

No. S109306

IN THE SUPREME COURT OF THE STATE OF CALIFORNIA

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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.*

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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

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

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**DEFENDANTS' OPENING BRIEF ON THE MERITS**

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## ISSUES PRESENTED FOR REVIEW

1. When Congress enacted the Modernization Act of 1997 (21 U.S.C. § 379r) and included a “savings clause” to protect certain state initiatives, including Proposition 65 (Health & Saf. Code § 25249.6), from *express* preemption under the Food, Drug and Cosmetic Act (“FDCA”), did it also reverse the normal operation of the Supremacy Clause of the United States Constitution in order to permit state law to reign supreme over conflicting federal law?

2. Do Proposition 65’s warning requirements trump those that the federal Food & Drug Administration (“FDA” or “Agency”) specifically designed and mandated for Defendants’<sup>1</sup> nicotine replacement therapy products where:

(a) FDA has determined that applying a Proposition 65 warning message to these particular smoking cessation products is without scientific foundation, inconsistent with FDA’s own warning requirements, a frustration of important federal government policy objectives, and violative of the FDCA’s prohibition against misbranding;

(b) FDA has prohibited Defendants from placing any Proposition 65 warning message on their products and has authority to pursue an enforcement action against Defendants for misbranding if they fail to comply with the federal government’s directives; and

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<sup>1</sup> Defendants are GlaxoSmithKline Consumer Healthcare, LP (“SmithKline”), McNeil Consumer Products Company (“McNeil”), Pharmacia & Upjohn, Inc. (“Pharmacia”), Aventis Pharmaceuticals Inc., Alza Corporation, Costco Wholesale Corporation, Lucky Stores, Inc., Rite Aid Corporation, Safeway Inc., and Walgreen Co. (collectively, “Defendants”).

(c) the federal government's own position is that FDA has the authority to preempt Proposition 65 in cases where its requirements conflict with the warning requirements of Proposition 65, and that FDA has exercised that authority here?

3. Did the Court of Appeal have authority to determine the legitimacy of FDA's stated objectives when FDA itself has already spoken directly to the issue and determined that the application of state law would undermine those objectives?

4. Can this decision be squared with the First District's recent decision in *Kanter v. Warner-Lambert Co.* (2002) 99 Cal.App.4th 780 [122 Cal.Rptr.2d 72] (*Kanter*)?

### **INTRODUCTION AND SUMMARY OF ARGUMENT**

This case concerns an irreconcilable conflict between State and federal regulation of the warning language required on smoking cessation products ("Products") made available to California consumers by Defendants. Plaintiff Dowhal ("Plaintiff") filed the underlying action pursuant to the citizen suit provision of Proposition 65, which authorizes any person to bring an enforcement action for alleged violation of the statute if the Attorney General declines to do so. (Health & Saf. Code § 25249.7, subd. (d).)<sup>2</sup>

Here, the California Attorney General did not pursue a Proposition 65 action against Defendants because, after corresponding with FDA about the matter, he correctly concluded in 1998 that: (1) "FDA, by imposing a

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<sup>2</sup> If successful, Proposition 65 entitles such persons to 25% of any penalty collected. (Health & Saf. Code § 25192, subd. (a), par. (2).) For this reason, Proposition 65's citizen suit provision is sometimes referred to as a "bounty hunter" provision.

specific warning and rejecting the Proposition 65 warning, clearly intended to preempt Proposition 65 as applied to these products” (see Joint Appendix (JA) at 1530-1531); and (2) “an action under Proposition 65 may have an adverse public health impact” because the “important products” at issue, unlike most products, “should be encouraged rather than discouraged” in order to promote public health. (See JA at 1528.)<sup>3</sup>

Notwithstanding the Attorney General’s findings, Plaintiff filed suit in 1999 alleging that the pregnancy warning specifically designed and mandated by FDA for the Products fails to satisfy Proposition 65’s requirements. While the litigation was pending, FDA continued to instruct Defendants that they must not deviate from the federally-mandated language. It did so repeatedly. FDA also notified Defendants at various times pre- and post-litigation that any deviation would render them at risk of federal prosecution for “misbranding” in violation of the FDCA. (See 21 U.S.C. §§ 331, 352.)

Defendants moved for summary judgment on grounds of federal conflict preemption based on the obvious conflict between FDA’s directives and the requirements Plaintiff was advocating under State law. In granting Defendants’ motion, the trial court agreed that — in the circumstances of this case — Proposition 65 conflicts with federal policy objectives and requirements and is therefore rendered inapplicable by ordinary conflict preemption on grounds of both “frustration of purpose” and “impossibility.” (JA at 2430-2432.)

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<sup>3</sup> In December 2000, the California Attorney General reversed his position (JA at 1546-1556) and subsequently appeared as amicus in support of Plaintiff in the Court of Appeal.

The Court of Appeal reversed. The justices were unanimous in their result, but sharply divided in their reasoning. In an unprecedented ruling, the majority held that Congress has precluded federal preemption of Proposition 65 under *any* circumstances. Thus, in the majority's view, FDA is entirely without authority to preempt application of Proposition 65 to nonprescription drugs even where, as here, the Agency's expert view is that the Proposition 65 warning message: (1) lacks a scientific basis as applied to the Products; (2) violates federal misbranding regulations; (3) is in direct conflict with FDA's own labeling requirements established pursuant to the FDCA; and (4) is overstated and thus likely to deter pregnant smokers from using the Products as an aid to quitting, thereby undermining the federal government's objective of avoiding the thousands of unnecessary infant deaths and birth defects caused by maternal smoking each year.<sup>4</sup> Justice Simons issued a separate concurrence and disagreed with the majority's reasoning; however, based on his erroneous finding that there is no "actual conflict" here, he too concluded that Proposition 65 is not preempted.

