & Loan Assn. v. De la Cuesta</i> (1986) 458 U.S. 141	19, 45

<i>Florida Lime & Avocado Growers v. Paul</i> (1963) 373 U.S. 132	20
<i>FTC v. Pantron I Corp.</i> (9 th Cir. 1994) 33 F.3d 1088	46
<i>FTC v. Standard Oil of California</i> (1980) 449 U.S. 232	40
<i>Geier v. American Honda Co.</i> (2000) 529 U.S. 861	<i>passim</i>
<i>Goldstein v. California</i> (1973) 412 U.S. 546	30, 43
<i>Hillsborough County, Fla. v. Automated Medical Laboratories, Inc.</i> (1985) 471 U.S. 707	<i>passim</i>
<i>Louisiana Public Service Commission v. FCC, et al.</i> (1986) 476 U.S. 355	26, 27
<i>Morton v. Ruiz</i> (1974) 415 U.S. 199	32
<i>Motus v. Pfizer</i> (C.D. CA 2000) 127 F.Supp.2d 1085	44
<i>Sprietsma v. Mercury Marine</i> (2002) 123 S.Ct. 518	37, 41
<i>The Wilderness Society v. U.S. Fish and Wildlife Service</i> (9 th Cir. 2003) 316 F.3d 913	35, 40
<i>Thomas v. New York</i> (D.C. Cir. 1986) 802 F.2d 1443	38
<i>Ting v. AT&T</i> (9 th Cir. 2003) 319 F.3d 1126	20
<i>U.S. v. Ferrara</i> (D.D.C. 1993) 847 F.Supp. 964	30, 34, 37

<i>U.S. v. Mead</i> (2001) 533 U.S. 218	30
<i>U.S. v. Sullivan</i> (1948) 332 U.S. 689	3, 15, 46
<i>Wabash Valley Power Association v. REA</i> (7 th Cir. 1990) 903 F.2d 445	<i>passim</i>

CALIFORNIA STATUTES AND REGULATIONS

Health & Safety Code §25249.6	1, 15, 29
Health & Safety Code §25249.10	15
22 CCR §12000	8, 45
22 CCR §12601	<i>passim</i>

FEDERAL STATUTES AND REGULATIONS

U.S. Constitution Art. VI, cl. 2.	4, 31
5 U.S.C. §553	16
15 U.S.C. §52	46
21 U.S.C. §301 <i>et seq.</i>	1
21 U.S.C. §331	16
21 U.S.C. §332	16, 40
21 U.S.C. §333	16, 40
21 U.S.C. §334	16, 40
21 U.S.C. §343-1	23

21 U.S.C. §352	16, 45
21 U.S.C. §355	16
21 U.S.C. §360e	36
21 U.S.C. §371	16
21 U.S.C. §379r	<i>passim</i>
49 U.S.C. §30103	27
Public Law 101-535	23
Public Law 105-115	18
21 C.F.R. §10.30	12, 38
21 C.F.R. §10.40	16
21 C.F.R. §10.65	33
21 C.F.R. §201.57	8, 9, 47
21 C.F.R. §201.63	17, 31
21 C.F.R. §201.66	31
21 C.F.R. §314	9
21 C.F.R. §314.70	<i>passim</i>
47 Fed.Reg. 54750 <i>et seq.</i>	17, 23
49 Fed.Reg. 28962 <i>et seq.</i>	41
62 Fed.Reg. 9024 <i>et seq.</i>	3, 17, 23
64 Fed.Reg. 13254 <i>et seq.</i>	<i>passim</i>

CONGRESSIONAL RECORD

143 Cong. Rec. S8856 (daily ed. September 5, 1997) *passim*
143 Cong. Rec. S8867-68 (daily ed. September 5, 1997) 29
143 Cong. Rec. S9842 (daily ed. September 24, 1997) *passim*
143 Cong. Rec. S9844 (daily ed. September 24, 1997) 1, 25, 26

INTRODUCTION AND SUMMARY OF ARGUMENT

Plaintiff Paul Dowhal (“Plaintiff”) filed this action to compel Defendants¹ to provide clear and reasonable warnings regarding the reproductive harm associated with the nicotine in their over-the-counter (“OTC”) nicotine patches and gums (the “Products”). The Products, by design, expose users to high levels of nicotine, a harmful chemical that is known to cause skeletal abnormalities and fetal brain damage in animals, and, according to the Food and Drug Administration (“FDA”), represents a risk of “embryo-fetal lethality” in humans. Nicotine is listed pursuant to Proposition 65 as a chemical known to the State of California to cause birth defects or other reproductive harm. Accordingly, Proposition 65 requires a warning that clearly and reasonably states that the Products contain a chemical that is known to the State to cause reproductive toxicity. (Health & Saf. Code, §25249.6.)

At the time Plaintiff filed this lawsuit, Defendants’ Products merely cautioned pregnant users that nicotine “can increase your baby’s heart rate.” The California Attorney General has determined that this warning does not comply with Proposition 65. FDA now agrees with Plaintiff that the “increased heart rate” warning understates the reproductive risks associated with maternal nicotine exposure. Nevertheless, Defendants contend that FDA’s prior approval of the “increased heart rate” warning, together with informal FDA letters, meeting notes and a litigation brief, preempts Plaintiff’s claims under the doctrine of “implied conflict

¹ The term “Defendants” refers to petitioners SmithKline Beecham Consumer Healthcare, L.P. (“SmithKline”), McNeil Consumer Products Company, a division of McNeil-PPC, Inc., Aventis Pharmaceuticals, Inc., Pharmacia Corporation, Alza Corporation, Costco Companies, Inc., Lucky Stores, Inc., Rite Aid Corporation, Safeway, Inc., and Walgreen Company.

preemption.”

Defendants’ implied preemption argument ignores the express intent of Congress. When amending the Food Drug and Cosmetic Act (21 U.S.C. §301 *et seq.*, “FDCA”) in 1997, Congress gave special consideration to a single state statute – Proposition 65. Recognizing that Proposition 65 “has provided important protections to the public,” Congress expressly exempted California’s unique right-to-know law from the broad preemptive reach of the FDCA, as amended by the FDA Modernization Act (“FDAMA”). (143 Cong.Rec. S9844 (daily ed. September 24, 1997); 21 U.S.C. §379r(d)(2).) Based on this Congressional enactment, the Court of Appeal correctly concluded that “Congress clearly did not intend to preempt Proposition 65 under the FDCA,” and rejected Defendants’ “implied conflict preemption” defense. (Majority Opinion [“Maj.Opn.”] at 10.)

There is no need for this Court to second guess Congress’ intent, as Defendants urge. In FDAMA, Congress plainly stated that preemption of state OTC drug requirements that “are different from [or] in addition to” requirements under the FDCA “*shall not apply*” to Proposition 65. (21 USC § 379r(d)(2).) This case presents the exact situation contemplated by Congress in FDAMA – Proposition 65 requires a warning for the Products that is different from, or in addition to, the warning approved by FDA. Proposition 65 requires that the Products bear a warning instructing that the *chemical* nicotine is known to the State of California to cause birth defects or other reproductive harm. FDA’s approved warning for the Products states only that “nicotine can increase your baby’s heart rate.” Thus, under FDAMA, preemption shall not apply to this Proposition 65 enforcement action.

Defendants argue that interpreting FDAMA to exempt all

Proposition 65 claims from preemption is akin to finding that Congress “designed . . . [the FDCA] to ‘defeat its own objectives, or . . . destroy itself.’” (See Defendants’ Opening Brief [“Ds’ Br.”] at 5, *citing Geier v. American Honda Co.* (2000) 529 U.S. 861, 872.) This argument ignores Congress’ manifest intent. Congress exempted Proposition 65 from preemption because the primary objective of this state law – to protect the People of the State of California “against chemicals that cause cancer, birth defects or other reproductive harm” (*People v. Superior Court (American Standard)* (1996) 14 Cal.4th 294, 306) – is fully consistent with, and in fact complements, the FDCA’s primary objective – “to protect consumers from dangerous products.” (*U.S. v. Sullivan* (1948) 332 U.S. 689, 696.) In fact, the legislative history of FDAMA confirms that Congress was willing to tolerate potential conflict between Proposition 65 and FDA’s requirements because Proposition 65 “has even led FDA to adopt more stringent standards,” resulting in stronger national protections. (143 Cong.Rec. S9842 (daily ed. September 24, 1997).)

Although FDA has taken a contrary position in this litigation, the agency formally adopted Congress’ unambiguous intent to exempt Proposition 65 from FDCA preemption in its own OTC drug labeling regulations. In March 1999, while well aware of Plaintiff’s claims, FDA finalized its OTC labeling rule and removed a proposed provision that was specifically intended to preempt Proposition 65 under the doctrine of implied conflict preemption. (64 Fed.Reg. 13254, 13272; 62 Fed.Reg. 9024, 9040-9043.) FDA did so based on an official determination that its proposal to impliedly preempt Proposition 65 had been “superseded” by FDAMA. (64 Fed.Reg. 13272.) There has been no change to the relevant statutes or regulations since this lawsuit was filed. Nor have any additional

statutes or regulations that bear on the preemption question before this Court been enacted or promulgated. Accordingly, no federal *law* conflicts with the requirements of Proposition 65 as to the Products.

Defendants do not contend otherwise. Rather, Defendants argue that Proposition 65's requirements conflict with "FDA's directives" contained in informal letters and other statements by employees and agents of the FDA. They contend that the unanimous determination by the Court of Appeal that there is no preemption in this case "deprives Defendants of the ability to rely on [such] FDA[] directives." (Ds' Br. at 8.) However, even if there were a conflict between Proposition 65 and "FDA's directives" with regard to the Products (which there is not, as discussed herein), such a conflict is constitutionally incapable of preempting Proposition 65. Under the Supremacy Clause, "the *laws* of the United States ... shall be the supreme law of the land." (U.S. Const., Art. VI, cl. 2, emphasis added.) For purposes of the Supremacy Clause, "the laws of the United States" includes both federal statutes and regulations. (*City of New York v. FCC* (1988) 486 U.S. 57, 63.) The Supremacy Clause has never been extended to include agency "directives" or any other federal action that does not have the force of law. (*See Wabash Valley Power Assoc. v. REA* (7th Cir. 1990) 903 F.2d 445, 453-454.) Accordingly, there is no constitutionally cognizable conflict here.

Defendants complain that by not allowing them to comply with FDA's directives, the Court of Appeal's decision creates a great deal of uncertainty regarding the requirements with which a regulated entity should comply. Not so. Regulated entities must always comply with state laws, unless such state laws are preempted by federal *laws*. In this case, no conflict between federal law – the FDCA and FDA's regulations – and

Proposition 65 exists. Indeed, the unique aspect of this case is the fact that the very state law claims involved here are specifically referenced, and excluded from preemption, in both the applicable federal statute and regulations. Thus, Defendants' claim that they were unaware of the applicable legal requirements is unconvincing.

