No. S109306

IN THE SUPREME COURT OF THE STATE OF CALIFORNIA

PAUL A. DOWHAL, an individual,

Plaintiff and Appellant,

vs.

SMITHKLINE BEECHAM CONSUMER HEALTH CARE, LP; MCNEIL CONSUMER PRODUCTS COMPANY, A DIVISION OF MCNEIL-PPC, INC.; PHARMACIA & UPJOHN, INC.; ALZA CORPORATION; AVENTIS PHARMACEUTICALS, INC.; PERRIGO COMPANY; COSTCO COMPANIES, INC.; LUCKY STORES, INC.; RITE AID CORPORATION; SAFEWAY, INC.; WALGREEN COMPANY,

Defendants and Respondents.

On Review From A Decision Of The Court of Appeal, First Appellate District, Division Five, No. A094460

Appeal From A Summary Judgment
San Francisco County Superior Court, No. 305893
Hon. David A. Garcia

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

APPLICATION FOR LEAVE TO FILE BRIEF AS AMICI CURIAE AND BRIEF OF THE CONSUMER HEALTHCARE PRODUCTS ASSOCIATION, THE COSMETIC, TOILETRY AND FRAGRANCE ASSOCIATION, THE GROCERY MANUFACTURERS OF AMERICA, AND THE PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA IN SUPPORT OF DEFENDANTS

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TO THE HONORABLE RONALD M. GEORGE, CHIEF JUSTICE OF CALIFORNIA, AND THE HONORABLE ASSOCIATE JUSTICES OF THE SUPREME COURT OF THE STATE OF CALIFORNIA:

Pursuant to Rule 29.1(f) of the California Rules of Court, the Consumer Healthcare Products Association ("CHPA"), the Cosmetic, Toiletry and Fragrance Association ("CTFA"), the Grocery Manufacturers of America ("GMA"), and the Pharmaceutical Research and Manufacturers of America ("PhRMA") respectfully request permission to file the attached brief as amici curiae in support of the Defendants. CHPA is the 122-year-old national trade association representing manufacturers and distributors of nonprescription (over-the-counter or "OTC") medicines and dietary supplements. CTFA, founded in 1894, is the leading U.S. trade association for the personal care products industry, with approximately 600 member companies. GMA is the world's largest association of food, beverage and consumer product companies. PhRMA represents the country's leading pharmaceutical and biotechnology companies, with member companies accounting for more than 75 percent of brand-name drug sales in the United States.

The members of these amici trade associations create products subject to the regulations and requirements established by the Federal Food and Drug Administration ("FDA"), acting pursuant to the authority established by the Federal Food, Drug, and Cosmetic Act ("FD&C Act"), 21 U.S.C. 321

et seq. They can therefore bring to bear particular extensive expertise and experience with respect to the issues raised in this litigation. Amici previously submitted a letter in support of the Court's review of this case.

The reasoning of the Court of Appeal decision, if left undisturbed, would undermine important legal principles regarding the preemptive effect of FDA mandates, and could have wide ranging implications for both the products at issue in this litigation and other FDA-regulated food, drugs, and cosmetics. Indeed, if left undisturbed, the decision could adversely affect fundamental principles of federalism going well beyond the preemptive effect of FDA's actions. The interests of amici's members may thus be directly affected by the resolution of this case.

Accordingly, CHPA, CTFA, GMA and PhRMA respectfully request that the Court accept their brief for filing.

Dated: July 21, 2003

Respectfully submitted,

COVINGTON & BURLING

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Attorneys for the Consumer Healthcare Products Association, the Cosmetic, Toiletry and Fragrance Association, the Grocery Manufacturers of America, and the Pharmaceutical Research and Manufacturers of America

BRIEF OF AMICI CURIAE IN SUPPORT OF DEFENDANTS

INTRODUCTION AND SUMMARY OF ARGUMENT

FDA dictated the specific language of the warning labels that Defendants must place on their products at the time it approved their sale, and has explicitly and repeatedly forbidden the use of any other warning language. Under federal law, a manufacturer that ignores such a directive is exposed to having its products seized as misbranded, and is subject to injunctive and criminal sanctions. The Court of Appeal nonetheless held that Defendants could be subject to state law penalties (potentially massive) for failure to use labeling that concededly differed from the federal label required by FDA.

The majority opinion reached this result by holding that the "savings clause" language in a federal statute, which provides only that a *specific section* of a *specific* federal statute was not intended to have preemptive effect with respect to certain state law requirements, meant that no federal requirement could preempt such state law requirements, even if the state law was in hopeless conflict with the federal requirement or compliance with both was a physical impossibility.

This interpretation runs counter to both the plain language of the savings clause at issue here, and the uniform interpretation of such clauses in other federal statutes. Indeed, a recent U.S. Supreme Court decision

interpreting these kinds of savings clauses questioned whether Congress would *ever* allow "state law [to] impose legal duties that would conflict directly with federal regulatory mandates" (*Geier v. American Honda Motor Co.*, 529 U.S. 861, 871-72 (2000)), and before the Court of Appeal decision at issue here, no court had ever held that Congress had done so. The concurring judge was clearly correct in finding the majority's reasoning "flawed," because the savings clause "lef[t] intact the ban on actual conflicts between state and federal law." (Conc. Opn., p. 1).