The Court of Appeal decision should be reversed for several reasons:

*First*, in saving Proposition 65 from "express" preemption under the Food and Drug Administration Modernization Act of 1997 (the "Modernization Act"), Congress did not also exempt Proposition 65 from operation of ordinary "conflict" preemption. Indeed, it is implausible on its face to conclude that Congress has authorized *any* state to impose warning

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<sup>4</sup> "It has been estimated that maternal smoking results in as many as 7000 infant deaths in the United States each year." (Joint Req. for Judicial Notice (Joint RJN), Ex. A at p. 2.)

requirements that conflict with FDA’s mandates and violate federal misbranding laws.

As the U.S. Supreme Court explained in *Geier v. American Honda Motor Co.* (2000) 529 U.S. 861, to accept that Congress has exempted a state law from ordinary conflict preemption is to accept the untenable premise that Congress designed the governing federal law to “defeat its own objectives, or potentially, as the Court has put it before, to ‘destroy itself.’” (*Geier, supra*, 529 U.S. at pp. 871-874 [120 S.Ct. 1913, 146 L.Ed.2d 914].) “[I]t would take from those who would enforce a federal law the very ability to achieve the law’s congressionally mandated objectives that the Constitution, through the operation of ordinary preemption principles, seeks to protect.” (*Id.* at pp. 871-872.) As such, *Geier* conclusively established that legislation defining the ambit of *express* federal preemption has no bearing on the operation of “ordinary experience-proved principles of *conflict* preemption.” (See *id.* at p. 874 (emphasis added).) Incorrectly concluding that *Geier* is limited to its facts, the Court of Appeal stands alone in its departure from this rule.

*Second*, the majority’s error is evident from the plain language of the Modernization Act, which was enacted to achieve national uniformity in nonprescription drug regulation by expressly preempting any state requirement that is different from federal requirements. (21 U.S.C. § 379r.) Congress decided to exempt from this new uniformity rule certain “state initiatives,” including Proposition 65. To that end, Congress included a “saving” clause in the statute that preserves Proposition 65’s pre-Modernization Act authority to impose requirements that are different from — but not in *conflict* with — federal law. That the saving clause is intended to do nothing more is clear from the language Congress chose to

employ — it states simply that “*this section* shall not apply” to state initiatives. (21 U.S.C. § 379r, subd. (d), par. (2) (emphasis added).) The majority decision ignores this language.

*Third*, the majority’s analysis is flawed because it failed to give any weight to FDA’s view that: (1) a Proposition 65 warning message would render the Products misbranded and thwart important federal objectives; and (2) “the FDCA’s requirements with respect to drug marketing preempt any *inconsistent* requirements imposed by Proposition 65.” (U.S. Amicus Br. at p. 17(emphasis added).)<sup>5</sup> The U.S. Supreme Court has consistently stated — most recently in *Sprietsma v. Mercury Marine* (2002) \_\_U.S.\_\_ [123 S.Ct. 518], decided last month — that a federal “agency’s own views” regarding whether state law is preempted are to be accorded substantial deference in a conflict preemption analysis. (*Id.* at p. 529; *Geier, supra*, 529 U.S. at p. 883.) This is particularly true where, as here, Congress has delegated to FDA the authority to implement the federal statute at issue. (*Geier, supra*, 529 U.S. at p. 883; *Medtronic, Inc. v. Lohr* (1996) 518 U.S. 470, 496 [116 S.Ct. 2240, 135 L.Ed.2d 700].) The majority failed to heed the high court’s direction. (Opinion (Opn.) at p. 11.)

*Finally*, in his concurring opinion, Justice Simons recognized that the majority’s immunization of Proposition 65 from conflict preemption cannot be squared with the recent and definitive preemption pronouncements of the U.S. Supreme Court, and finds no support in the text or legislative history of the Modernization Act. (Concurring Opinion (Conc. Opn.) at pp. 3-4.) However, in proceeding to the next step in his

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<sup>5</sup> Amicus Curiae Brief of the United States of America in Support of Defendants/Respondents SmithKline Beecham Consumer Healthcare LP, filed March 22, 2002. (U.S. Amicus Br.)

analysis — whether an “actual conflict” exists between Proposition 65 and the federal requirements or objectives at issue — he too ignored the high court’s teaching and erroneously concluded that there is no conflict here. Accordingly, Justice Simons rejected the trial court’s ruling that both the “frustration of purpose” and “impossibility” doctrines of conflict preemption render Proposition 65 inapplicable to the Products.

Notwithstanding that the U.S. Supreme Court has declared repeatedly that a federal agency is “‘uniquely qualified’ to comprehend” its own regulations, requirements, scientific determinations, and public health objectives, (see, e.g., *Geier, supra*, 529 U.S. at p. 883), the concurring opinion accorded no deference to FDA’s stated view regarding these matters. Justice Simons’s conclusion rested instead on his *own view* of what FDA’s warning requirements and objectives are or *should be*.