Defendants' obligations under Proposition 65 have always been clear. Nevertheless, instead of complying with Proposition 65, Defendants chose to elicit and rely on a series of informal, private letters from FDA employees. At any time, Defendants could have added a Proposition 65 warning to the Products' labels pursuant to an FDA regulation that expressly permits drug makers to "add or strengthen" a warning without prior FDA approval. (*See* 21 C.F.R. §314.70(c)(2)(i).) Indeed, the manufacturer of another OTC nicotine patch not involved in this case has done exactly that, and has never been cited for "misbranding" violations by FDA. Moreover, as Justice Simons observed in his concurring opinion below, Defendants also could have communicated Proposition 65 warnings via store signs or public advertising, as FDA has no regulatory authority over OTC drug advertising. (*See* Concurring Opinion ["Conc.Opn."] at 8, n.5.)

In order to find "implied conflict preemption" sufficient to reverse the Court of Appeal's ruling, this Court must, therefore, accept that compliance with Proposition 65 and the FDCA is either a physical impossibility, or stands as an obstacle to the accomplishment and execution of the full purposes of Congress. (*Hillsborough County v. Automated Medical Laboratories, Inc.* (1985) 471 U.S. 707, 713.) In order to so find, each of the following obstacles must be surmounted:

- (1) Congress' clear intent to exempt Proposition 65 from FDCA preemption;

- (2) FDA’s formal determination that passage of FDAMA superseded its proposed regulation impliedly preempting Proposition 65;
- (3) the strong presumption against preemption of state health and safety laws;
- (4) the constitutional requirement that federal agency action, unlike the informal FDA actions at issue in this appeal, must have the “force of law” to preempt state law;
- (5) the fact that the FDA letters in the record do not create a direct conflict with Proposition 65;
- (6) the fact that the alleged federal objective, on which Defendants’ frustration of purpose argument hinges, conflicts with FDA’s primary responsibility under the FDCA;
- (7) the availability of at least two methods of Proposition 65 compliance that fall outside the scope of FDA’s purportedly preemptive statements to Defendants; *and*
- (8) the fact that FDA, in its post-summary judgment statements regarding this case, has only rejected one of many possible Proposition 65-compliant warnings.

For Defendants to obtain a reversal of the Court of Appeal’s decision, they must overcome *each* of these hurdles. As discussed below, Defendants’ arguments stumble on all of them.

STATEMENT OF THE CASE

I. FACTUAL BACKGROUND

A. Defendants Expose Individuals To Nicotine, A Chemical Known To Cause Reproductive Harm.

Defendants’ Products are designed, marketed and sold for the express purpose of exposing users to significant levels of nicotine in order to help them stop smoking.² (JA 1574, 1211-1212.) Nicotine has been

² Although smoking cessation is clearly a laudable purpose, the Products are not particularly effective with respect to pregnant smokers.

(continued...)

shown in repeated animal studies to cause severe reproductive harm, including fetal brain damage. (JA 1210, ¶7.) In addition, recent studies demonstrate that maternal nicotine exposure causes: (1) adverse effects on lung development; (2) a reduction in placental transport of nutrients to the fetus; and (3) disturbances in cardiorespiratory function that may predispose infants to Sudden Infant Death Syndrome. (JA 1211, ¶13.)

FDA acknowledges that nicotine causes reproductive harm, and currently requires pregnancy warnings regarding such harm in the labeling of prescription nicotine replacement products, including the following FDA-approved warnings:

- “Nicotine has been shown in animal studies to cause fetal harm.” (JA 0987-0988, 1013.)
- “Nicotine was shown to produce skeletal abnormalities in the offspring of mice.” (JA 0958, 0972, 0993-0994, 1013.)
- “Cigarette smoking during pregnancy is associated with an increased risk of spontaneous abortion, low birth weight infants and perinatal mortality. Nicotine and carbon monoxide are considered the most likely mediators of these outcomes.” (*Ibid.*)
- “Spontaneous abortion during nicotine replacement therapy has been reported; as with smoking, nicotine as a contributing factor cannot be excluded.” (*Ibid.*)³

²(...continued)

According to a study published in *Obstetrics & Gynecology* in December 2000, nicotine patches have “no influence on smoking cessation during pregnancy.” (Joint Appendix [“JA”] 1249.)

³ In clinical studies performed on behalf of SmithKline during the Nicoderm Rx/OTC conversion, one in five women who became pregnant while using the Nicoderm patch suffered a serious adverse reproductive outcome. (JA 1036.) Two of the twelve women who became pregnant while using the Nicoderm patch suffered spontaneous abortions while a third was diagnosed with a severe birth defect. (*Ibid.*) In commenting on the spontaneous abortions reported during nicotine

(continued...)

In addition, according to FDA, exposure to nicotine has been shown to “represent some risk in humans for embryo-fetal lethality.” (Joint Request for Judicial Notice [“Joint RJN”], Ex.1 at 4.) Nicotine is also listed by the State of California as a chemical known to the State to cause reproductive toxicity pursuant to Proposition 65. (22 Cal. Code of Regulations [“CCR”] §12000(c).)

B. The FDA-Required Warnings For Prescription Nicotine Replacement Products Have Always Warned, And Continue To Warn, That Exposure To Nicotine Can Cause Reproductive Harm.

The Products were originally sold on a prescription-only basis. (JA 1574.) Since the advent of nicotine delivery products in the early 1980's, FDA has consistently required that prescription versions of the Products contain patient warnings regarding the reproductive toxicity of nicotine. (JA 0951, 0960, 0973.) Based on FDA’s belief that nicotine products had the potential for causing severe reproductive harm, nicotine products were originally categorized as pregnancy “category X” (the risk of using the product during pregnancy outweighs the benefits). (JA 1055; Joint RJN, Ex. 1 at 3; 21 C.F.R. §201.57(f)(6)(i)(e).) However, FDA later changed the nicotine patch products to pregnancy “category D” (“*there is positive evidence of human fetal risk* based on adverse reaction data from investigational or marketing experience or studies in humans, but the potential benefits from the use of the drug in pregnant women may be acceptable despite its potential risks”). (JA 1055; Joint RJN at 3; 21 C.F.R. §201.57(f)(6)(i)(d), emphasis added.)

Accordingly, the pregnancy warnings required by FDA in the

³(...continued)
replacement therapy,³ FDA concluded that “nicotine as a contributing factor cannot be excluded.” (JA 0958, 0972, 0994, 1013.)

patient instructions for the original Nicorette, Nicoderm and Nicotrol prescription products, as well as those required in the patient instructions of other nicotine products sold by prescription today, state: “nicotine in any form may cause harm to your unborn baby.” (JA 0951, 0960, 0973, 1003, 1023.) The prescription nicotine patch and gum products are identical to their OTC counterparts in active ingredient, dosage form, route of administration and strength. (JA 1574.)

C. FDA Acquiesced To SmithKline’s Request To Use The Diluted “Increased Heart Rate” Pregnancy Warning On Its OTC Products.

Beginning in the mid 1990's, Defendants applied for and obtained FDA approval to sell and market Nicorette gum, as well as the Nicoderm and Nicotrol patches, as OTC drugs. (JA 1059, 1070.)

Defendants pursued OTC approval of the Products through the new drug application (“NDA”) process.⁴ (*Ibid.*)

Although the OTC Products are chemically identical to their prescription-only counterparts, Defendants sought to change the pregnancy warning for the Products. (JA 1107-1116, 0807-0808.) Specifically, in 1994, SmithKline proposed that the pregnancy warning for Nicorette — the first of the Products to receive OTC approval from FDA — be modified to read “nicotine can affect your baby’s heart rate.” (*Ibid.*) FDA suggested instead a “nicotine may harm your baby” warning — similar to the patient warning used with the Nicorette prescription product. (JA 1105.) But, in February 1996, without any public notice or rationale, FDA acquiesced to SmithKline and approved the following statement for use on OTC Nicorette

⁴ The vast majority of OTC drugs are regulated pursuant to FDA monographs, which are published “notice and comment” regulations applicable to a class of OTC drug products. (*See Kanter v. Warner Lambert Co.* (2002) 99 Cal.App.4th 780, 786.) The NDA process, on the other hand, is a private process between FDA and the applicant. (*See* 21 C.F.R. §314.)

and, later, the other Products: “*nicotine can increase your baby’s heart rate.*”⁵ (JA 1118-1121.)

Undisputed scientific evidence demonstrates that an increase in fetal heart rate, in and of itself, is *not* a birth defect and causes *no* reproductive harm. (JA 1212-13.) Accordingly, the California Attorney General determined that the “increased heart rate” statement on the Products does not clearly communicate that nicotine is a chemical known to the State to cause birth defects or other reproductive harm, and thus, is not a “clear and reasonable” warning under Proposition 65. (JA 1314; *see* 22 CCR §12601(a).) FDA now agrees with Plaintiff that the “increased heart rate” warning is insufficient to apprise pregnant women of the reproductive risks associated with nicotine exposure. (Joint RJN, Ex. 1 at 5.) FDA now believes that such warning “may . . . lead pregnant consumers to believe that increasing a baby’s heart rate is the only possible effect of nicotine on the baby,” when, in fact, it is not. (*Ibid.*)

D. FDA Approved The Proposition 65-Compliant “Harm Your Baby” Warning For The OTC Habitrol Nicotine Patch.

In November 1999, after passage of FDAMA, FDA approved the Habitrol nicotine patch, manufactured by Novartis Consumer Health, Inc. (“Novartis”), and sold under the private label brands of Defendants Walgreens and Rite-Aid, for OTC sale. (JA 1928-1930, 1932-1933, 2267.) The Habitrol nicotine patch is identical to the Nicoderm CQ patch sold by SmithKline in active ingredient, dosage form, route of administration and

⁵ Defendants contend that FDA “initially established” its rationale for allowing this diluted pregnancy warning – in order to promote use of the Products by avoiding over-warning – at a meeting of an FDA advisory committee. (Ds’ Br. at 40.) However, this meeting took place on April 19, 1996 – over two months after FDA acquiesced to SmithKline’s request to use the diluted warning. (JA 0295.)

strength. (*Compare* JA 1928-1930, 1932-1933 *with* JA 1581-1582.) FDA has concluded that the Products are identical to Habitrol for purposes of pregnancy warnings. (Joint RJN, Ex. 1 at 5.) Nonetheless, FDA approved a different pregnancy warning for Habitrol. (JA 2267, 2113, 2125.) The FDA-approved Habitrol warning states: “***Nicotine, whether from smoking or medication, can harm your baby.***” (*Ibid.*) The California Attorney General determined that this warning “appears to satisfy the Proposition 65 requirement for a ‘clear and reasonable’ warning.” (JA 1314.)

Subsequent to FDA’s approval of the “harm your baby” warning for use on Habitrol, Novartis elected to add a version of the Proposition 65 “safe harbor” warning to the Habitrol label *in addition to* the “harm your baby” warning already on the label.⁶ (JA 2103.) Novartis did so pursuant to FDA regulations which expressly permit companies to “add or strengthen” a warning or contraindication on an OTC product label without FDA pre-approval. (*Ibid.*; *see* 21 C.F.R. §314.70(c)(2)(i).) FDA has never issued a warning letter, a misbranding citation, or taken other action against Novartis for selling a nicotine patch with a Proposition 65 compliant label warning. (JA 2103-2104.)