The concurring opinion, although rejecting the majority's interpretation of the effect of the savings clause, nonetheless held that there was no actual conflict between federal and state law requirements, notwithstanding FDA's contrary position as reflected in both its explicit mandates to the Defendants and its statements before that court. The concurring judge substituted his own views for FDA's regarding whether federal objectives would be impeded by the state warning language, and based his right to do so in part on the fact that FDA had not acted through the promulgation of formal regulations. (Conc. Opn., p. 11).

In fact, this case *does* directly implicate the requirements of a published regulation with respect to pregnancy-related warnings. But of equal importance, the concurring opinion fundamentally misconstrues both the operation of federal preemption and the discretion afforded federal agencies to determine the methods by which they promulgate their

requirements. A federal agency's expert views regarding the requirements of a statute it administers, and the existence of a conflict between those requirements and state imposed obligations, are entitled to deference. No particular mechanism need have been followed by the agency in developing or expressing those views.

Moreover, federal agencies are expressly empowered to act through means other than regulations. FDA frequently imposes mandatory requirements on manufacturers through mechanisms other than the promulgation of regulations. Congress has prescribed the use of these alternate mechanisms for new drug applications, which are at issue here. FDA's adherence to these mechanisms bolsters, rather than undercuts, the preemptive force of the agency's application of FD&C Act requirements.

In this regard, Plaintiff makes concessions fatal to his case. He argues that "[c]ourts routinely reject the argument that agency statements made outside of formal regulations *or final adjudications* are sufficient to preempt state law." (Plaintiffs' Opp. Brief on the Merits at 29) (emphasis added). Building on this theme, Plaintiff concludes that "[t]he 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." *Id* at 32.

While Amici do not agree that either rulemaking or adjudication is in fact necessary to trigger preemption, plaintiff is simply mistaken in claiming

that no adjudications are at issue here. To the contrary, as a matter of federal law, FDA's approval of Defendants' new drug applications, and subsequent modifications of those approvals, *do* constitute the very "*adjudications*" that Plaintiff concedes can have preemptive effect. Also as a matter of federal law, those approvals constituted "*final* agency action," notwithstanding Plaintiff's wholly unsupported allegation that no such final FDA action occurred here.

STATEMENT OF THE CASE

I. FDA'S REGULATORY REGIME.

Under the FD&C Act, Congress has exclusively charged FDA with approving all drugs before they may be sold, 21 U.S.C. § 355(a), and with "investigating any problems associated with drugs currently on the market," *Grundberg* v. *Upjohn Co.*, 140 F.R.D. 459, 469 (D. Utah 1991). "Under the scheme of the Act the ultimate determination of the safety of a drug is not a matter given to courts, but one to be determined by" FDA. *United States* v. *1,048,000 Capsules of Afrodex*, 494 F.2d 1158, 1160 (5th Cir. 1974).[1]

To obtain FDA approval of a new drug, a manufacturer submits a new drug application ("NDA"). 21 U.S.C. § 355(b). The NDA must include the

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[1] There is no private cause of action under the FD&C Act, 21 U.S.C. § 337; *Bailey v. Johnson*, 48 F.3d 965, 967 (6th Cir. 1995), *see also Merrell Dow Pharmaceuticals, Inc. v. Thompson*, 478 U.S. 804 (1986), but if FDA determines that a warning is inadequate, it may require the drug manufacturer to revise its labeling and it may disseminate precautionary information to doctors, 21 U.S.C. § 375(b).

drug's proposed labeling, which includes the drug's warnings. 21 U.S.C. § 355(b)(1)(F); 21 C.F.R. § 314.50. FDA then reviews the NDA. This is a "rigorous process," involving careful review by scientific experts who must be convinced that the drug is safe and effective for its intended use. *Brooks* v. *Howmedica, Inc.*, 273 F.3d 785, 788 (8th Cir. 2001) (en banc); *see also* 21 U.S.C. § 355(b); *Premo Pharm. Labs., Inc.* v. *United States*, 629 F.2d 795, 803 (2d Cir. 1980) (noting that Congress has charged FDA with the "difficult task of investigation and scientific evaluation" necessary to enforce the requirement that drugs be "safe and effective").

When FDA approves the NDA, it must review and approve the drug's labeling, including its warnings, to assure that the labeling is not "false or misleading." 21 U.S.C. § 352(a). "Misleading" warnings are those that fail to reveal material facts "with respect to consequences which may result from the use" of a drug. 21 U.S.C. § 321(n). Therefore, when FDA approves a warning, it finds that the warning fully informs users of the potential consequences that may result from using a drug. A drug accompanied by false or misleading labeling is "misbranded," as is any drug lacking "adequate warnings...as are necessary for the protection of users," and misbranded drugs may not be manufactured or distributed. 21 U.S.C. §§ 331(a)-(c), 352(a), (f).

An additional rule comes into play where, as here, the warning is pregnancy-related. FDA has formally promulgated a pregnancy warning

regulation, 21 C.F.R. § 201.63. Subsection (a) of that regulation provides the generally applicable warning language to be used on all products for which FDA does not mandate a product-specific warning, while Subsection (b) addresses product-specific warnings:

> Where a specific warning relating to use during pregnancy or while nursing has been established [by FDA] for a particular drug product in a new drug application (NDA)...*the specific warning shall be used* in place of the warning in paragraph (a) of this section, unless otherwise stated in the NDA.... (emphasis added).