In rejecting the “frustration of purpose” doctrine of conflict preemption, the concurrence also incorrectly concluded that FDA’s statements of its health policy objectives with respect to maternal smoking were insufficiently formal to preempt conflicting state law. In his dissent, Justice Stevens asserted the same position with respect to the federal agency objectives in *Geier* — a position flatly rejected by the majority of the Supreme Court. (Compare *Geier, supra*, 529 U.S. at pp. 888, 910-912 (Stevens, J., dissenting) with 529 U.S. at pp. 884-885.) Furthermore, Justice Simons’s ruling that FDA warning directives and objectives established in the nonprescription drug approval process lack preemptive force ignores the applicable FDA pregnancy warning regulation (21 C.F.R. § 201.63, subd. (b)), and conflicts with the recent decision of the First District in *Kanter*.

The concurring opinion is also flawed in its rejection of the “impossibility” doctrine of conflict preemption on the mistaken assumption that Defendants are free to place an FDA-prohibited warning on “point-of-sale signs” — *i.e.*, to communicate to the consumer by means other than the label affixed to the Products the very same warning that FDA has repeatedly stated is “not supported by current human and animal data” and “overstates” the Products’ risk of harm. (Opn. at p. 11; Joint RJN, Ex. A at pp. 5, 7.) To do so would subvert FDA’s authority and undermine its health policy against overwarning on the Products; moreover, it would not save Defendants from federal prosecution as the concurrence suggests. For this additional reason, Justice Simons’s opinion is in error and should not be adopted.

In sum, the Court of Appeal decision deviates dramatically from controlling U.S. Supreme Court precedent and is at odds with the plain language of the Modernization Act. Both the majority and concurring opinions deprive Defendants of the ability to rely on FDA’s directives as to matters that Congress delegated to the Agency and that fall squarely within the Agency’s unique regulatory and scientific expertise. They also deprive Defendants of the ability to comply simultaneously with their federal and State obligations, or even to ascertain what those obligations are without resorting to litigation. For all of these reasons, this Court should reverse the judgment of the Court of Appeal, thereby affirming the trial court’s judgment, which permits the federal regulatory scheme to operate as Congress intended and prevents State law from impeding the important federal objective of reducing harm to pregnant women and their unborn or infant children.

## STATEMENT OF THE CASE.

### I. THE PRODUCTS.

The Products — Nicorette, NicoDerm CQ, and Nicotrol — are designed to help people quit smoking through nicotine replacement therapy (“NRT”). They are “a safer alternative to smoking” and “often critical to smokers’ success in quitting.” (California Med. Assoc. Amicus Letter Br., filed September 6, 2002, at p. 2; see also JA at 215-217, 223-225, 226-230, Joint RJN, Ex. A at pp. 2-3, 5, 6-7.)

The Products are sold over-the-counter (“OTC”). SmithKline markets Nicorette (original, mint, and orange gum) and NicoDerm CQ (original and clear transdermal patches). (See JA at 1574 [¶ 7].) McNeil and Pharmacia have at different times marketed Nicotrol (transdermal patch). (See *id.* at 1574 [¶ 8], 1491 [33:20-22].) Aventis Pharmaceuticals Inc. is involved in the packaging of NicoDerm CQ. (*Id.* at 800.) Alza Corporation manufactures NicoDerm CQ. (*Id.* at 769, 784.) Costco Wholesale Corporation, Lucky Stores, Inc., Rite Aid Corporation, Safeway Inc., and Walgreen Co. are all retailers of Nicorette, NicoDerm CQ, and/or Nicotrol. (*Id.* at 785, 830-831, 838-839, 854, 861-862.)

### II. THE FDA APPROVAL PROCESS AND CONTINUING STRICT REGULATION OF THE REQUIRED WARNING LANGUAGE.

#### A. In The Course Of The OTC Approval Process, FDA Designed A Product-Specific Pregnancy Warning With The Objective Of Avoiding Overwarning And The Unnecessary Infant Deaths And Birth Defects Caused By Maternal Smoking.

Initially, the Products were available only on a limited basis by prescription — Nicorette in 1983, followed several years later by NicoDerm and Nicotrol. (See JA at 1574 [¶¶ 9, 10].) In 1993, SmithKline and McNeil commenced the required procedures for obtaining FDA

approval to sell the Products OTC. (See *id.* [¶ 11], JA at 1490 [30:3-6].) Like prescription products, nonprescription or OTC drugs are strictly regulated by FDA; they can be sold only if their labels are first approved by FDA, and only if they are marketed in compliance with FDA's strict labeling and warning requirements mandated through FDA's rigorous "new drug" or "supplemental new drug" approval process ("NDA/SNDA process"). (See *infra.* at pp. 15-16.)

At every stage in the lives of the Products (pre-and post-approval for prescription sale and pre- and post-approval for OTC sale), a period covering approximately twenty years, the Products' pregnancy risks and benefits, and the warning language appropriate to communicate them, have been the subject of close and continuing scrutiny by FDA, various independent Medical Advisory Boards (including more than one hundred doctors and medical experts), and the Products' sponsors (i.e., SmithKline, McNeil, etc.). (See JA at 1574 [¶ 12].) Throughout this entire period, FDA and its medical advisors reviewed scientific data and studies on health risks and benefits as the information became available. (See *id.* [¶ 13].) As appropriate, FDA would mandate a revision of pregnancy and other warning information associated with the Products, always specifying the language required to clearly and accurately reflect the current status of the science. (See *id.*) This process continued as the Products switched from prescription-only to OTC status, at all times thereafter (see *id.*) and continues today. (See Joint RJN, Ex. A.)