E. FDA’s Informal Correspondence With Defendants Never “Prohibited” Them From Complying With Proposition 65.

Since FDA’s approval of the “harm your baby” warning for Habitrol, FDA has corresponded with Defendants on a number of occasions

⁶ Specifically, this version of the “safe harbor” warning states: “WARNING: This product contains nicotine, a chemical known to the State of California to cause birth defects or other reproductive harm.” (JA 1930, 1933.)

regarding the Products. This correspondence falls into two categories: (1) boilerplate approval letters and label comments (JA 1612-1617, 1622-1624, 1626-1630, 1632-1636, 1640-1641, 1643-1644); and (2) letters responding to inquiries from Defendants' counsel (JA 1638, 2401). The first category consists of letters indicating FDA approval of several new versions of Defendants' Products. In connection with such approvals, FDA recommended that Defendants continue to include the "increased heart rate" statement on their labeling. (JA 1614, 1624, 1626, 1632-1636, 1634, 1640.)

The letters responding to Defendants' counsel similarly instruct Defendants to continue using the approved "increased heart rate" statement (JA 1638), and state, without reference to any specific alternative or additional warning language, that "[a]ny additional or modified warning *may* render the product misbranded." (JA 2401, emphasis added.) None of the letters make any reference to preemption of Proposition 65. (*Ibid.*)

F. FDA's August 17, 2001 Letter To Plaintiff's Counsel Tentatively Rejected Both Of The Warnings It Had Previously Approved.

On August 2, 2000, Plaintiff filed a citizen petition with the FDA pursuant to 21 C.F.R. §10.30. (JA 1150-1156.) Plaintiff's petition sought "to change the pregnancy nursing warning on certain OTC nicotine replacement products, including nicotine gum and nicotine patches . . . from the current 'increased heart rate' warning to a warning that more broadly communicates all of the potential reproductive harm associated with nicotine use." (JA 1150.) In the citizen petition, as in this case, Plaintiff argued that the "increased heart rate" statement improperly implies that the Products are as safe as abstinence from all forms of nicotine during pregnancy and thus provides no incentive for pregnant women to quit smoking without using the Products during pregnancy. (JA 1153-1154.)

On August 17, 2001 – *five months after the trial court’s summary judgment ruling* – FDA responded to Plaintiff’s citizen petition in a letter to Plaintiff’s lawyer (the “August 17 letter”). (Joint RJN, Ex. 1.) FDA granted the petition in part, adopting Plaintiff’s reasoning and objective that there should be:

a consistent pregnancy warning for all OTC [nicotine] drug products that clearly and reasonably communicates all of the known harm and conveys the relative reproductive harm of smoking, use of [nicotine] drug products, and total abstinence from nicotine.

(*Id.* at 2, 8.) FDA then repudiated both of the pregnancy warnings it had previously approved for use on OTC nicotine products. In particular, FDA stated that the “increased heart rate” statement included on the Products’ labeling “may not be sufficient to convey the appropriate message to pregnant consumers who are considering using these products.” (*Id.* at 5.) Although FDA acknowledged that it was aware of no new scientific evidence, the August 17 letter also states that the “harm your baby warning” *may* “overstate[] the known risks of [nicotine] products.” (*Id.* at 4, 5.) While this latter assessment was based on FDA’s view that additional research is needed regarding the adverse reproductive effects of using the Products, FDA gave no indication that it would require Defendants to undertake such research. (*Id.* at 4.)

FDA concluded the August 17 letter by proposing the following new warning in place of the “increased heart rate” and “harm your baby” warnings:

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.

(*Id.* at 8). The August 17 letter does not require either FDA or Defendants to take any specific actions to implement this proposed warning.

II. PROCEDURAL BACKGROUND

Plaintiff filed the underlying action on August 23, 1999 in order to compel Defendants to provide consumers of the Products with a clear and reasonable warning regarding the known reproductive harm associated with nicotine exposure pursuant to Proposition 65. The trial court entered judgment in favor of Defendants on March 23, 2001, ruling that FDA's informal correspondence with Defendants created a preemptive conflict with the requirements of Proposition 65. Plaintiff immediately noticed his appeal. On July 12, 2002, the Court of Appeal reversed the judgment of the trial court. On October 23, 2002, this Court granted review.

III. STATUTORY BACKGROUND

A. Proposition 65

Proposition 65 is designed to protect the People of the State of California “against chemicals that cause cancer, birth defects or other reproductive harm.” (*American Standard, supra*, 14 Cal.4th at 306.) In order to accomplish this goal, Proposition 65 provides that:

No person in the course of doing business shall knowingly and intentionally expose any individual to a chemical known to the state to cause cancer or reproductive toxicity without first giving clear and reasonable warning to such individual, except as provided in Section 25249.10.

(Health & Saf. Code, §25249.6.) Section 25249.10 contains several exceptions to the warning requirement, such as where “federal law governs

warning in a manner that preempts state authority.” (Health & Saf. Code, §25249.10(a).) This exception simply refers to, and incorporates, traditional preemption principles under the Supremacy Clause. (*See, e.g. People ex rel. Lungren v. Cotter & Co.* (1997) 53 Cal.App.4th 1373, 1380.)

Proposition 65 does not require specific warning language or a specific method of communicating the warning. (22 CCR §12601(a).) The sole requirement for a Proposition 65 warning is that it “must clearly communicate that the *chemical* in question is known *to the state* to cause . . . birth defects or other reproductive harm.” (*Ibid.*, emphasis added.) While the regulations promulgated under Proposition 65 set forth specific “safe harbor” warning messages⁷ and methods that are deemed clear and reasonable, a defendant is not required to use them. (*Id.*, §12601(b).)

B. Federal Food, Drug and Cosmetic Act

1. General Provisions

The primary goal of the FDCA is “to protect consumers from dangerous products.” (*U.S. v. Sullivan, supra*, 332 U.S. at 696.) Accordingly, the FDCA is designed to “ensure that any product regulated by the FDA is ‘safe’ and ‘effective’ for its intended use.” (*FDA v. Brown & Williamson Tobacco Corporation, et al.* (2000) 529 U.S. 120, 133.)

One of the means by which this goal is accomplished is by preventing the sale of misbranded drugs. (21 U.S.C. §331(b).) An OTC drug is deemed to be misbranded under the FDCA only “[i]f its labeling is false or misleading in any particular” or if its labeling fails to include “such adequate warnings against use . . . where its use may be dangerous to health

⁷ For consumer products containing reproductive toxicants such as nicotine, the “safe harbor” warning is: “Warning: this product contains a chemical known to the State of California to cause birth defects or other reproductive harm.” (22 CCR §12601(b)(4)(B).)

. . . in such manner and form as are necessary for the protection of users.” (*Id.* at §§352(a), 352(f).) FDA is authorized to bring an action in federal court against companies allegedly selling misbranded drugs. (21 USC §§332-334.) In any such action, FDA bears the burden of proving that such company is guilty of, or liable for, misbranding. (*Ibid.*)

Congress has authorized FDA to promulgate regulations in order to implement and enforce the FDCA. (21 U.S.C. §371.) All such regulations are subject to formal notice and comment procedures, as prescribed under the Administrative Procedure Act (“APA”), so that FDA’s rulemaking authority is not unchecked. (*See* 21 C.F.R. §10.40; 5 U.S.C. §553.) Congress has also expressly authorized FDA to hold formal adjudicatory hearings in a variety of contexts, including a drug maker’s challenge to an FDA determination regarding a NDA. (21 U.S.C. §§371, 355(c).)

2. Preemption Of State OTC Drug Requirements Under The FDCA

Implied conflict preemption under the FDCA changed dramatically with passage of FDAMA in November 1997. Prior to FDAMA, FDA’s regulations contained detailed implied preemption analyses which demonstrated the agency’s intent to preempt state warning requirements. Subsequent to FDAMA, FDA has excised all implied preemption provisions from its OTC drug regulations and instead relies on the statute in addressing preemption issues.

In 1982, FDA published its pregnancy/nursing warning regulation, now codified at 21 C.F.R. §201.63, mandating cautionary language for pregnant and nursing women to be included on OTC drug labels. (47 Fed.Reg. 54750.) The final rule adopting the regulation includes a formal statement of the agency’s intent to preempt state

pregnancy warning requirements, including a California warning regulation, under the doctrine of implied conflict preemption. (*Id.* at 54756-57.) FDA arrived at this conclusion only after providing public notice of its proposed rule and responding to 49 separate comments, including one from the California Department of Health Services. (*Id.* at 54750, 54756.)

In February 1997, FDA published a proposed rule to establish standardized format and content for the labeling of OTC drugs that would have preempted all state requirements related to OTC drug labeling, including Proposition 65. (62 Fed.Reg. 9040-9043.) In the proposed rule, FDA again included an extensive discussion of implied conflict preemption, including detailed discussions regarding: (1) the agency’s determination of the need for preemption; (2) the scope of proposed preemption; (3) the legal authority for preemption; and (4) compliance with Executive Order 12612.⁸ (*Id.* at 9040-42, 9044-45.) FDA specifically sought comment on its determination that it could displace Proposition 65 via conflict preemption. (*See* 64 Fed.Reg. 13272.)

On November 21, 1997, Congress enacted FDAMA as an amendment to the FDCA. (Public Law 105-115; 111 Stat. 2296.) FDAMA contains a provision expressly preempting any state requirement regarding OTC drugs that is “different from, in addition to, or otherwise not identical with” an FDA requirement. (21 U.S.C. §379r(a).) This broad provision is subject to a narrow exemption which states that the preemptive scope of the FDCA “shall not apply to a State requirement adopted by a State public

⁸ Executive Order 12612 was issued by President Ronald Reagan on October 26, 1987 in order to direct executive agencies and departments regarding the principles of federalism. Section 4 of Executive Order 12612 permits federal agencies to preempt state law only where there is evidence of Congressional intent to do so. (*Ibid.*) Agencies are further directed to consult with and provide notice to states whenever a federal adjudication or rulemaking is intended to preempt state law. (*Ibid.*)

initiative or referendum enacted prior to September 1, 1997.” (21 U.S.C. §379r(d)(2).) Proposition 65 is the only law covered by this express exemption from preemption.

On March 17, 1999, FDA adopted its final OTC drug labeling rule based on its February 1997 proposal. (64 Fed.Reg. 13254.) FDA deleted the implied conflict preemption provision from the final rule. (*Id.* at 13272.) FDA’s decision was based on a determination that section 379r of FDAMA “supersede[d]” the agency’s proposed regulation. (*Ibid.*) Noting that Congress’ decision to exempt Proposition 65 from preemption directly responded to the agency’s inquiry regarding the implied preemptive effect of its proposed regulation on Proposition 65,⁹ FDA announced that “[t]he agency . . . will, at this time, rely on the terms of the statute in addressing preemption issues.” (*Ibid.*, emphasis added.) FDA has neither promulgated a regulation nor published any formal statement of agency policy regarding OTC drug preemption since its official determination to rely on the terms of section 379r in addressing OTC drug labeling preemption.