"FDA's determination of what labeling best reflects current scientific information regarding the risks and benefits" of a drug "involves a high degree of expert scientific analysis." *Henley* v. *FDA*, 77 F.3d 616, 620 (2d Cir. 1996) (quoting *Henley* v. *FDA*, 873 F. Supp. 776, 782 (E.D.N.Y. 1995)); *Pub. Citizen Health Res. Group* v. *Comm'r, FDA*, 740 F.2d 21, 29 (D.C. Cir. 1984) (Whether a drug "is sufficiently dangerous to require a warning label is a factual question demanding the medical expertise that FDA possesses and [courts] lack.").[2] Statements of precaution, contraindication, or warning

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[2] *See also Howmedica*, 273 F.3d at 788 (The "NDA is a rigorous process," involving study and review "by a panel of FDA experts."); *Henley*, 77 F.3d at 621 ("The FDA possesses the requisite know-how to conduct [an analysis of conflicting studies], by sifting through the scientific evidence to determine the most accurate and up-to-date information regarding a particular drug...."); *Schering Corp.* v. *FDA*, 51 F.3d 390, 399 (3d Cir. 1995) (FDA's "judgments as to what is required to ascertain the safety and efficacy of drugs fall squarely within the ambit of the FDA's expertise and merit deference from us."); *Premo*, 629 F.2d at 803 (Whether a drug is safe "is to be determined by the FDA which, as distinguished from a (continued...)

are a result of FDA's intense study and omitted warnings are omitted because FDA deems them false or misleading. According to FDA's chief counsel:

> FDA carefully reviews every statement in the labeling . . . before approval of a new drug. The agency demands scientific substantiation . . . for statements of precaution, contraindication, and warning. A statement in the labeling of a prescription drug has been found by FDA to represent the most current and complete scientific evidence. If a statement has been omitted, it is generally because FDA has not found it scientifically substantiated or necessary to assure safe use of the drug.

Daniel E. Troy, *FDA Involvement in Product Liability Lawsuits*, Update 4, 4 (Jan.-Feb. 2003). There are "a number of sound reasons why the FDA may prefer to limit warnings on product labels. Warnings about dangers with less basis in science," for example, could take attention away from those that present confirmed, higher risks." *Howmedica*, 273 F.3d at 796.

Once FDA approves an NDA, an applicant may not deviate from FDA-approved labeling without submitting an NDA supplement. 21 C.F.R. § 314.70(a). Although FDA permits supplements for "changes that may be made before FDA approval," in addition to supplements "requiring FDA approval before the change is made," *id.* § 314.70(b), (c), under either

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court, possesses superior expertise, usually of a complex scientific nature, for resolving the issue.").

procedure, the manufacturer cannot make the change if FDA disagrees with it, 21 U.S.C. § 352, 355(a). An applicant's evidentiary burden is not reduced and it must still provide a "full explanation" of the basis for a change made before FDA approval. 21 C.F.R. § 314.70(c). The applicant's supporting evidence may include "company-conducted or independent studies," and FDA will "evaluate[] the scientific evidence pertaining to the proposed change." *Amicus Curiae* Br. of the United States at 5, *Dowhal* v. *SmithKline Beecham Consumer Health Care, LP*, 100 Cal. App. 4th 8 (Cal. Ct. App. 2002) (No. A094460). According to FDA, "in actual practice, only minor product labeling changes, like an editorial change," are "made without FDA's prior approval." *Id* at 6.

II. THE LEGAL STATUS OF NDA APPROVALS.

An NDA approval represents FDA's official grant of permission to the manufacturer to market the drug. As such, the approval has the status of a "license" under federal law, and the FDA process for approving an NDA, including its imposition of labeling requirements, constitutes "licensing." This is plainly spelled out in the Administrative Procedure Act, 5 U.S.C. § 551 *et seq.*, which defines a "***license***" to include "the whole or a part of *an agency* permit, certificate, *approval*, registration, charter, membership, statutory exemption *or other form of permission*," 5 U.S.C. § 551(8) (emphasis added); and "***licensing***" as "*agency process respecting the grant*, renewal, denial, revocation, suspension, annulment, withdrawal, limitation,

amendment, modification, *or conditioning of a license*," 5 U.S.C. § 551(9) (emphasis added). The courts and commentators have uniformly recognized these characterizations of FDA's actions.[3]

Because the NDA approval process constitutes "licensing," the license granted by FDA through its NDA approval also constitutes an "order," and the FDA process for granting that approval constitutes an "adjudication." This is so because "***order***" is defined as "*the whole or a part of a final disposition*, whether affirmative, negative, injunctive, or declaratory in form, of an agency in a matter other than rule making but *including licensing*," 5 U.S.C. § 551(6) (emphasis added), and "***adjudication***" is defined as "agency process *for the formulation of an order*," 5 U.S.C. § 551(7) (emphasis added). Again, the courts have routinely endorsed these observations.[4]

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[3] *See Schering Corp. v. Illinois Antibiotics Co.*, 62 F.3d 903, 905 (7th Cir. 1995) (FDA permission to sell an animal drug is a "license"); *Barr Laboratories, Inc. v. Quantam Pharmics*, Inc., 827 F. Supp. 111, 115 (E.D.N.Y. 1993) (describing approvals to sell generic drugs as "licenses"); 39 Fed. Reg. 44602, 44631-32 (Dec. 24. 1974) (FDA Federal Register notice describing its approvals to sell antibiotic drugs as "licenses"); Ashley Sellers & Nathan Grundstein, *Administrative Procedure and Practice in the Department of Agriculture under the Federal Food, Drug and Cosmetic Act of 1938* 62 (1940) (NDA approvals are licenses); *see generally* Atl. *Richfield Co. v. United States,* 774 F.2d 1193, 1200 (D.C. Cir. 1985) ("The APA defines a 'license' to include '*any* agency permit ... approval ... or other form of permission.'"); *Air North Am. v. Dep't of Transp.*, 937 F.2d 1427, 1437 (9th Cir. 1991) (quoting 5 U.S.C. § 551(8)).