**B. FDA Conditioned Its OTC Approval On Use Of The Precise Pregnancy Warning Language It Mandated.**

In December 1994, SmithKline filed a Supplemental New Drug Application ("SNDA") with FDA to convert Nicorette gum from a

prescription product to an OTC product. (See JA at 1575 [¶ 14], 1584-1586.) During this review process, FDA evaluated a number of alternative pregnancy warnings — including the “harm your baby” warning advocated by Plaintiff during the latter part of this litigation — before determining the final, mandated warning. (See JA at 1575 [¶ 16].) After more than a year of FDA review of the data and label, and after countless changes were made to the label originally proposed, FDA approved Nicorette for OTC sale. (Compare JA at 1574 [¶ 17], 1588-1589 with JA at 1574 [¶ 17], 1591-1594.)

Pursuant to 21 Code of Federal Regulations, section 201.63, subdivision (b), FDA conditioned its approval 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.

(See JA at 1575 [¶ 18], 1591-1594, 1596-1599.) FDA cautioned SmithKline that failure to provide the warning, “*exactly as requested*, ... may render the product misbranded” under the FDCA’s misbranding provisions. (*Id.* at 1575 [¶ 18], 1597 (emphasis added).)

The OTC pre-market approval process for the Products was an unusually exhaustive one as compared to other OTC products. (See JA at 1575 [¶ 15].) The warning requirements were given extraordinary attention because “[w]hen determining the proper labeling ... [FDA was] faced with the difficult task of relaying the relative risks of the *potential* harm from [the Products] versus the *known* harm caused by the continued use of tobacco products.” (Joint RJN, Ex. A at pp. 2-3 (emphasis added).) In addition, unlike with most nonprescription products, FDA’s objective was

to encourage use of the Products to help smokers quit smoking, which meant that it was critical to avoid *overwarning*. In this regard, the chairperson of FDA's independent Nonprescription Drugs Advisory Committee, Dr. Randy P. Juhl, stated as follows:

[T]his is one of the few instances where we have a product that has come before this committee that I would like lots of people to use, that I think we are under using. Other products tend to go in the other direction.

So we want to make sure that we are not introducing barriers that would prevent people from using them, and what is worse, somebody continuing to smoke or not calling their physician and talking with him ....

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I think, at least as I am interpreting the sense of the committee is that *let's be real careful on something we want people to use more of that we don't introduce barriers that would reduce their willingness to use the product.*

(JA at 300-301 (emphasis added).) In designing the warning, therefore, FDA sought to identify not only the minimum warning required (*i.e.*, a regulatory floor), but also the maximum warning permitted (*i.e.*, a regulatory ceiling). (See *id.*)

In June 1995, McNeil submitted its SNDA for Nicotrol OTC approval. (See JA at 1492 [39:3-14].) It too underwent rigorous scientific review and, when approved for OTC sale in July 1996, FDA mandated use of the same pregnancy warning required for Nicorette. (See *id.* at 1510-1512.)<sup>6</sup>

Following another extensive review process, including review by an independent Medical Advisory Board, FDA approved SmithKline's

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<sup>6</sup> There were minor, immaterial editorial differences in the warning language mandated for each of the Products.

NicoDerm CQ for OTC sale in August 1996. (See JA at 1576 [¶ 20], 1601-1605.) As with Nicorette and Nicotrol, FDA mandated the precise pregnancy warning to be used and again made clear that, unless the label for NicoDerm CQ was “*identical*” to that specified by FDA, it could render the product misbranded. (See *id.* at 1601 (emphasis added).)

**C. FDA Has Repeatedly Rejected The Warnings Advocated By Plaintiff And Prohibited Use Of A Proposition 65 Warning Message On The Products.**

FDA has explicitly and repeatedly rejected the warnings that Plaintiff has advocated in this action. In addition, FDA has declared that—as applied to the Products—Proposition 65’s required warning *message* set forth under California Code of Regulations, title 22, section 12601, subdivision (a), is inaccurate, scientifically unsupported, and violative of the FDCA’s misbranding provisions.

**1. FDA rejected McNeil’s request for permission to place a Proposition 65 warning on the Products.**

In early 1997, FDA flatly denied Defendant McNeil’s request (made pursuant to FDA’s “[c]hanges-[b]eing-[e]ffected” regulation, 21 C.F.R. § 314.70, subd. (c)) for permission to add a Proposition 65 warning message to the Nicotrol warning. Specifically, McNeil proposed the Proposition 65 “safe harbor” warning language set forth at California Code of Regulations, title 22, section 12601, subdivision (b), which reads: “This product contains nicotine, a chemical known to the State of California to cause birth defects or other reproductive harm.” (JA at 1499-1500 [122:16-123:12], 1514-1515.) FDA denied McNeil’s request and instructed it to resubmit its draft label “without the Proposition 65 Statement[,]” insisting that McNeil “[m]ust use the labeling that was approved at the time of [the] NDA approval.” (See *id.* at 1501 [134:2-14], 1505-1507 [141:12-143:7],

1517, 1520.) The Agency told McNeil that “it was *unacceptable* to include California’s Proposition 65 in the labeling.” (See *id.* at 1520 (emphasis added).)