ARGUMENT

I. THE COURT OF APPEAL CORRECTLY CONCLUDED THAT PLAINTIFF’S PROPOSITION 65 CLAIMS ARE EXPRESSLY EXEMPTED FROM PREEMPTION UNDER THE FDCA.

Recognizing Congress’ unique treatment of Proposition 65 in section 379r of FDAMA, the Court of Appeal correctly determined that Plaintiff’s Proposition 65 claims are expressly exempted from preemption

⁹ Specifically, FDA stated: section 379r “addresses the two issues on which FDA had specifically requested comment, i.e., the preemptive effect of the proposed OTC drug product labeling requirements on product liability lawsuits and *the preemptive effect of the proposed labeling requirements on State initiatives such as California Proposition 65.*” (64 Fed.Reg. 13272, emphasis added.)

under the FDCA. (See Maj.Opn. at 10.) This holding properly implements Congressional intent and should thus be upheld.

“Preemption fundamentally is a question of congressional intent.” (*Geier v. American Honda, supra*, 529 U.S. at 884.) Under the Supremacy Clause, federal law can only preempt state law in three ways. First, Congress may expressly preempt state law by defining the extent to which a federal statute supplants state law. (*Cipollone v. Liggett Group, Inc.* (1992) 505 U.S. 504, 516.) Second, Congress may impliedly preempt state law by establishing a “scheme of federal regulation . . . so pervasive as to make reasonable the inference that Congress left no room for the States to supplement it.” (*Fidelity Fed. Savings & Loan Assn. v. De la Cuesta* (1986) 458 U.S. 141, 153.) Third, state law is impliedly preempted “to the extent that it actually conflicts with federal law.” (*English v. General Electric Co.* (1990) 496 U.S. 72, 79.)

Defendants’ preemption defense in this case focuses exclusively on the third form of preemption – “implied conflict preemption.” (Ds’ Br. at 24.) Implied conflict preemption is found where compliance with both federal and state law is a “physical impossibility,” or where state law “stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.” (*Florida Lime & Avocado Growers v. Paul* (1963) 373 U.S. 132, 142-43; *Geier, supra*, 529 U.S. at 899.) When a court is asked to “infer preemption based on . . . conflict preemption,” the court is required “*to imply Congress’ intent* from the statute’s structure and purpose.” (*Ting v. AT&T* (9th Cir. 2003) 319 F.3d 1126, 1135-36, emphasis added.) Moreover, “[r]egulation of health and safety matters is primarily, and historically, a matter of local concern.” (*Hillsborough County v. Automated Medical Labs, supra*, 471 U.S. at 719.)

Accordingly, “[c]onsideration of issues arising under the Supremacy Clause starts with the assumption that the historic police powers of the States are not to be superseded by Federal [law] unless that is the *clear and manifest purpose of Congress*.” (*Smiley v. Citibank* (1995) 11 Cal.4th 138, 148, emphasis added.)

Proposition 65 is a health and safety statute which falls within the traditional police powers of the State of California. (*Chemical Specialties Mfrs. Assn. v. Allenby* (9th Cir. 1992) 958 F.2d 941, 943.) Thus, Proposition 65 claims such as Plaintiff’s may only be impliedly preempted if such preemption is clearly intended by Congress. Here, however, Congress has manifested the opposite intent, and done so explicitly.

When Congress has considered the issue of pre-emption and has included in the enacted legislation a provision explicitly addressing that issue, and when that provision provides a “reliable indicium of congressional intent with respect to state authority,” [citation] “there is no need to infer congressional intent to pre-empt state laws from the substantive provisions” of the legislation.

(*Cipollone, supra*, 505 U.S. at 517.) By singling out Proposition 65 and expressly exempting it from the preemption provision of FDAMA, Congress has provided a uniquely “reliable indicium” of its intent regarding preemption of Proposition 65. (*See* 21 U.S.C. §379r(d)(2).)

Defendants nevertheless urge this Court to imply preemption from a series of informal agency statements. To find conflict preemption based on such statements would be a significant departure from the preemption jurisprudence of the United States Supreme Court, and would be particularly inappropriate here, where Congress has expressly stated its intent to permit Proposition 65 to co-exist with different or additional federal requirements. Accordingly, the Court of Appeal properly

determined that it was unnecessary to search through the record of informal FDA statements in this case for an “implied” Congressional intent to preempt.¹⁰

A. The Plain Language Of FDAMA Evidences Congress’ Clear Intent To Exempt Proposition 65 From FDCA Preemption.

Where Congress “makes its intent known through explicit statutory language, the Court’s task is an easy one.” (*English, supra*, 496 U.S. at 79.) This is especially true here, where Congress drafted, debated and enacted an express preemption provision that addresses the very state law claims at issue in this case. (*See* Maj.Opn. at 10, 13.)

In FDAMA, Congress amended the FDCA to create an express preemption provision which provides that:

[N]o State may establish or continue in effect any requirement . . . that relates to the regulation of a drug . . . ***that is different from or in addition to, or that is otherwise not identical with,*** a requirement under [the FDCA].

(21 U.S.C. §379r(a), emphasis added.) As a subsection to this broad preemption provision, Congress simultaneously enacted the following specific “exception”:

This section ***shall not apply*** to a State requirement adopted by a State public initiative or referendum enacted prior to September 1, 1997.

(21 U.S.C. §379r(d)(2), emphasis added.) Proposition 65, passed in 1986, is the ***only*** state public initiative or referendum covered by this exception.

Thus, under the plain language of FDAMA, federal

¹⁰ Maj.Opn. at 11 (“we are not aware of any case that holds a court can ignore Congress’ clearly articulated and directly applicable *express* intent to . . . ‘save’ a particular state statutory scheme from preemption . . . based on an analysis of what Congress *impliedly* intended to do,” emphasis in original.)

requirements for OTC drugs do not preempt “different” or “additional” Proposition 65 requirements. This is precisely the situation presented here. Defendants’ argue that this Proposition 65 action is preempted because it seeks to impose a warning that is different from or in addition to the federal warning for the Products. Plaintiff agrees that, but for the specific exemption set forth in section 379r(d)(2), his claim would be expressly preempted under section 379r(a). However, section 379r(d)(2) “clearly articulates an express intent to save the precise types of claims that are [at] issue in this case.” (Maj.Opn. at 13.) To hold, as Defendants request, that Proposition 65 claims are impliedly preempted to the extent that they would impose different or additional warnings on the Products, would be to render section 379r(d)(2) a nullity.

Defendants contend that the express savings provision is not relevant here because the provision somehow “makes clear” that the Proposition 65 exception “leaves the preexisting preemption landscape undisturbed.” (Ds’ Br. at 29.) Defendants’ argument is undermined by the fact that Congress explicitly stated its intent to leave the preexisting preemption landscape undisturbed in another express preemption provision in the FDCA, but did **not** do so in enacting section 379r. The law adopting the FDCA’s express preemption provision regarding food labeling requirements, 21 U.S.C. §343-1, states that such provision: “**shall not be construed to affect preemption, express or implied,** of any such requirement of a State or political subdivision...” (Public Law 101-535, §6(c)(3), 104 Stat. 2353, emphasis added.) The absence of any similar statement preserving implied preemption under FDAMA demonstrates that no such preservation was intended. (*See Comm. of Seven Thousand v. Sup.Ct.* (1988) 45 Cal.3d 491, 507 [“[w]here a statute, with reference to one

subject contains a given provision, the omission of such provision from a similar statute concerning a related subject is significant to show that a different intention existed”].)

The regulatory history of FDA’s OTC drug regulations further undercuts Defendants’ argument. When FDA first promulgated its pregnancy warning regulation in 1982, FDA stated that the regulation preempted all state pregnancy warning requirements for OTC drugs under the doctrine of implied conflict preemption. (47 Fed.Reg. 54756.) In February 1997, when the agency issued its proposed OTC drug labeling rule, FDA expanded such preemption to include all state OTC labeling requirements, including Proposition 65. (62 Fed.Reg. 9040-9043.) Thus, in November 1997, when Congress preempted all state requirements relating to OTC drugs, and specifically exempted Proposition 65 from such preemption, Congress most certainly changed the preexisting preemption landscape. When FDA subsequently finalized the OTC drug labeling rule, the agency recognized that section 379r(d)(2) “supersedes” any pre-existing preemption of Proposition 65 under the doctrine of implied conflict preemption. (64 Fed.Reg. 13272.)¹¹

¹¹ Defendants rely on FDA’s amicus brief from the Court of Appeal which stated that “FDAMA simply does not affect the application of conflict preemption.” (FDA Amicus Brief [“FDA Br.”] at 30.) This disavowal of FDA’s prior interpretation of the scope of the Proposition 65 exemption is not entitled to deference in this litigation. (See *Yamaha Corp. of America v. State Bd. of Equalization* (1998) 19 Cal.4th 1, 14 [judicial deference to agency action depends on “*it’s consistency with earlier and later pronouncements*”], emphasis in original; *Ass’n. of Int’l Automobile Mfrs. v. Mass. D.E.P.* (1st Cir. 2000) 208 F.3d 1, 5 [questions of preemption law are “issues which fall squarely within [the] Court’s jurisdiction, but not within any particular expertise or special administrative competence” of the agency].)

B. The Legislative History Of FDAMA Further Demonstrates Congress' Intent To Exempt Proposition 65 From *Any* Federal Preemption Under The FDCA.

The legislative history of FDAMA confirms that Congress intended Proposition 65 warnings to co-exist with different or additional federal warnings. With reference to the meaning of the section 379r(d)(2), the chief Senate sponsor of FDAMA, Senator James Jeffords, stated:

We said, 'OK California, fine, we will not get involved with preempting you with respect to your laws that are on the books. We will allow those laws to stand. *The FDA can work around that.*'

(143 Cong.Rec. S8856 (daily ed. September 5, 1997), emphasis added; *see Federal Energy Admin. v. Algonquin* (1976) 426 U.S. 548, 564 [statements by sponsors of federal legislation "accorded substantial weight in interpreting the statute"].)

Statements by California Senators Barbara Boxer and Diane Feinstein further show that "Congress clearly did not intend to preempt Proposition 65 under the FDCA." (Maj.Opn. at 10.) Senator Feinstein described section 379r(d)(2) as follows:

The bill does include, at my request, an explicit protection — *an exemption from preemption* — for California's "Proposition 65" . . . Proposition 65 has provided important protections to the public and has prompted manufacturers to reformulate products . . . I am pleased that the Senate agreed with my request to *explicitly exempt Proposition 65*, preserving this important California law.