[4] *E.g., Seacoast Anti-Pollution League v. Costle*, 572 F.2d 872, 875 n.4 (1st Cir. 1978) ("The agency process for formulating an order is an adjudication.... A license is an order.") (citations omitted); *Nat'l Wildlife Fed'n v. Marsh*, 568 F. Supp. 985, 992 n.12 (D.D.C. 1983) ("A permit decision-making proceeding is clearly adjudication rather than rule making. The APA defines 'adjudication' as (continued...)

FDA's issuance of an NDA approval, which establishes the manufacturer's legal right to market the drug, constitutes a *final* adjudication. *See* 21 C.F.R. § 314.105(a) (NDA approval is "final" upon its effective date); 21 C.F.R. §§ 5.20(a), 5.103 (FDA officials to whom NDA approval authority has been designated exercise "final authority" on behalf of the Commissioner); *see generally, e.g., Pfizer Inc. v. Shalala*, 182 F.3d 975, 979 (D.C. Cir. 1999) (FDA's approval of an NDA is a "final decision"); *Bennett v. Spear*, 520 U.S. 154, 178 (1997) ("agency action [is] 'final' [if it] mark[s] the consummation of the agency's decisionmaking process [and is] one by which rights or obligations have been determined or from which legal consequences will flow").[5]

III. THE FACTS OF THIS CASE.

The nicotine replacement therapy ("NRT") products at issue here initially went through FDA's NDA approval process in the 1980s, as prescription drugs. (JA 1574 ¶¶ 9, 10). In December 1994, Defendant

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the process of issuing an 'order,' which in turn is defined to include 'licensing.'") (citation omitted).

[5] While Plaintiff may be correct that FDA has not made a "final" decision regarding how it would exercise its enforcement authority were any Defendant to violate the requirements imposed through the NDA process, that has no bearing on the finality of the requirements themselves. Amici are not aware of any court that has required that a federal agency have taken enforcement action as a prerequisite to determining whether preemption is present.

SmithKline filed a Supplemental New Drug Application ("SNDA")[6] with FDA to convert its product (Nicorette) gum from a prescription product to a nonprescription over the counter product. (JA 1575 ¶ 14, 1584-86). During this review process, FDA evaluated a number of alternative pregnancy warnings—including the "harm your baby" warning advocated by Plaintiff—before determining the final, mandated warning. (JA 1575 ¶ 16).

After more than a year of FDA review and alterations to the label as originally proposed, FDA granted the SNDA, thus approving Nicorette for OTC sale, conditioned on SmithKline's use of the following pregnancy warning language: "Nicotine can increase your baby's heart rate; if you are pregnant or nursing a baby, seek the advice of a health professional before using this product." (JA 1575 ¶ 18, 1591-94, 1596-99). FDA warned SmithKline that failure to provide the warning, "exactly as requested, ... may render the products misbranded" under the FDCA's misbranding provisions. (*Id.* at 1575 ¶ 18, 1597). The same process was followed, with substantively identical warnings required, with respect to the two other products at issue in this litigation, Nicotrol and NicoDerm CQ. (JA 1492 (39:3-14); 1510-12; 1576 ¶ 20, 1601-05, 1081-86). FDA admonished that "[t]he final printed labeling (FPL) *must be identical* to the draft labeling..."

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[6] A "supplemental" NDA is one requesting FDA approval of changes to a previously approved NDA, *see* 21 C.F.R. § 314.70.

(JA 1601, 1081) (emphasis added).[7] The review and approval process involved not only FDA's internal staff but also independent expert advisory committees brought together by FDA. (JA 237 ¶ 5).

In early 1997, FDA denied Defendant McNeil's request (made pursuant to FDA's "changes being effected" regulation, 21 C.F.R. § 314.70(c)) for permission to add an additional warning message to the Nicotrol warning that would comport with the requirements of California's Proposition 65 statute, Health & Safety Code § 25249.6 ("Proposition 65"). That statute requires the use of "clear and reasonable" warnings that inform consumers that a product contains a chemical "known to" the State of California to cause cancer or reproductive toxicity. *Id.* FDA denied McNeil's request and instructed it to resubmit its draft label "without the Prop[osition] 65 Statement[,]" insisting that McNeil "[m]ust use the labeling that was approved at the time of [the] NDA approval." (JA 1501 (134:2-14), 1505-07 (141:12-143:7), 1517, 1520). The Agency told McNeil "it was unacceptable to include California's Proposition 65 in the labeling." (*Id.* at 1520).

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[7] The FDA officials who signed the SNDA approvals with respect to Defendants' NRT products had been delegated "final authority" to perform the Commissioner's functions with respect to new and/or supplemental drug approvals, *see* 21 C.F.R. §§ 5.20(a), 5.103.