**2. FDA informed the California Attorney General that the Proposition 65 warning message is scientifically unsupported as applied to the Products.**

In Spring 1998, pursuant to Health and Safety Code section 25249.7, subdivision (d)(1), Plaintiff served a Proposition 65 “60-Day Notice” requesting that the Attorney General (“AG”) bring a Proposition 65 enforcement action against Defendants in connection with the Products. (See JA at 1523). Subsequently, the AG’s office sent a letter to FDA regarding Proposition 65 and the Products. (See *id.* at 1525-1526.)<sup>7</sup>

FDA replied to the AG in June 1998, stating that placing the Proposition 65 safe harbor warning on the Products would be “inaccurate and could possibly render [them] misbranded.” (JA at 1558-1563). FDA’s position was not limited, however, to the specific language of the safe harbor warning. Rather, FDA rejected entirely the Proposition 65 warning *message* — a “*message* [that] must clearly communicate that the chemical in question is *known*” to cause “birth defects or other reproductive harm.” (22 Cal. Code Regs. § 12601, subd. (a) (emphasis added).) Specifically, FDA stated that the scientific data “*do not* support the conclusion that the nicotine in OTC smoking cessation products *in fact causes reproductive harm,*” i.e., is *known* to cause such harm. (JA at 1559 (emphasis added).) It further explained:

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<sup>7</sup> California has designated FDA as an authoritative body for purposes of selecting chemicals for listing as reproductive toxins under Proposition 65. (Health & Saf. Code § 25249.8; 22 Cal. Code Regs. § 12306, subds. (b), (k), pars. (1), (4).)

In this instance, the agency believes it is more accurate and more useful to specifically identify the risk (i.e., increased fetal heart rate), and to recommend consultation with a doctor, than to state categorically that the products are “*known* to cause reproductive harm.”

(JA 1559-1560 (emphasis added).) Moreover, “the pregnancy warning [FDA] *requires* for [the Products] ... clearly and accurately identifies the reproductive risks associated with the nicotine in these products, and does so in terms that are understandable to the ordinary consumer.” (*Id.* (emphasis added).) FDA concluded that, in any event, “the current labeling meets the standard applied by [the AG] for determining that a warning is ‘clear and reasonable’ under Proposition 65.” (*Id.* at 1561.)

Given FDA’s position, the AG declined to pursue any action against Defendants, citing both conflict preemption and concern about the detrimental public health effects of overwarning. (See JA at 1528-1535.)<sup>8</sup>

**3. FDA repeatedly instructed Defendants to use only the federally mandated pregnancy warning on the Products.**

On November 12, 1999, FDA approved sale of the Habitrol product — a different smoking cessation product not at issue here and marketed by a company who is not a party. Habitrol began selling with a pregnancy warning different from that required by FDA for the Products at issue in this case. (Compare JA at 1581-1582, 1646-1647, 1650-1651 with JA at 1565-1566.) Nicorette, NicoDerm CQ, and Nicotrol were required by FDA to warn that “nicotine can increase your baby’s heart rate,” while

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<sup>8</sup> The State of California recognizes FDA as the leading expert in the regulation of nonprescription drugs. (See, e.g., Health & Saf. Code § 110111 [adopting FDA nonprescription drug regulations as the law in California].)

Habitrol appeared in the market with a warning that nicotine “can harm your baby.” (*Id.*)

Upon learning of the Habitrol warning, SmithKline immediately submitted a Freedom of Information Act (“FOIA”) request to FDA seeking information about the Habitrol product, its labeling, and the scientific basis for its pregnancy warning so that SmithKline could ascertain whether scientific information about Habitrol might also be relevant to its Products. (See JA at 1576-1577 [¶ 23], 1653, 1655.) SmithKline did not receive a substantive response to that FOIA request for information. (See, *id.* at 1576-1577 [¶ 23].)

When Plaintiff learned of the Habitrol warning, he immediately adopted it as his warning of choice in this litigation and abandoned the two warnings he previously had been advocating. (Compare JA at 166-182 with JA at 1153-1155.)

While Defendants awaited a response to the FOIA request relating to Habitrol, they sought instructions from FDA regarding their own warning labels. (See JA at 1577 [¶ 24]; Joint RJN, Ex. A at pp. 1-2.) In early 2000, FDA advised SmithKline to continue using the same pregnancy warning previously mandated by FDA for the Products while the Agency was “reviewing its position as it relates to the warning on nicotine products concerning pregnancy and breast feeding.” (See JA at 1577 [¶ 24], 1614.)

Having still not received a response to the FOIA request, SmithKline and McNeil each wrote to FDA on May 10, 2000, *again* pointing out that Habitrol carried a pregnancy warning different from that mandated by FDA for Nicorette, NicoDerm CQ, and Nicotrol, that they were being sued by Plaintiff who was demanding use of the Habitrol warning, and asking whether the Agency nevertheless required them to use the warning

mandated by FDA, without change. (See JA at 1657-1659, 1662-1664.) FDA's response came on June 20, 2000, when, as part of the OTC label review of a new Nicorette flavor, FDA advised SmithKline again that, although FDA was reviewing its position on the pregnancy warning, SmithKline must continue to "use [the] current warning." (See JA at 1577 [¶ 26], 1634.)

To be absolutely certain that FDA's instructions applied to *all* of the SmithKline and McNeil Products, counsel sent a letter to FDA on July 11, 2000, seeking confirmation of FDA's instructions regarding the pregnancy-warning language required for the Products, and again reminding the Agency that Plaintiff's suit claims that state law requires a different warning. (See JA at 1568-1569.) Ten days later, FDA sent its written response, once more stating unequivocally that the Products "*must*" use the exact pregnancy warning specified by FDA for the Products. (See *id.* at 1571 (emphasis added).)

On September 25, 2000, in connection with approval of a new Nicorette flavor (orange), FDA yet again instructed SmithKline to use a pregnancy warning "*identical*" to that previously-mandated for the Products. (See JA at 1640, 1643 (emphasis added).)

Finally, on March 2, 2001—in response to yet another inquiry by SmithKline's counsel—FDA sent a letter to SmithKline stating that, even though the Habitrol product was using a different warning, FDA's instructions concerning Defendants' Products remained unchanged:

As we have stated previously, the agency is currently reviewing its position regarding the pregnancy/nursing warning on OTC nicotine products.