(143 Cong.Rec. S9844 (daily ed. September 24, 1997), emphasis added.) Senator Boxer described the rationale for the Proposition 65 exemption as follows:

Proposition 65 has successfully reduced toxic

contaminants in a number of consumer products sold in California and *it has even led the FDA to adopt more stringent standards for some consumer products . . .* So I am very pleased that the FDA reform bill now being debated *will exempt California's Proposition 65.*

(143 Cong.Rec. S9842 (daily ed. September 24, 1997), emphasis added.)

These statements by key players in the enactment of section 379r(d)(2) make clear that the express exemption of Proposition 65 is an “exemption from preemption” *generally*, not merely an exemption from express preemption, as Defendants contend. The words “exempt” and “preserving” are used without limitation. Indeed, such statements evidence a Congressional determination that: (1) the purposes of Proposition 65 and the FDCA complement one another; and (2) the requirements of Proposition 65 have, in fact, improved public health on a national level by driving FDA to adopt more protective standards. As such, the Court of Appeal’s holding correctly implements Congress’ clear intent not only to tolerate, but to affirmatively preserve Proposition 65 when, as in this case, its requirements are “more stringent” than FDA’s. (*cf. Geier, supra*, 529 U.S. at 872.)

C. Under FDAMA, FDA Has No Authority To Preempt “Different or Additional” Warnings Required By Proposition 65.

In holding that the Proposition 65 preemption exemption in section 379r controls in this case, the Court of Appeal observed that FDA’s informal and litigation-inspired actions on behalf of Defendants are reflective of “a federal bureaucracy that . . . was either unwilling or unable to recognize the limited scope of its authority . . . since the enactment of FDAMA.” (Maj.Opn. at 15.) The Court of Appeal was correct: in light of the express Congressional mandate that FDA “work around” Proposition 65, FDA has no authority to create a preemptive conflict with Proposition

65. (See 21 U.S.C. §379r; 143 Cong.Rec. S8856 (daily ed. September 5, 1997).)

One of the critical questions in any agency preemption case is “whether the [federal agency] is legally authorized to pre-empt state” law. (*City of New York, supra*, 486 U.S. at 66.) This is because “an agency literally has no power to act, let alone pre-empt the validly enacted legislation of a sovereign State, unless and until Congress confers power upon it.” (*Louisiana Pub. Service Comm. v. FCC* (1986) 476 U.S. 355, 374.) Here, any preemptive action by FDA contravenes Congress’ clearly stated purpose. (See 143 Cong.Rec. S9842, S9844 (daily ed. September 24, 1997).) Accordingly, FDA’s suggestion that it has the authority to preempt Proposition 65 at will¹² amounts to an agency attempt to do an “end-run” around the Congressional limitation placed on its authority. “To permit an agency to expand its power in the face of a congressional limitation on its jurisdiction would be to grant to the agency power to override Congress” – something this Court should not and can not do. (*Louisiana Pub. Serv. Comm., supra*, 476 U.S. at 374-75; see also *City of New York, supra*, 486 U.S. at 64 [agency’s choice to preempt invalid if it appears from the statute or its legislative history that the choice “is not one that Congress would have sanctioned”].).)

D. *Geier* Does Not Permit A Court To Ignore The Clear Intent Of Congress.

Defendants attempt to avoid Congress’ clear intent to exempt Proposition 65 from preemption by overstating the effect and holding of the U.S. Supreme Court’s decision in *Geier*. (*Supra*, 529 U.S. 861.)

¹² Defendants and FDA contend that FDA’s “requirements with respect to drug marketing preempt *any* inconsistent requirements imposed by Proposition 65.” (Ds’ Br. at 20; FDA Am. Br. at 17, emphasis added.)

Defendants contend that “*Geier* conclusively established that legislation defining the ambit of express preemption has no bearing on the operation of ‘ordinary workings of conflict preemption.’” (Ds’ Br. at 5.) Under Defendants’ interpretation of *Geier*, Congress could *never*, by means of an express preemption clause, exempt state regulation from agency preemption. The holding in *Geier*, however, is not nearly so broad.

The *Geier* court examined the effect of a particular general tort law savings clause on a preemption analysis under the National Traffic and Motor Vehicle Safety Act of 1966 (“Safety Act”). (*Supra*, 529 U.S. at 868.) The Safety Act contains a savings clause that states: “compliance with a federal safety standard does not exempt any person from any liability under common law.” (15 U.S.C. §1397(k) (1988), now codified at 49 U.S.C. §30103(e).) The Supreme Court found that:

Nothing in the language of the saving clause suggests an intent to save state-law tort actions that conflict with federal regulations. The words “compliance” and “does not exempt,” . . . sound as if they simply bar a special kind of defense, namely, a defense that compliance with a federal standard automatically exempts a defendant from state law.

(529 U.S. at 869.) The Court specifically noted the possibility that a federal statute could evince a Congressional intent to save a particular state law from preemption. (*Id.* at 872 [“[w]e do not claim that Congress lacks the constitutional power to write a statute [that allows for conflict between state and federal requirements]. But there is no reason to believe that Congress has done so here.”].)

In stark contrast, as the Court of Appeal correctly held, section 379r(d)(2) “not only ‘suggests’ an intent to save some state law claims, it clearly articulates an express intent to save the precise types of

claims that are issue in this case.” (Maj.Opn. at 13.) The legislative history provides the rationale for Congress’ toleration of potential conflict between Proposition 65 and FDA’s requirements under the FDCA. Specifically, Senator Boxer recognized that Proposition 65 has driven FDA to adopt more stringent standards, leading to stronger public health protections nationally. (See 143 Cong.Rec. S9842 (daily ed. September 24, 1997).) Thus, both the plain language and the legislative history of FDAMA demonstrate Congress’ intent that FDA “work around” Proposition 65.

In addition, the scope of a general tort savings clause, such as the one considered in *Geier*, is far broader than the limited requirements of Proposition 65. The savings clause at issue in *Geier* encompasses tort law from all fifty states, covering an infinite number of potential standards regarding all aspects of design, manufacture, marketing, sale and eventual use of an automobile. Accordingly, the *Geier* Court was reluctant to find that the general tort savings clause in the Safety Act immunized all possible common law actions from preemption, finding that such a reading could allow the federal law to “defeat its own objectives, or potentially . . . ‘destroy itself.’” (*Geier, supra*, 529 U.S. at 872.)

By comparison, Proposition 65 has a very narrow set of requirements when applied to OTC drugs. Under Proposition 65, companies that manufacture or sell OTC drugs containing a listed chemical must provide warnings that such chemical is known to the State of California to cause cancer, birth defects or other reproductive harm. (See Health & Saf. Code, §25249.6.) Congress was well aware of these limited requirements during the debate regarding the Proposition 65 exemption. (See 143 Cong.Rec. S8867-S8868 (daily ed. September 5, 1997).) Thus, when Congress chose to exempt Proposition 65 from the preemptive reach

of section 379r, it knew the extent of the claims it was exempting. This Court should, therefore, effectuate the language and purpose of section 379r(d)(2), and affirm the Court of Appeal’s determination that Congress exempted Proposition 65 from both express and implied preemption under the FDCA.

II. EVEN IF THIS COURT UNDERTAKES AN IMPLIED PREEMPTION ANALYSIS, NO CONFLICT BETWEEN PROPOSITION 65 AND FEDERAL LAW EXISTS IN THIS CASE.

No state right is cherished more dearly or guarded more closely than a state’s right to protect the health and safety of its own citizens. Thus, there is a strong presumption against federal preemption of state health and safety laws like Proposition 65. (*Allenby, supra*, 958 F.2d at 943.) This presumption is especially strong where the alleged preemption results from regulatory action by a federal agency. (*Hillsborough County, supra*, 471 U.S. at 716-717.) Defendants nevertheless contend that unpublished FDA letters and meeting transcripts – which constitute the only evidence of “conflict preemption” in the record – qualify as “laws of the United States” under the Supremacy Clause sufficient to overcome this strong presumption against preemption. Defendants are wrong. Courts routinely reject the argument that agency statements made outside of formal regulations or final adjudications are sufficient to preempt state law.¹³ Similarly, courts routinely refuse to accord deference to such informal agency statements.¹⁴ Accordingly,

¹³ See, e.g., *Wabash Valley Power Ass’n v. REA, supra*, 903 F.2d at 453-454; *U.S. v. Ferrara* (D.D.C. 1993) 847 F.Supp. 964, 969; *American Deposit Corp. v. Schacht* (N.D. Ill. 1995) 887 F.Supp. 1066, 1080.

¹⁴ See, e.g. *Christensen v. Harris County* (2000) 529 U.S. 576, (continued...)

Defendants’ conflict preemption argument fails as a matter of law.

Moreover, even if this Court determines that the “FDA directives” in the record constitute “federal law,” such FDA statements do not create an “impossible” conflict with Proposition 65. The FDA “directives,” at most, form a hypothetical conflict with Plaintiff’s claims, and by no means prohibit *all* methods of compliance with Proposition 65. Accordingly, such “directives” do not create a preemptive conflict with Plaintiff’s claims.¹⁵

Likewise, even if FDA’s purported objective regarding “over-warning” were capable of preemption under the Supremacy Clause, such objective is entirely improper under the FDCA. Moreover, because FDA has rejected only one Proposition 65 warning, Defendants can easily comply with Proposition 65 without frustrating any federal purpose.

A. Informal FDA “Directives” And “Objectives” Do Not Have The “Force Of Law” And May Not Preempt State Law Under The Supremacy Clause.

Defendants acknowledge that the principles of conflict preemption arise solely from the Supremacy Clause of the United States Constitution. (Ds’ Br. at 24.) However, they ignore a critical limitation on such constitutional preemption. The Supremacy Clause states:

This Constitution, and *the laws of the United States* which shall be made in pursuance thereof . . . shall be

¹⁴(...continued)

587; *U.S. v. Mead* (2001) 533 U.S. 218, 229; *People v. Cotter, supra*, 53 Cal.App.4th at 1392-93.

¹⁵ See *Younger v. Jensen* (1980) 26 Cal.3d 397, 408 (“hypothetical conflict . . . is not ground for preemption”); *Goldstein v. California* (1973) 412 U.S. 546, 554 (preemption lies only in “situations where conflicts will necessarily arise”); *Allenby, supra*, 958 F.2d at 943 (no preemption unless all methods of Proposition 65 compliance conflict with federal law); *Cotter, supra*, 53 Cal.App.4th at 1393 (same).

the supreme law of the land; and the judges in every state shall be bound thereby, anything in the Constitution or laws of any State to the contrary notwithstanding.

(U.S. Const. Art. VI, cl. 2, emphasis added.) By its own terms, the Supremacy Clause applies only to *laws* of the United States. In this case, the applicable federal law – the FDCA – expressly exempts Proposition 65 from its broad preemption of all state requirements relating to OTC drugs, thus requiring FDA regulators to “work around” Proposition 65. (21 U.S.C. §379r(d)(2); 143 Cong.Rec. S8856 (daily ed. September 5, 1997).)