In correspondence with the California AG in June 1998, FDA stated that placing the Proposition 65 "safe harbor" warning[8] on the NRT therapy products would be "inaccurate and could possibly render [them] misbranded." (JA 1558-63). FDA went beyond the specific safe harbor warning language itself, and concluded that, while any Proposition 65 warning message "must clearly communicate that the chemical in question is *known*" to cause "birth defects or other reproductive harm" (*see* 22 Cal. Code Regs. § 12601(a)), FDA had reached the conclusion that the scientific data "*do not* support the conclusion that the nicotine in OTC smoking cessation products in fact causes reproductive harm." (JA 1559) (emphasis added).

In late 1999, FDA approved sale of an NRT product not at issue in this litigation (Habitrol) that contained a different pregnancy warning than those imposed on the three products at issue in this lawsuit. (JA 1565-66). In response to SmithKline's inquiries regarding this development, FDA in July 2000 confirmed to Defendants in writing that their products "must" continue to use their current warnings. (JA 1577 ¶26; 1634; 1571). In connection with approval of a new Nicorette flavor, FDA instructed

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[8] The Proposition 65 regulations provide a "safe harbor" warning that will be deemed to comply with the statute's "clear and reasonable" warning requirement: "WARNING: This product contains a chemical known to the State of California to cause birth defects or other reproductive harm [and/or cancer]." 22 Cal. Code Regs. § 12601(b)(4).

SmithKline in September 2000 to use a pregnancy warning "identical" to that previously-mandated for the existing products. (JA 1640, 1643).

Any person may petition FDA to issue a regulation or take any other form of administrative action. 21 C.F.R. §§ 10.25, 10.30. Plaintiff invoked that right and in August 2000 petitioned FDA to impose the same warning language he seeks here. (JA 1150-56). FDA in August 2001 rejected that request because this warning language "overstates what is actually known about nicotine and its effect on the unborn child"; "is not supported by current human and animal data"; would do "a disservice to pregnant women struggling to avoid the known harms of smoking"; and "contradicts [his] proposal for a warning that clearly and reasonably quantifies the relative reproductive harms of smoking and use of NRT drug products." (Joint RJN, Ex. A at pp. 2-8).

Rather than require that Defendants' products carry the same warning that had been used for Habitrol, *see supra*, as Plaintiff requested, FDA informed Plaintiff of its decision to instruct Habitrol to *stop* using the "harm your baby" warning. (*Id.* at pp. 5-8). FDA also decided that in the future it would require all forms of OTC NRT products, including both Habitrol and Defendants' products, to bear the following pregnancy warning: "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 p. 8.)

FDA's response to Plaintiff's citizens petition was signed by the Associate Commissioner for Regulatory Affairs, a person to whom the entirety of the "final authority" of the Commissioner has been delegated, 21 C.F.R. §§ 5.20(a), (b)(2). The rejection of Plaintiff's citizen's petition constituted final agency action that Plaintiff was entitled to challenge in court, 21 C.F.R. § 10.45(d), but no such challenge was ever brought.

Consistent with the views it has taken throughout, FDA in the court below confirmed that "Defendants' use of the pregnancy warning that [Plaintiff] advocated for these products would cause them to violate the FDCA's prohibition on selling misbranded drug products." *Amicus Curiae* Br. of the United States at 13, *Dowhal* v. *SmithKline Beecham Consumer Health Care, LP*, 100 Cal. App. 4th 8 (Cal. Ct. App. 2002) (No. A094460).

ARGUMENT

I. THE SAVINGS CLAUSE OF THE MODERNIZATION ACT DID NOT ABOLISH CONFLICTS PREEMPTION.

Under the Supremacy Clause, U.S. Const. art. VI, cl. 2, federal law preempts state law in several circumstances:

> first, when Congress, in enacting a federal statute, has expressed a clear intent to pre-empt state law ["express preemption"]; second, when it is clear, despite the absence of explicit preemptive language, that Congress has intended, by legislating comprehensively, to occupy an entire field of regulation and has thereby left no room for the States to

> supplement federal law ["implied preemption"]; and, finally, when compliance with both state and federal law is impossible, or when the state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress ["conflict preemption"].

Capital Cities Cable, Inc. v. *Crisp*, 467 U.S. 691, 699 (1984) (internal citations and quotation marks omitted); *see also United States* v. *Locke*, 529 U.S. 89, 109 (2000). The authors of Proposition 65 recognized that they are subject to these rules. *See* Health & Safety Code § 25249.10(a) (Proposition 65 does not apply to "exposure for which federal law governs warning in a manner that preempts state authority.")

The Court of Appeal majority held that the labeling requirements of Proposition 65 need not—indeed, as a matter of law, could not—be examined to determine whether they conflict with federal law, because of a savings clause found in the Food and Drug Administration Modernization Act of 1997, Pub. L. 105-115, Nov. 21, 1997, 111 Stat. 2296, 2373-75 (the "Modernization Act"). That conclusion was in error.

In a section entitled "National Uniformity for Nonprescription Drugs," the Modernization Act provides that "no State or political subdivision of a State may establish or continue in effect any requirement...that relates to the regulation of a [nonprescription] drug...that is different from or in addition to, or that is otherwise not identical with, a requirement under [the FD&C Act]...." Pub. L. 105-115, title IV, Sec. 412(a), *codified at* 21 U.S.C. § 379r(a)(2). Section 397r also contains a

savings clause, which provides: "*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 meets this description.