.... As we have stated previously, until the agency's review is complete, all sponsors of

OTC nicotine replacement products should continue to use the pregnancy/nursing warning that was approved by the agency as part of *their* NDA. ***Any additional or modified warning may render the product misbranded.***

(JA at 2401 (emphasis added).)

**4. FDA informed Plaintiff directly that it rejects his Proposition 65 demands.**

On August 1, 2000, one year after filing the Complaint and seven months before the trial court’s summary judgment decision, Plaintiff submitted a Citizen Petition to FDA requesting the very same relief that he seeks in this action — that Defendants use the “‘harm your baby’ warning or another similar warning” on their Products. (See JA at 1155.) On August 17, 2001, FDA responded to the Petition by rejecting Plaintiff’s Proposition 65 demands and informing him that:

- Plaintiff’s Petition raised issues “similar to those that the agency was already considering[;]”
- the Agency had once again evaluated all the relevant scientific and medical data concerning NRT products;
- the scientific and medical references in his Petition “do not provide substantial new data” of risks associated with the Products;
- “FDA *denies*” his “request to require a warning on all NRT drug products similar to the ‘harm your baby’ warning on the Habitrol product[;]”
- Plaintiff’s proposed warning “*overstates* what is actually known about nicotine and its effect on the unborn child[;]”
- Plaintiff’s proposed warning “is *not supported* by current human and animal data[;]”
- “[t]he Agency is concerned that a pregnancy warning label that *overstates* the known risks of NRT products does a disservice to pregnant women struggling to avoid the known harms of smoking[;]” and
- “the Agency believes that [his] request for the requirement of the ‘harm your baby’ warning *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 (emphasis added).)

Indeed, rather than require the Products to bear the Habitrol warning as he requested, FDA informed Plaintiff of its decision to instruct Habitrol to *stop* using the “harm your baby” warning. (See Joint RJN, Ex. A at pp. 5-8.) FDA also decided that in the future it would require all forms of OTC NRT products, including Habitrol and the Products, to bear a uniform pregnancy warning as follows:

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.) In accordance with FDA procedures, and consistent with its directives to Defendants all along, FDA reiterated that it would not entertain use of a different warning unless the request for the change is supported by scientific data. (See *id.*)<sup>9</sup>

**III. IN THE COURT OF APPEAL, FDA CONFIRMED THAT A PROPOSITION 65 WARNING ON THE PRODUCTS WOULD CONFLICT WITH FEDERAL REQUIREMENTS, FRUSTRATE FEDERAL POLICY OBJECTIVES, AND VIOLATE FEDERAL MISBRANDING LAW.**

In the United States’ Amicus Brief filed with the Court of Appeal, the federal government confirmed that Proposition 65 currently is and always has been preempted as applied to the Products, because it conflicts both with federal objectives and FDA’s product-specific pregnancy

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<sup>9</sup> For the Court’s convenience, attached as Exhibit A hereto is an abbreviated chronology of the history of relevant State, federal, and party action. The words appearing in Exhibit A have been included in the total word count in Defendants’ Certification of Length of Brief.

warning. (See U.S. Amicus Br. at pp. 13, 16, 23.) The Amicus Brief spoke to each of the key disputed issues in the case.

As to FDA's authority to preempt Proposition 65 where there is a conflict, the federal government's view is:

- “It cannot be reasonably disputed here that the FDCA’s requirements with respect to drug marketing preempt any inconsistent requirements imposed by Proposition 65.” (U.S. Amicus Br. at p. 17.)
- “Given the rejection of Dowhal’s proposed warning labeling by FDA, the federal agency with expertise and paramount responsibility in the area of drug regulation, the agency’s determination that use of such warning labeling would make Defendants’ products misbranded carries controlling weight in a state court action brought by the very party that asked FDA to act on the matter.” (*Id.* at p. 18.)

As to whether a Proposition 65 warning on the Products violates federal misbranding regulations, the federal government's view is:

- “Defendants’ use of the pregnancy warning that Dowhal advocated for these products would *cause them to violate* the FDCA’s prohibition on selling misbranded drug products.” (*Id.* at p. 13 (emphasis added).)

As to whether application of Proposition 65 to the Products frustrates federal objectives, the federal government's view is:

- Defendants “had good reason to avoid labeling changes that might render their products misbranded,” because the resultant “harmful consumer confusion” would have “increase[ed] the risk that consumers would continue to be exposed to the much greater health risks of inhaled tobacco smoke.” (*Id.* at p. 25.)
- Depriving Defendants of their ability to rely on FDA’s directives without “risk of sustaining liability under a complementary state law system would plainly frustrate the objectives Congress sought to advance under the FDCA.” (*Id.* at p. 25.)
- Proposition 65 “must be applied in a way that preserves the latitude necessary for the federal regulatory scheme to operate as Congress intended.” (*Id.* at p. 24.)

As to whether the Modernization Act has any bearing on conflict preemption, the federal government's view is:

- “[T]he Modernization Act simply does not affect the application of conflict preemption.” (*Id.* at p. 30.)