The phrase “laws of the United States” also includes regulations lawfully promulgated by federal agencies pursuant to their congressionally-delegated authority. (*City of New York, supra*, 486 U.S. at 63.) Thus, agency *regulations* may have preemptive effect when they actually conflict with state law. (*Ibid.*) Here, the pertinent FDA regulations – 21 C.F.R. §§201.66 and 201.63 – were finalized and amended in March 1999 to remove FDA’s implied conflict preemption provision, stating that FDA intends to rely on the terms of section 379r with respect to preemption of Proposition 65. (64 Fed.Reg. 13272.) Thus, the applicable federal regulations contain a formal statement of FDA’s intent *not* to preempt Proposition 65.¹⁶

The only evidence of “conflict preemption” cited by Defendants is a series of informal “FDA directives” and other statements consisting of: (1) notes from a private meeting (JA 1520); (2) a letter from FDA to the Attorney General criticizing one particular Proposition 65

¹⁶ This statement alone is sufficient to defeat Defendants’ implied preemption argument. (*See Hillsborough County, supra*, 471 U.S. at 714-715 [formal statement in FDA regulation of agency’s “intention not to preempt” is “*dispositive*” on the question of implied preemption], emphasis added.)

warning (JA 1558-61); (3) a series of boilerplate FDA NDA approval letters (JA 1596-1599, 1601-1605, 1607-1610, 1612-1617, 1622-1624, 1626-1630, 1632-1636, 1640-1641, 1643-1644); (4) two letters from FDA to SmithKline’s counsel (JA 1638; 2401); (5) a letter from FDA to Plaintiff’s counsel (Joint RJN, Ex. 1); and (6) a page of transcript from an FDA advisory committee meeting (JA 0300-0301). These unpublished, *ad hoc* statements by employees and agents of FDA do not have the substantive and procedural qualities required to carry the “force of law.” (See, e.g., *Chrysler Corp. v. Brown* (1979) 441 U.S. 281, 301; *Batterton v. Marshall* (D.C. Cir. 1980) 648 F.2d 694 , 701 [“[a]dvance notice and public participation are required for those actions that carry the force of law”]; *Morton v. Ruiz* (1974) 415 U.S. 199, 232 [APA rulemaking procedures designed to “avoid the inherently arbitrary nature of unpublished ad hoc determinations”].)

The Supremacy Clause has never been extended to the type of informal or non-final federal actions set forth above. (See *Wabash Valley Power Ass’n, supra*, 903 F.2d at 453-454 [“In order to preempt state authority, [agencies] must establish rules with the *force of law* . . . We have not found *any case* holding that a federal agency may preempt state law without either rulemaking or adjudication”], emphasis added.)¹⁷ The FDA actions relied on by Defendants as purported evidence of conflict constitute neither rulemaking nor adjudication, and are thus incapable of preempting the requirements of a state health and safety law.

¹⁷ The Seventh Circuit’s holding makes sense given the chaos that would result from allowing informal agency actions to preempt state law. If informal agency actions were given preemptive effect, where would the line get drawn? Could a telephone call from an agency director serve to preempt state law? What about a remark made by an agency official over lunch? Furthermore, how would a state know when it may enforce its own laws if non-published agency actions could preempt state law?

1. The Informal FDA Letters Before The Trial Court Are Not Constitutionally Capable Of Creating A Preemptive Conflict With Plaintiff's Claims.

Of the six categories of FDA statements set forth above, only the first four were before the trial court on summary judgment. Those meeting notes and letters (referred to herein as the “FDA letters”) formed the basis of the trial court’s finding of “impossibility.” Justice Simons, on the other hand, concluded that such FDA letters were “entirely too informal to establish a policy that would justify invoking the supremacy clause to invalidate state law.” (Conc.Opn. at 11.) FDA confirmed this analysis, stating that it had not “*issued a formal directive*” nor “*issued any definitive advice* concerning whether use of Dowhal’s proposed warning labeling would render Defendants’ products misbranded under the FDCA” at the time of the trial court’s ruling in March, 2001.¹⁸ (FDA Br. at 20, emphasis added.)

These conclusions are consistent federal case law. For example, in *Wabash Valley Power*, the Seventh Circuit found that a letter from the Rural Electrification Administration purporting to preempt state regulatory authority over electricity rates contained “none of the elements of rulemaking under the APA,” *i.e.* “no opportunity for comment, no statement of basis, no administrative record, no publication in the Federal Register.” (*Supra*, 903 F.2d at 454.) The Seventh Circuit concluded that such an informal letter does not have the “force of law” and is thus incapable of preempting state law. (*Ibid.*)¹⁹ The FDA letters at the heart of

¹⁸ This is consistent with FDA’s regulations, which provide that agency correspondence does not constitute “final administrative action.” (21 C.F.R. §10.65.)

¹⁹ Other courts have followed this reasoning finding that agency
(continued...)

Defendants' "impossibility" argument similarly lack the procedural elements of rulemaking, and are thus incapable of preempting Plaintiff's claims.

The FDA letters also lack the "force of law" because they are, by their own terms, preliminary and non-binding. In *Biotics Research Corp. v. Heckler* ((9th Cir. 1983) 710 F.2d 1375, 1377-78), the Ninth Circuit held that regulatory letters issued by "subordinate officials of the FDA," which actually charged the recipient company with misbranding violations, did not constitute final action by the agency because such letters did not commit the FDA to enforcement action. Here, the FDA letters are even more preliminary than those in *Biotics Research* in that they simply warn that use of warnings other than the "increased heart rate" statement "may" or "could possibly" constitute misbranding. (See, e.g., JA 2401, 1560; see also *Brock v. Cathedral Bluffs Shale Oil Co.* (D.C. Cir. 1986) 796 F.2d 533, 538 [in determining whether an agency action has the force of law, "*[w]e have . . . given decisive weight to the agency's choice between the words 'may' and 'will'*"], emphasis added.) Nowhere in any of the FDA letters does the agency ever state that use of any Proposition 65 warning (let alone all possible Proposition 65 warnings) *will* render the products misbranded.²⁰

¹⁹(...continued)

letters and memoranda do not have the force of law sufficient to preempt state law. (See *U.S. v. Ferrara, supra*, 847 F.Supp. at 969 [policy memorandum written by head of Justice Department is not "sufficient to supplant state regulation under the Supremacy Clause"]; *American Deposit Corp. v. Schacht, supra*, 887 F.Supp. at 1080 [agency letter conflicting with state law "simply cannot be accorded preemptive effect"].

²⁰ The first and only time that FDA has stated that a particular Proposition 65 warning would (rather than may) render the Products misbranded is in the agency's amicus brief before the Court of Appeal. (FDA Br. at 13.) However, "an agency interpretation 'advanced for the first time in a litigation brief' is due almost no deference at all." (*The*

(continued...)

In support of their contention that the FDA letters have implied “preemptive force,” Defendants cite a single sentence of dicta from *Kanter v. Warner Lambert Co.*, wherein the court of appeal observed that FDA OTC drug labeling “requirements . . . can have preemptive effect.” (*Supra*, 99 Cal.App.4th at 794; Ds’ Br. at 42.) However, *Kanter* is an ***express preemption case*** under FDAMA which did not involve Proposition 65 or any other exception to FDAMA’s express preemption provision (section 379r(a)). The *Kanter* court held that the plaintiffs’ state law claims were squarely covered by, and therefore preempted under, section 379r(a). (*Id.* at 796.) Thus, in stating that FDA “requirements” can have “preemptive effect,” the court was merely construing the language of section 379r(a), which provides that all state requirements “different from or in addition to . . . a requirement” under the FDCA are preempted, subject to certain exceptions.²¹ (21 U.S.C. §379r(a).)

If *Kanter* is applicable, as Defendants suggest it is, it supports, rather than undermines, Plaintiff’s position. Plaintiff concedes that his claims would be expressly preempted under FDAMA ***but for*** the Proposition 65 exemption in section 379r(d)(2). Thus, even if certain of the FDA letters in the record impose a federal “requirement” as that term is used in section 379r(a), section 379r(d)(2) exempts Plaintiff’s Proposition 65 claims from the preemptive effect of such federal requirement – even

²⁰(...continued)

Wilderness Society v. U.S. Fish and Wildlife Service (9th Cir. 2003) 316 F.3d 913, 921.)

²¹ The *Kanter* court’s dicta regarding the preemptive effect of a NDA approval is based on a faulty comparison between the pre-market approval process applicable to medical devices (the “PMA process”) and the NDA process. Unlike the NDA process, the PMA process requires the promulgation of a formal regulation as a prerequisite to approval of a medical device. (21 U.S.C. §360e(b).)

under Defendants’ narrow construction of section 379r(d)(2). In other words, if *Kanter* supports Defendants’ “preemptive force” argument in opposition to Justice Simons’ concurrence, it destroys their argument against the Majority’s construction of section 379r(d)(2). Defendants can not have it both ways.

Defendants also attempt to discredit Justice Simons’ finding regarding the informality of the FDA letters by equating it with the dissent in *Geier*. (Ds’ Br. at 39-40.) Defendants’ argument misses the mark. The question posed by the dissent in *Geier* was whether an agency is required to “put *[its] pre-emptive position* through formal notice-and-comment rulemaking” *in addition to* its “promulgation of the allegedly pre-emptive regulation.” (529 U.S. at 912.) The *Geier* majority determined that no “formal agency statement of pre-emptive intent” is required. (*Id.* at 884.) Here, the issue is not that FDA failed to articulate its preemptive intent in a formal manner, but rather that FDA took no action that could have preemptive effect in the first instance.²²

2. FDA’s August 17 Letter To Plaintiff’s Counsel Does Not Carry The Force Of Law.

FDA’s August 17, 2001 letter to Plaintiff’s counsel also lacks

²² Defendants also chastise Justice Simons for not explicitly mentioning what they refer to as the “Advisory Committee Report” in his concurring opinion. (D’s Br. at 40.) This “report” is actually a transcript of an advisory committee meeting at which Defendants claim the purported federal objective of promoting use of the Products by avoiding “over-warning” was “initially establish[ed].” (*Ibid*; JA 0300-0301.) However, a single statement by a member of an advisory committee who is not even employed by the federal government is not the kind of formal, binding statement of agency purpose capable of nullifying a state health and safety law. Nor does it “convey an ‘authoritative’ message of a federal policy.” (*See Sprietsma v. Mercury Marine* (2002) 123 S.Ct. 518, 528.) Accordingly, Justice Simon’s decision not to discuss the advisory committee transcript was justified.

the substantive and procedural qualities of federal “law.”²³ The August 17 letter was not published in the Federal Register nor subject to any public comment. Additionally, the August 17 letter has no binding effect. Therein, FDA states that it “intends to request” that nicotine manufacturers submit supplemental NDAs to change the pregnancy warning on their Products in accordance with the agency’s new warning “proposal.” (Joint RJN, Ex. 1 at 7-8.) It further states that “sponsors may also consider a different warning, [but] they will have to provide data to support alternative wording.” (*Id.* at 5.) These statements demonstrate that the August 17 letter does not impose any binding obligation with respect to the Products’ labeling, but merely reflects the agency’s “tentative intentions for the future.” (*See Thomas v. New York* (D.C. Cir. 1986) 802 F.2d 1443, 1447 [agency letters expressing “tentative intentions for the future” do not have the “force of law”].)²⁴ As such, the August 17 letter is neither a “final” agency action nor a binding determination with the force of law as to the Products’ labeling.