Even in the absence of controlling case law, it would be obvious that this savings clause has no bearing on the preemption claim asserted here. On its face, the savings clause only saves state requirements from the operation of "this section," that is, Section 412 of the Modernization Act, 21 U.S.C. § 379r. But Defendants do not argue express preemption under Section 379r. Instead, they argue that Proposition 65 conflicts with the FD&C Act provisions governing FDA's approval of new drugs and new drug labeling (21 U.S.C. § 355) and its determination whether labeling would be false and misleading (21 U.S.C. §§ 321n, 352(a)) and thereby render the drug misbranded (21 U.S.C. §§ 331(a)-(c), 352(a), (f)); *see* pp. 4-5 *supra*.

FDA determined that *under those sections* the specific labeling Proposition 65 requires would be false and misleading for NRT products and render the products misbranded. *See* pp. 10-15, *supra*. The savings clause cannot possibly be read to reach those other sections of the FD&C Act, because the clause only refers to and negates the effect of the single section in which it is contained. *See United States v. Locke*, 529 U.S. 89, 104-06 (2000) (savings clause referring to specific title of an Act does "not extend to subjects addressed in the other titles of the Act or other acts").

Controlling case law confirms this obvious reading. As the United States Supreme Court held in *Freightliner v. Myrick*, 514 U.S. 280, 287 (1995), the argument "that implied pre-emption cannot exist when Congress has chosen to include an express pre-emption clause in a statute...is without merit." To the contrary, "neither an express pre-emption provision nor a savings clause bars the ordinary working of conflict pre-emption principles." *Buckman Co. v. Plaintiff's Legal Comm.*, 531 U.S. 341, 351 (2001) (citation omitted); *accord Geier v. American Honda Motor Co.*, 592 U.S. at 869. Indeed, the *Geier* Court questioned whether Congress would ever allow "state law [to] impose legal duties that would conflict directly with federal regulatory mandates." *Id.* at 871-72.

The potential implications of the Court of Appeal majority's holding are far reaching, given that similar savings clauses appear in dozens of federal statutes covering the full gamut of federal powers. *See, e.g.*, 12 U.S.C. § 399 (Indian mineral lands); 47 U.S.C. § 533(d) (cable television); 23 U.S.C. § 131(k) (outdoor advertising billboards); 18 U.S.C. § 43(e) (animal enterprise terrorism); 17 U.S.C. § 1101(d) (sound recording copyrights); 15 U.S.C. § 2227(e) (fire prevention and control); 15 U.S.C. § 717h(a) (natural gas rates). That Congress has chosen to exempt specific state law requirements from the preemptive effect that specific federal requirements set forth in these statutes would otherwise have had cannot be interpreted as a decision by the federal government to provide the states

unfettered authority to establish legal requirements that stand as a direct obstacle to federal objectives in these important arenas of federal activity.

Plaintiff's rejoinder, besides citing inapposite and legally-irrelevant legislative history,[9] is that reading the savings clause in the manner Defendants and Amici suggest would render the savings clause devoid of meaning. Not so. The Modernization Act express preemption clause is very broad, invalidating a state requirement if it is *in any way* "different from or in addition to, [or] otherwise not identical with" FD&C Act requirements, *see* 21 U.S.C. § 379r(a)(2). Given that language, states cannot enact *any* of "their own additional requirements"—*all* such requirements are preempted. *Kraft Foods North America, Inc. v. Rockland County Dep't of Weights and Measures*, 2003 WL 554796 at * 5 (S.D.N.Y. Feb. 26, 2003).

But for state requirements that fall within the Modernization Act savings clause, a challenger to such a requirement cannot succeed merely by pointing out that the state requirement is different from the federal requirement. Rather, the challenger must carry the traditional burden of showing that compliance with both the state requirement and federal law is impossible, or that the state law stands as an obstacle to the accomplishment

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[9] As Defendants have demonstrated, the cited remarks by individual Senators did not even address conflicts, and they would not be of legal relevance even if they did. *See Estate of Floyd Cowart* v. *Nicklos Drilling Co.*, 505 U.S. 469, 475 (1992) ("In a statutory construction case, the beginning point must be the language of the statute, and when a statute speaks with clarity to an issue judicial inquiry into the statute's meaning, in all but the most extraordinary circumstances, is finished.").

and execution of the full purposes and objectives of Congress. *See* pp. 15 - 16, *supra*.

As the Court of Appeal concurring opinion correctly concluded: "Proposition 65 is saved by being left precisely where it was before the uniform labeling law of the Modernization Act of 1997 took effect, allowed to impose *different*, but not *conflicting* requirements." (Conc. Opn., p. 6) (emphasis added). The savings clause thus does have real meaning, notwithstanding the fact that the only federal requirements from which Proposition 65 is saved are those set forth in Section 379r itself.

II. PROPOSITION 65 LABELING REQUIREMENTS ARE PREEMPTED WITH RESPECT TO THE NRT PRODUCTS.

This litigation seeks to penalize Defendants, potentially severely, because they have not labeled their products in a manner that FDA has consistently and repeatedly forbidden. The concurring opinion suggests, and Plaintiff contends, that this is of no moment, because (a) FDA is simply wrong in concluding (as it has) that "Defendants' use of the pregnancy warning that [Plaintiff] advocated for these products would cause them to violate the FDCA's prohibition on selling misbranded drug products," *see* p. 15, *supra,* and (b) the manner in which FDA has acted does not have preemptive force. Neither proposition is correct.