As to whether FDA regulations permitted Defendants to effect a warning change based on state law, the federal government's view is:

- “Although use of a ‘changes being effected’ supplement permits a manufacturer to make labeling changes as soon as it files its supplement, the regulation requires the manufacturer to provide FDA with a satisfactory evidentiary basis for the change, especially with respect to any significant labeling change like the one Dowhal advocated.” (*Id.* at p. 24.)
- “Defendants had no new facts to present to FDA to support different warning labeling.” (*Id.* at p. 14.) No “significant evidentiary change occurred from the time Dowhal filed this suit until the agency’s disposition of his citizen petition.” (*Id.* at p. 23.)
- “[T]he fact that state law requires use of a particular warning *cannot* constitute the necessary factual predicate [for a ‘changes being effected’ supplement].” (*Id.* at p. 24 (emphasis added).)

#### **IV. STATE AND FEDERAL LAW IN CONFLICT.**

##### **A. California’s Proposition 65.**

Proposition 65 was enacted as a ballot initiative in 1986. In its provisions relevant to this case, Proposition 65 requires a “clear and reasonable warning” of “reproductive toxicity” with respect to all products sold in California that contain certain chemicals identified in the regulations. (Health & Saf. Code § 25249.6.) To meet this requirement, the “message” articulated in the pregnancy warning for these products “must clearly communicate that the chemical in question is *known*” to cause “birth defects or other reproductive harm.” (22 Cal. Code Regs. § 12601, subd. (a) (emphasis added).) California has designated FDA as an authoritative body for purposes of selecting chemicals for listing as

reproductive toxins under Proposition 65. (Health & Safety Code § 25249.8; 22 Cal. Code Regs. § 12306, subds. (b), (k), pars. (l), (4).)

Proposition 65 also contains a provision addressing federal preemption. This provision states that the warning requirements of the statute do not apply in any circumstance in which “federal law governs warning in a manner that preempts state authority.” (Health & Saf. Code § 25249.10, subd. (a).) The Court of Appeal decision makes no mention of this preemption provision.

**B. The FDCA.**

The FDCA establishes a comprehensive scheme of drug regulation to ensure that drugs are safe and effective for their intended use. The FDCA specifically authorizes FDA to regulate the labeling of nonprescription drugs, such as the Products, including appropriate warnings. (21 U.S.C. §§ 331, subds. (a), (b), (k), 352, subds. (a), (f); 21 C.F.R. Part 201, Subpart C.) The FDCA mandates that FDA prohibit the marketing or sale of misbranded food and drugs. (See 21 U.S.C. § 331, subd. (b).)

Title 21 Code of Federal Regulations section 201.63, subdivision (b), addresses FDA’s procedures for mandating product-specific pregnancy warnings through the NDA/SNDA process, as FDA did for the Products here (see *supra* at pp. 9-19.) This regulation requires that, “[w]here 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*” by the regulated entity “unless otherwise stated in the NDA....” (21 C.F.R. § 201.63, subd. (b) (emphasis added).) A regulated entity who fails to comply with FDA’s

requirements is subject to an enforcement action for misbranding. (21 U.S.C. §§ 331, subd. (b), 352, subds. (a), (f), 333, subd. (a)).

The FDCA defines “misbranded” to include drugs lacking “adequate warnings ... in such manner and form, as are necessary for the protection of users. “ (21 U.S.C. § 352, subd. (f).) “Adequate warnings” are those that, in the judgment of FDA, are “clear and truthful in all respects,” not “misleading in any particular,” and that accurately communicate the “benefit-to-risk ratio” and the proper use of the product in terms “likely to be read and understood by the ordinary individual.” (See 21 C.F.R. § 330.10, subd. (a), pars. (4), (iii), (v); see also 21 U.S.C. § 352, subds. (a), (f).)

The FDCA was amended in 1997 by the Modernization Act, which established national uniformity in regulation of nonprescription drugs by preempting applicable state requirements that are not identical to FDA’s. (21 U.S.C. § 379r.) As discussed *infra* at pp. 28-30, the Modernization Act also “saved” from this uniformity requirement certain state initiatives, including Proposition 65, leaving them subject to the same preemption rules that applied prior to enactment of the uniformity provision. (See 21 U.S.C. § 379r, subd. (d), par. (2).)

## ARGUMENT

### **I. THE COURT OF APPEAL MAJORITY ERRED IN HOLDING THAT PROPOSITION 65 IS NOT PREEMPTED EVEN IN LIGHT OF ITS DIRECT CONFLICT WITH FEDERAL REQUIREMENTS AND OBJECTIVES.**

Proposition 65, by its own terms, contemplates federal preemption. (See Health & Saf. Code § 25249.10, subd. (a) [Proposition 65 does not

apply to “exposure for which federal law governs warning in a manner that preempts state authority”].<sup>10</sup> Federal preemption derives from the Supremacy Clause of the United States Constitution, which, in pertinent part, declares that federal law is “the supreme Law of the Land; and the Judges in every State shall be bound thereby, any Thing in the Constitution or Laws of any State to the Contrary notwithstanding.” (U.S. Const. art. VI, cl. 2.)

There are three forms of preemption: (1) express preemption —“when Congress has made its intent known through explicit statutory language;” (2) implied *field* preemption —“in the absence of explicit statutory language, state law is pre-empted where it regulates conduct in a field that Congress intended the Federal Government to occupy exclusively;” and (3) implied *conflict* preemption —“state law is pre-empted to the extent that it actually conflicts with federal law,” which it does *either* where “it [is] impossible for a private party to comply with both state and federal requirements [typically referred to as ‘impossibility’], or where state law ‘stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress’ [typically referred to as ‘frustration-of-purpose’].” (*English v. General Elec. Co.* (1990) 496 U.S. 72, 78-79 [110 S.Ct. 2270, 110 L.Ed.2d 65] (internal citation omitted); see also *Geier, supra*, 529 U.S. at pp. 873, 874.)