3. FDA’s Amicus Brief Is Not Capable Of Elevating Its Prior Informal Actions To The Status Of Law.

²³ The August 17 letter was not before the trial court and is thus not relevant to the determination of this appeal. (*See, e.g. McCall v. PacifiCare of Cal.* (2001) 25 Cal.4th 412, 424 [preemption analysis must be based on “then applicable law”]; *U.S. v. Ferrara, supra*, 847 F.Supp. at 969 [agency policy memorandum issued “well over six months after” the alleged conduct at issue can not constitute “federal law” for purposes of preempting state regulation].)

²⁴ FDA’s own regulation governing citizen petitions confirms this point. Under this regulation, when FDA grants a citizen petition (which FDA did, in part, in this case), the agency “shall concurrently take appropriate action (e.g. publication of a Federal Register notice) implementing the approval.” (21 C.F.R. §10.30(e)(2)(i).) The regulation underscores what is obvious from the face of the August 17 letter – that it constitutes a mere statement of the agency’s intention to take some other implementation action in the future.

In an attempt to compensate for the informal, preliminary, and non-binding nature of the FDA statements which form the basis of the federal-state conflict Defendants allege, Defendants seek to breathe preemptive life into such statements through extensive citations to FDA's amicus brief in the Court of Appeal. (*See* D's Br. at 34-37). However, this approach has been squarely rejected by the U.S. Supreme Court.

Like letters and other informal agency statements, amicus briefs filed by federal agencies are "merely precatory" and "lack the force of law" capable of preempting state law. (*Barclays Bank PLC v. Franchise Tax Bd. of California* (1994) 512 U.S. 298, 329-330.) In *Barclays Bank PLC*, one of the petitioners, Colgate Palmolive, made the same argument Defendants make here: that "a series of Executive Branch actions, statements and *amicus* filings . . . taken together . . . constitute a 'clear federal directive'" that displaces state law. (*Id.* at 328.) The Supreme Court held that the informal federal "statements to which Colgate refers, however, cannot perform the service for which Colgate would enlist them," and are thus incapable of preempting state law. (*Id.* at 328-329; *see also Brock, supra*, 796 F.2d at 537-538.) Likewise, here, FDA's prior informal actions can not be elevated to the status of "law" by virtue of *post hoc* statements in a subsequent legal brief.

B. FDA's Litigation-Inspired Interpretations Of Its Informal Actions Are Not Entitled To Deference.

Recognizing that neither the FDA "directives" in the record nor the litigation-inspired statements in FDA's amicus brief are Constitutionally capable of preempting state law, Defendants insist that this Court give "substantial deference" to such statements. (D's Brief, p. 34.) However, none of the various FDA statements relied upon by Defendants are entitled to judicial deference in this case, because they are: (1)

inconsistent with the agency's prior actions regarding nicotine products; (2) made for the first time in a litigation brief; and/or (3) informal agency opinions that do not purport to interpret a statute or regulation.

In support of their "impossibility" argument Defendants rely heavily on FDA's assertion, made for the first time in its amicus brief, that the "harm your baby" warning "would cause" the Products to be misbranded. (Ds' Br. at 20; FDA Br. at 13.) Yet, in November 1999, FDA ***approved and required*** the "harm your baby" warning for use on an OTC nicotine patch product that is identical to Defendants' Products for warning purposes. (JA 2267; Joint RJN, Ex. 1 at 5). In fact, FDA has always required a version of this warning on prescription nicotine products. (JA 0951, 0960, 0973, 1003, 1023.) Because FDA's assertion contradicts prior determinations by FDA and was advanced for the first time in a litigation brief, it is entitled to no deference. (*See Yamaha Corp. of America, supra*, 19 Cal.4th at 14 [deference depends on consistency with prior agency statements]; *The Wilderness Society, supra*, 316 F.3d at 921 ["agency interpretation 'advanced for the first time in a litigation brief' due almost no deference"]; *Cotter, supra*, 53 Cal.App.4th at 1392-93 [litigation-inspired agency statements not entitled to deference].)

Moreover, FDA is not authorized to make unilateral determinations that a product is misbranded. Rather, if FDA believes that a product violates the misbranding provisions of the FDCA, FDA must go to court and prove it. (*See* 21 U.S.C. §§332-334; *Biotics Research, supra*, 710 F.2d at 1377-78 [FDA conclusion that a product is misbranded is not "final administrative action"]; *FTC v. Standard Oil of California* (1980) 449 U.S. 232, 243 [agency's legal complaint in enforcement action "has no legal force or practical effect upon [defendant's] business," and does not

constitute final agency action].) In fact, the defendant in a misbranding action is entitled to a jury trial. (21 U.S.C. §332 [injunctions], §333 [criminal penalties], §334 [seizure].) Thus, deferring to FDA’s mere assertion in a legal brief that the “harm your baby” warning is “misbranded” is tantamount to permitting FDA to side-step due process as if it were prosecutor, judge and jury all in one.

Defendants also contend that the statements in FDA’s amicus brief, which Defendants cite in support of their “frustration of purpose” argument, merit deference under *Geier*. (Ds’ Br. at 38-42; FDA Br. at 25, 19.) Defendants’ reliance on *Geier* is misplaced. In *Geier*, the Supreme Court gave “some weight” to the Department of Transportation’s (“DOT’s”) conclusion regarding conflict preemption as stated in the government’s brief, because such conclusion was based on DOT’s reasonable interpretation of “*its own regulation* and its objectives” therefor. (*Geier, supra*, 529 U.S. at 883, emphasis added; *see also Sprietsma, supra*, 123 S.Ct. at 528-529.) In *Geier*, DOT had determined that the plaintiff’s State law claims conflicted with the objectives of a lawfully promulgated regulation – Federal Motor Vehicle Safety Standard (“Safety Standard”) 208.

Moreover, the federal objectives at issue in *Geier* were not merely stated at a meeting or asserted in a letter by an employee of the agency. Rather, such objectives were: (1) developed after the agency had received 7,800 public comments (*see* 49 Fed.Reg. 28962, 28964); and (2) published as the official DOT statement of purpose “*which accompanied the promulgation*” of Safety Standard 208 in the Federal Register. (*Geier, supra*, 529 U.S. at 875, emphasis added.) Indeed, the *Geier* Court’s detailed discussion of DOT’s objectives is based exclusively on citations to

numerous official agency statements published in the Federal Register. (*Id.* at 874-876.) Thus, the *Geier* Court accorded “some weight” to the government’s amicus brief because it merely affirmed DOT objectives that had been developed and expressed through a formal rulemaking process involving extensive public participation and resulting in a regulation with the force of law. (*Id.* at 883.)

In contrast, FDA’s purported objectives and directives here have never been published in the Federal Register, never been subjected to any public scrutiny or participation, and never accompanied the promulgation of a regulation or any other FDA action carrying the force of law. Thus, the “directives” and objective here are not entitled to deference. (*See Christensen, supra*, 529 U.S. at 587 [agency statements which lack the force of law do not warrant deference]; *cf. Geier, supra*, 529 U.S. at 883, 874-75).

C. The Application Of Proposition 65 To OTC Nicotine Products Does Not Conflict With Any Federal Requirement Or Purpose.

Even if FDA’s purported “over-warning” objective and/or the informal “FDA directives” in the record were capable of overcoming the significant hurdles to preemption discussed above, they do not create an actual conflict with Plaintiff’s claims. None of the informal correspondence between FDA and Defendants prohibits Defendants from adding a warning to the Products. Nor does such correspondence prohibit Defendants from complying with Proposition 65 through use of public advertising. Thus, the evidence before the trial court is insufficient to prove that it was “physically impossible” for Defendants to comply with both Proposition 65 and “FDA’s directives.”

Similarly, the federal objective cited by Defendants in support

of their frustration of purpose argument does not, and can not, form the basis of a preemptive conflict with Proposition 65. FDA's purported objective – to promote the use of Products the agency does not know to be safe – directly conflicts with FDA's primary responsibility under the FDCA – to ensure that drugs it regulates are safe. (*See FDA v. Brown & Williamson, et al., supra*, 529 U.S. at 133.) Moreover, FDA has, at most, rejected one of many possible Proposition 65-compliant warnings. As demonstrated by an exemplar warning proposed by Plaintiff below, Defendants can certainly comply with Proposition 65 without violating any FDA requirement or frustrating any FDA objectives for the Products.

1. The FDA Letters Do Not Prohibit Defendants From Complying With Proposition 65.

FDA's actions may only preempt the application of Proposition 65 if they prohibit *all* methods of compliance with such state law. (*Cotter, supra*, 53 Cal.App.4th at 1393; *Allenby, supra*, 958 F.2d at 943.) Here, because Defendants could have complied with Proposition 65 by either using non-label warnings such as public advertising, or adding a label warning without prior FDA approval pursuant to FDA's "changes being effected" regulation (21 C.F.R. §314.70(c)(2)(i)), Proposition 65 is not preempted by FDA's statements regarding the Products.

Defendants' "impossibility" argument is premised on their assertion that "FDA repeatedly and explicitly directed [them] to use only the federally mandated warning and *prohibited* compliance with Proposition 65." (Ds' Br. at 31, emphasis in original.) This distorted version of the factual record formed the basis of the trial court's ruling below. (JA 2430.) However, the record before the trial court demonstrates that FDA: (1) never directly prohibited Defendants from *adding* the "harm your baby" warning to their existing labels; and (2) never stated that such additional warning

would render the Products misbranded. (See JA 1596-1599, 1601-1605, 1607-1610, 1612-1617, 1622-1624, 1626-1630, 1632-1636, 1638, 1640-1641, 1643-1644, 2401.) The reason for this is simple – Defendants never even asked FDA for permission to use the “harm your baby” warning. (JA 0869, 0880, 0893, 0902 (RFA No. 7); 0919, 0926, 0933, 0940, 0947 (RFA No. 8); 0763, ¶57.) Accordingly, the FDA letters, at most, create a hypothetical conflict with Proposition 65. (See *Younger, supra*, 26 Cal.3d at 408; *Goldstein, supra*, 412 U.S. at 554.)

Given this record, Defendants could have simply added a Proposition 65-compliant warning to the Products pursuant to the “changes being effected” regulation, *without prior FDA approval*. (21 C.F.R. §314.70(c)(2)(i).) Based on the existence of this regulation, the court in *Motus v. Pfizer* concluded that “there appears to be no inherent conflict” between FDA’s approval of warning language on a drug’s label and a claim under California law that a stronger warning is required. (*Motus v. Pfizer* (C.D. Cal. 2000) 127 F.Supp.2d 1085, 1094.)