A. FDA Has Correctly Found a Conflict.

The Proposition 65 regulations provide that, *regardless of the precise words utilized*, a pregnancy warning "message must clearly communicate that the chemical in question is known" to cause "birth defects or other reproductive harm." 22 Cal. Code Regs. § 12601(a).[10] Yet FDA has repeatedly forbidden this warning language because it "overstates what is actually known about nicotine and its effect on the unborn child"; "is not supported by current human and animal data"; would do "a disservice to pregnant women struggling to avoid the known harms of smoking"; and "contradicts [Plaintitff's] proposal for a warning that clearly and reasonably quantifies the relative reproductive harms of smoking and use of NRT drug products." (Joint RJN, Ex. A at pp. 2-8); *see also* JA 1559 ("the data at this time do not support the conclusion that the nicotine in OTC smoking cessation products in fact causes reproductive harm"); JA 1501 (134:2-14), 1505-07 (141:12-143:7), 1517-18, 1520-21 (FDA stated that "it was unacceptable to include California's Proposition 65 statement in the labeling").

A federal agency's own views regarding whether state law conflicts with federal requirements it administers are to be accorded substantial

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[10] Plaintiff's observation that Defendants are not required to use Proposition 65's precise "safe harbor" warning language (*see* note 8 *supra*) is thus beside the point.

deference. *Sprietsma v. Mercury Marine,* 537 U.S. 51, __, 123 S. Ct. 518, 529 (2002); *Geier*, 529 U.S. at 883. FDA's views on appropriate drug labeling merit particular respect. *See Henley* v. *FDA*, 77 F.3d at 620 ("FDA's determination of what labeling best reflects current scientific information regarding the risks and benefits" of a drug "involves a high degree of expert scientific analysis.") (citation omitted); *Pub. Citizen Health Res. Group,* v. *Comm'r, FDA*, 740 F.2d at 29 (Whether a drug "is sufficiently dangerous to require a warning label is a factual question demanding the medical expertise that FDA possesses and [courts] lack.") This expertise extends both to the warnings that should be given and those that should not. *Howmedica*, 273 F.3d at 796.

FDA's conclusions here are well grounded and warrant the highest judicial respect.

B. FDA Took Action Through Means That Trigger Federal Preemption.

Federal preemption applies here because the FD&C Act explicitly grants authority to FDA to determine what labeling would constitute misbranding, *see* p. 5 *supra*, and FDA in its initial approval of the SNDA, and its subsequent action (including but not limited to the rejection of Plaintiff's citizens petition), has consistently applied that authority to reject the labeling that Proposition 65 would require. Defendants cannot simultaneously label their products with and without a Proposition 65

warning; that is a physical impossibility. Defendants cannot accede to Plaintiff's demand for a Proposition 65 warning without creating an obstacle to FDA's objective of establishing warnings that reflect what the expert agency (FDA) believes to be the true state of the science regarding NRT products and the effect of nicotine on pregnant women.[11]

Either physical impossibility or an obstacle to the fulfillment of federal objectives gives rise to conflict preemption, *see* pp. 15-16, *supra.* The Proposition 65 requirements accordingly cannot be applied here.

Plaintiff nonetheless suggests that the manner in which FDA has acted is somehow insufficient, because the agency purportedly has engaged in neither rulemaking nor adjudication. This is wrong for three reasons.

First and foremost, preemption arises out of the fact that Congress explicitly tasked FDA with the responsibility to apply its scientific expertise and determine whether proposed warning language would be inappropriate, in the exact manner that FDA has done here. Congress gave FDA the power to subject all new drugs to a review and approval process; to examine their labeling; to assess their warnings; and to forbid their sale unless the manufacturer adopted labeling and warnings the agency deemed appropriate

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[11] For obvious reasons, that purpose would be equally undermined whether the Proposition 65 warning were placed on the product or, as Plaintiff now suggests, on point-of-sale advertising.

under the standards Congress prescribed. "FDA is the federal agency to which Congress has delegated its authority to implement the provisions of the Act, the agency is uniquely qualified to determine whether a particular form of state law 'stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress, and, therefore, whether it should be pre-empted.'" *Medtronic, Inc. v. Lohr,* 518 U.S. 470, 496 (1996).

Second, although not required as Plaintiff contends, this case does in fact involve rulemaking; specifically, the pregnancy warning regulation, which explicitly requires manufacturers to use any product-specific labeling that FDA has chosen to mandate. *See* pp. 5-6, *supra*.

Third, both Plaintiff's repeated efforts to denigrate FDA's action as nothing more than a series of "letters" (*e.g.*, Plaintiffs' Opp. Brief on the Merits 33-37), and the concurring opinion's suggestion that "[t]he correspondence between the FDA and [Defendants] was entirely too informal to establish a policy that would justify invoking the supremacy clause to invalidate a state law" (Conc. Opn., p. 11), fundamentally misperceive the nature of FDA's actions. True, FDA's actions did involve letters, but as anyone old enough to have received a Draft Board notice well knows, not every epistle is a billet-doux.

To the contrary, FDA's "letters" approving Defendants' SNDA were the means employed by FDA to carry out the responsibility placed on it by Congress to determine appropriate labeling and warning requirements for

new drugs. *See* 21 U.S.C. § 355(b) (setting forth requirements for NDAs including the submission of proposed labeling); 21 U.S.C. § 355(d)(7) (FDA shall disapprove NDA if, *e.g.,* the proposed "labeling is false or misleading in any particular"); 21 U.S.C. § 355(c)(1)(A) (FDA shall approve the NDA if none of the grounds for denial applies); 21 C.F.R. 314.105(a) ("The Food and Drug Administration will approve an [NDA] and send the applicant an approval letter if none of the reasons in Sec. 314.125 for refusing to approve the application applies.")