Defendants assert that they are not permitted to utilize the “changes being effected” regulation without having a “scientific basis” for doing so. (Ds’ Br. at 35.) This is incorrect. When adding a stronger warning without prior FDA approval, FDA regulations provide only that “a supplement under this paragraph is required to give a full explanation of the basis for the change.” (21 C.F.R. §314.70(c).) No scientific basis is specifically required. In any event, FDA has acknowledged that nicotine has been shown to “represent some risk in humans for embryo-fetal lethality” (Joint RJN, Ex. 1 at 4) – which clearly constitutes reproductive harm. Thus, there is undoubtedly a scientific basis for adding a Proposition 65 warning to the Products.

Perhaps most damaging to Defendants’ “impossibility” argument is the fact that, pursuant to the “changes being effected” regulation, Novartis added a version of the Proposition 65 “safe harbor” warning to the Habitrol label, in addition to the “harm your baby” warning already on the label, without prior FDA approval. (JA 2103.) FDA has never initiated a misbranding action against Novartis for selling Habitrol with the Proposition 65 safe harbor warning. (JA 2103-04.) Thus, the *Motus* court’s holding that the “changes being effected” regulation “militates strongly in favor of finding *no* conflict preemption” applies with equal force here. (*Supra*, 127 F.Supp.2d at 1093, emphasis added.)

In addition to simply adding a Proposition 65-compliant warning to the Product labels, Defendants have, at all times, been free to utilize public advertising to satisfy their obligations under Proposition 65. Under Proposition 65, warnings for consumer products may be provided by any reasonable method, including product labeling, store signs and public advertising. (22 CCR §12601.) In contrast, the FDCA only grants FDA authority to regulate OTC drug labeling. (21 U.S.C. §§352(a) and (f).) Consequently, compliance with Proposition 65 using non-label warnings is entirely possible without even implicating FDA’s jurisdiction.

Defendants concede as much, yet argue that provision of Proposition 65 warnings via non-label methods would frustrate FDA’s alleged purpose of avoiding over-warning on the Products’ labeling. (Ds’ Br. at 44-45.) This argument has no merit, because FDA’s preemptive reach can not extend beyond the boundaries of its own regulatory authority and FDA simply has no authority over OTC drug advertising. (*See De La Cuesta, supra*, 458 U.S. at 154 [under conflict preemption principles, a federal agency action can not preempt state law unless such action “is

within the scope of the [agency's] delegated authority"].)

Recognizing this, Defendants argue that if they attempted to comply with Proposition 65 by public advertising, the Federal Trade Commission (“FTC”) would prosecute them for false advertising. (Ds’ Br. at 45-48.) This argument is absurd. The Proposition 65 warning “nicotine is known to the State of California to cause birth defects or other reproductive harm” is indisputably true. (*See* 22 CCR §12000(c).) Thus, publication of such warning could not subject Defendants to prosecution for false advertising.

Moreover, Defendants’ argument attributes powers to FTC that the agency clearly does not have. FTC’s authority with regard to false advertising is limited to enforcement against false advertisements disseminated “in order to *induce the purchase* of food, drugs, devices or cosmetics.” (15 U.S.C. §52(a)(2), emphasis added; *see also, FTC v. Pantron I Corp.* (9th Cir. 1994) 33 F.3d 1088, 1095.) Here, Defendants not only concede, but affirmatively argue (albeit without any supporting evidence) that use of the Proposition 65 warning would *hinder* rather than promote the purchase of the Products. (*See, e.g.,* Ds’ Br. at 4.) Accordingly, use of Proposition 65 warnings in advertising for the Products would not run afoul of the FTC.

2. The Alleged Federal Objective Defendants Cite In Support Of Their Frustration Of Purpose Argument Is Not Valid Under The FDCA.

In order for Defendants to prevail under a “frustration of purpose” theory, they must show that Plaintiff’s claims “stand[] as an obstacle to the accomplishment and execution of the full purposes and objectives of *Congress*.” (*Geier, supra*, 529 U.S. at 899, emphasis added.) However, the purposes and objectives of Congress, as set forth in the

FDCA, are fully aligned with those of Proposition 65: both statutes were designed to protect consumers from harmful products. (*Compare, American Standard, supra*, 14 Cal.4th at 306, and *Sullivan, supra*, 332 U.S. at 696.) In fact, one of the reasons Congress exempted Proposition 65 from FDCA preemption is because this unique California law has driven FDA to adopt more protective standards nationally. (143 Cong.Rec. S9842 (daily ed. September 24, 1997).)

Nonetheless, Defendants claim that Proposition 65 conflicts with a purported FDA objective “to reduce death and disease nationwide by encouraging smokers – particularly pregnant women – to use Defendants’ Products.” (D’s Br. at 42.)²⁵ Defendants fail to cite a single source of published “law” establishing this purported federal objective.²⁶ This is not surprising, because promoting use of the Products carries serious risks of conflicting with FDA’s primary objective under the FDCA, which is to ensure that the products they regulate are safe and effective. (*Brown & Williamson, supra*, 529 U.S. at 133.)

This risk is particularly strong here, because FDA has explicitly acknowledged that “there continue to be unanswered questions” regarding the Products’ reproductive risks, and now recommends a warning stating that such risks are “not fully known.” (Joint RJN, Ex. 1 at 4, 7.) It

²⁵ Defendants allege this “federal objective” despite the fact that the only peer-reviewed scientific study in the record regarding the efficacy of nicotine products for pregnant smokers found that such products have “no influence on smoking cessation during pregnancy.” (JA 1249.)

²⁶ There is an FDA regulation related to “over-warning” which requires that only “known hazards” be listed as contraindications on prescription drug labels. (21 C.F.R. §201.57(d); *see Carlin v. Super. Ct.* (1996) 13 Cal.4th 1104, 1114.) Ironically, pursuant to this regulation, FDA required Defendants to provide the “harm your baby” warning on the prescription versions of the Products. (JA 0951, 0960, 0973.)

makes no sense for FDA to affirmatively promote the use of products it does not know are safe. Moreover, FDA *does* know that certain reproductive harms – such as spontaneous abortions – are associated with use of the Products. (*Id.* at 4; JA 0958.)

3. Defendants Can Comply With Both Proposition 65 And FDA’s Requirements And Objectives For The Products.

Defendants place considerable weight on FDA’s post-summary judgment statements contained in the August 17, 2001 letter and FDA’s March 2002 amicus brief. However, in the August 17 letter and amicus brief, FDA rejected only *one* possible Proposition 65-compliant warning – the Habitrol “harm your baby” warning that the agency had previously approved. (*See* Joint RJN, Ex. 1.) Defendants, in claiming that the Court of Appeal’s decision puts them in an untenable position, simply ignore the fact that Proposition 65 does not require any one specific warning. (*See* 22 CCR §12601(a).) They also ignore Justice Simons’ finding that their “preemption defense can succeed only if all possible consumer product warnings that would satisfy Proposition 65 actually conflict with the federal standards.” (Conc.Opn. at 10, *citing Comm. of Dental Amalgam Mfrs. & Distribs. v. Stratton* (9th Cir. 1996) 92 F.3d 807, 810, *Cotter, supra*, 53 Cal.App.4th at 1393-94; and *Allenby, supra*, 958 F.2d at 943.) Thus, Defendants’ complaints of being “deprived . . . of the ability to comply simultaneously with their federal and State obligations” are unfounded. (*See* Ds’ Br. at 8.)

Compliance with Proposition 65 could be achieved without violating any FDCA misbranding prohibition or frustrating any federal purpose with respect to the Products as set forth by FDA in the August 17 letter and FDA amicus brief. For example, consider the following warning

message advocated by Plaintiff:

If you are pregnant or breast-feeding, only use this medicine on the advice of your health care provider. This product contains nicotine, a chemical known to the State of California to cause birth defects or other reproductive harm. While smoking can seriously harm your child, this medicine is believed to be safer than smoking. However, the risks to your child from this medicine are not fully known.

This exemplar warning harmonizes the purposes and requirements of the federal and state schemes at issue. With respect to Proposition 65, the warning “clearly communicates that the *chemical* in question is known *to the state* to cause . . . reproductive harm.” (22 CCR §12601(a), emphasis added.) It is, therefore, “clear and reasonable” under the statute.

The warning also fully complies with FDA’s stated requirements and purposes. By stating “smoking can seriously harm your child, this medicine is believed to be safer than smoking,” the warning, which closely resembles FDA’s new proposed warning, accomplishes FDA’s stated goal of “convey[ing] the relative reproductive harm of smoking, use of [nicotine] products, and total abstinence from nicotine.” (See Joint RJN, Ex. 1 at 8.) Additionally, by stating that “the risks to your child from *this medicine* are not fully known,” the warning achieves FDA’s goal of not overstating what is actually known about the reproductive harm associated with *use of the Products*. (See *Id.* at 5.)

Although the warning states that nicotine is known to cause reproductive harm, use of such language in the context of this exemplar warning does not raise the problems identified by FDA in connection with the Habitrol “harm your baby” warning. In particular, by deleting the phrase “whether from smoking or medication” and including the language from FDA’s proposed warning regarding smoking, FDA’s (and Plaintiff’s)

concerns about conveying the relative harms of smoking are addressed. Likewise, by stating that nicotine is a *chemical* which is known to cause harm, while also stating that the risks to the child from *this medicine* are not fully known, the exemplar warning alleviates FDA's concerns regarding overstatement of the Products' risks. Moreover, FDA has acknowledged that nicotine "represent[s] some risk" of fetal harm. (*Id.* at 4.)

Given the Congressional mandate that FDA "work around" Proposition 65 (143 Cong.Rec. S8856 (daily ed. September 5, 1997)), it is difficult to imagine a legitimate basis on which FDA could reject the warning proposal set forth herein or a similar warning that would allow Defendants to comply with both Proposition 65 and FDA's alleged objectives. Indeed, such rejection would only further validate the Court of Appeal's description of FDA in this case as "a federal bureaucracy that . . . [is] either unwilling or unable to recognize the limited scope of its authority." (Maj.Opn. at 15).

CONCLUSION

For all of the foregoing reasons, Defendants' "implied conflict preemption" defense fails. Congress has expressly exempted Proposition 65 from the broad scope of FDCA preemption. Moreover, Defendants have failed to show, either legally or factually, that Plaintiff's claims conflict with a single provision of federal law. Meanwhile, Defendants Products' continue to expose pregnant and nursing women, without clear and reasonable warning, to significant levels of nicotine – a chemical which all parties acknowledge is known to cause reproductive harm. Therefore, Plaintiff respectfully requests that this Court affirm the decision of the Court of Appeal, thereby permitting this important action to proceed.

Dated: April 15, 2003

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CERTIFICATION OF LENGTH OF BRIEF

Based on the word count provided by the Word Perfect computer program used to generate this brief, I certify that this brief (excluding cover page, table of contents, table of authorities and signature page) contains 13,998 words.

Dated: April 15, 2003

Todd E. Robins