When Congress has granted FDA the power to determine appropriate labeling, and prescribed the means by which that determination shall be made, then FDA's actions in conformity with those requirements fulfill any possible procedural requirement necessary to trigger the preemptive effect of the relevant FD&C Act provisions. *See Geier,* 529 U.S. at 884 (rejecting the dissenter's view that any particular formalities need have been followed by the agency); *Bank of Am. v. City of San Francisco,* 309 F.3d 551, 563-564 (9th Cir. 2002), *cert denied*, 123 S. Ct. 2220 (2003) (conflict preemption found based on interpretation of national bank powers set forth in "amicus brief" and "two interpretive letters").

Moreover, FDA's "letters' approving Defendants' SNDAs, which represented the culmination of an intensive scientific review of both the products and their appropriate labeling, constituted a final "adjudication" under federal law. *See* pp. 4-10, *supra.* While Amici do not concede that

this or any other particular formalities need have been followed, *see Geier, Bank of Am.*, ***an adjudication is the very kind of agency action that Plaintiff himself identifies as sufficient to trigger federal preemption***. *See* Plaintiffs' Opp. Brief on the Merits at 29 ("[c]ourts routinely reject the argument that agency statements made outside of formal regulations *or final adjudications* are sufficient to preempt state law") (emphasis added); *id.* at 32 ("we have not found any case holding that a federal agency may preempt state law without either rulemaking *or adjudication.*" (citation omitted; emphasis added).

A federal agency's right to exercise its authority through adjudication is well established. "The choice between rulemaking and adjudication is committed to the sound discretion of administrative agencies governed by the [APA]." *State Corp. Comm'n v. Kansas*, 787 F.2d 1421, 1428 (10th Cir. 1986); *Laborers' Int'l Union of North Am. v. Foster Wheeler Corp.*, 26 F.3d 375, 387 n.8 (3d Cir. 1994) ("agencies are free to exercise their legislative powers in adjudications").

As a necessary corollary to that rule, the courts have held that "adjudication or notice-and-comment rulemaking" have the "force of law." *United States v. Mead*, 533 U.S. 218, 226-27 (2001); *see also Microcomputer Tech. Instit. v. Riley*, 139 F.3d 1044, 1047 (5th Cir. 1998) ("Congress has long been aware of the common practice of both courts and

agencies to make *binding policy* through case-by-case adjudication.'") (emphasis added; citations omitted).

The courts have accordingly recognized that a federal agency's "resort to declaratory adjudication does not vitiate the effectiveness of preemption." *State Corp. Comm'n v. Kansas*, 787 F.2d at 1428 (emphasis added); *see also Gen. Motors Corp. v. Abrams*, 897 F.2d 34, 39-40 (2d Cir. 1990) ("a consent order reflecting a reasonable policy choice of a federal agency and issued pursuant to a congressional grant of authority may preempt state legislation"); *Grocery Mfrs. of Am. v. Gerace*, 755 F.2d 993, 1002 (2d Cir. 1985) (adjudications have preemptive effect).

Furthermore, an adjudicatory status applies not only to FDA's initial approvals of the Defendants' SNDAs, but to the agency's August 2001 decision to modify the required warning language for all NRT products, while forbidding the use of a Proposition 65 warning (*see* pp. 14-15, *supra*). This is so because "licensing" (and hence "adjudications," *see* pp. 8-9, *supra*) includes not only the original grant of a license but also "*agency process respecting the...modification...of a license*," 5 U.S.C. § 551(9) (emphasis added).[12]

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12 The cases relied upon by Plaintiff all pre-date the Supreme Court's decision in *Geier*, which as noted made clear that no particular formality need be followed before preemption will be found. In any event, these decisions do not support Plaintiff's case. In *Wabash Valley Power Ass'n v. REA*, 903 F.2d 445, 454 (7th Cir. 1990), the court observed that it had "not found any case holding that a federal (continued...)

For all these many reasons, the case law clearly establishes the preemptive nature of FDA's interpretation and application of the FD&C Act under the facts of this case.

CONCLUSION

The Court should reverse the Court of Appeal and thereby affirm the judgment of the trial court.

Respectfully submitted,

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agency may preempt state law without either rulemaking or adjudication," but as Defendants have shown, this does not reflect the current state of the law, and as Amici have shown, the instant case does involve an adjudication. The court in *United States v. Ferrara,* 847 F. Supp. 964, 969 (D.D.C. 1993), refused to afford preemptive power to a U.S. Department of Justice *internal memorandum*, quoting *Wabash Valley* for the need for "either rulemaking *or adjudication*." (emphasis added). In *Amer. Dep. Corp. v. Schacht*, 887 F. Supp. 1066 (N.D.Ill. 1995), the court drew a distinction between the deference owed to a "formal approval" letter issued "in response to [an] application for same" (as is at issue here), and a mere "no objection letter" (as was at issue there), 887 F. Supp. at 1076. The court ultimately found that the agency had not acted within its delegated authority, *id.* at 1080.

CERTIFICATION OF LENGTH OF BRIEF

Based on the word count provided by the Microsoft computer program, I certify that this brief (excluding the cover page, table of contents, table of authorities, and signature page) contains 7081 words.

Dated: July 21, 2003

Darren D. Cooke

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