It is the third form of preemption — “conflict” preemption— that applies here, under both the “impossibility” and “frustration-of-purpose”

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<sup>10</sup> Defendants challenge the applicability of Proposition 65 only in the narrow circumstances of conflict preemption. They do not challenge the statute’s general applicability to nonprescription drug products marketed or sold in California.

doctrines.<sup>11</sup> FDA has made clear that, in the unique circumstances of this case, Proposition 65 conflicts both with FDA’s regulatory requirements and its policy objectives because the Proposition 65 warning message as applied to the Products is without scientific foundation, inconsistent with FDA’s own warning requirements, an obstacle to federal public health objectives concerning smoking, and violative of the FDCA’s prohibition against misbranding. (See, e.g., *supra* at pp. 19-21.)

Notwithstanding FDA’s position, the Court of Appeal held that Proposition 65 is *not* preempted. Indeed, the majority ruled that FDA lacks authority to preempt Proposition 65 under *any* circumstances. The court erroneously concluded that Congress enacted a saving clause in the Modernization Act not only to allow *concurrent* California and federal regulation of nonprescription drugs, but also to permit California to impose requirements that *directly conflict* with a party’s federal obligations and frustrate federal objectives under the FDCA. (Opn. at pp. 11, 15.) This is squarely at odds with: (1) the Supreme Court’s holding in *Geier*, which addressed precisely this issue (see *Geier, supra*, 529 U.S. at pp. 873-874); (2) critical statutory language in the relevant provisions of the Modernization Act — language that the majority decision entirely ignored; and (3) FDA’s own view concerning this matter, which should have been (but was not) accorded substantial deference.

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<sup>11</sup> Each of these doctrines alone constitutes an independent and sufficient ground for sustaining conflict preemption. (See *Geier, supra*, 529 U.S. at p. 873 [“[B]oth forms of conflicting state law are ‘nullified’ by the Supremacy Clause.” (Citations omitted)].)

**A. The Court Of Appeal Majority Failed To Heed The U.S. Supreme Court’s Recent And Definitive Pronouncements Regarding Conflict Preemption.**

As Justice Simons noted in his concurrence, neither the Court of Appeal nor any party has cited a single precedent in which Congress was found to have reversed operation of the Supremacy Clause to allow state law to reign supreme over federal law where the two might conflict. (Conc. Opn. at pp. 3-4; see also *Hillsborough County v. Automated Med. Labs., Inc.* (1985) 471 U.S. 707, 712 [105 S.Ct. 2371, 85 L.Ed.2d 714] [“It is a familiar and well-established principle that the Supremacy Clause, U.S. Const., art. VI, cl. 2, invalidates state laws that ‘interfere with, or are contrary to,’ federal law.” (Citation omitted)].) Finding that Congress so intended here, the majority decision is in error and stands alone in its departure from the Supreme Court’s definitive pronouncement “that neither an express pre-emption provision nor a saving clause ‘bars the ordinary working of conflict pre-emption principles.’” (*Buckman Co. v. Plaintiffs’ Legal Comm.* (2001) 531 U.S. 341, 352 [121 S.Ct. 1012, 148 L.Ed.2d 854]; *Geier, supra*, 529 U.S. at p. 869.)

The question in *Geier* was whether federal Department of Transportation safety regulations preempted a common-law tort claim based on a car manufacturer’s failure to install an air bag. (See *Geier, supra*, 529 U.S. at pp. 873-874.) The federal regulations included both an express preemption clause and a saving clause preserving certain state tort claims. (See *id.*) The Court held that neither an express preemption provision nor a saving clause from express preemption suggests, by “negative implication” or otherwise, that Congress intends to “bar the ordinary working of conflict pre-emption principles.” (*Id.* at p. 869.) As

such, a saving clause does not establish even a *presumption* against conflict preemption:

Neither do we believe that the pre-emption provision, the saving provision, or both together, create some kind of “special burden” beyond that inherent in ordinary pre-emption principles — which “special burden” would specially disfavor pre-emption here.

(*Geier, supra*, 529 U.S. at p. 870.) “In a word, ordinary pre-emption principles, grounded in longstanding precedent, apply.” (*Id.* at p. 874, citation omitted.) To conclude otherwise would be unsound, as the Court explained:

Why ... would Congress not have wanted ordinary pre-emption principles to apply where an actual conflict with a federal objective is at stake? Some such principle is needed. In its absence, state law could impose legal duties that would conflict directly with federal regulatory mandates....

(*Geier, supra*, 529 U.S. at p. 871.) Finding that the state tort law rule advocated by the plaintiffs “would stand as an ‘obstacle’ to the accomplishment of [the federal agency’s] objective,” the high court held the state tort action preempted. (*Id.* at p. 886.)

According to the Court of Appeal majority, *Geier* does not require the same outcome in this case because *Geier* is limited to its facts, *i.e.* the specific saving and express preemption clauses that were before the Supreme Court. (Opn. at pp. 12-13.) To the contrary, *Geier* speaks generally about saving clauses and the workings of ordinary conflict preemption (see, e.g., *Geier, supra*, 529 U.S. at pp. 869-874) and, as Justice Simons’s concurrence notes, the Supreme Court expressed “substantial skepticism” that Congress would “ever” intend to permit state law to conflict with its own laws or objectives. (Conc. Opn. at p. 3.)

Moreover, the majority ignored that in the later case of *Buckman* — which did not even involve a saving clause and addressed preemption under the FDCA’s Medical Devices Amendments of 1976 — the Supreme Court reaffirmed the general applicability of the conflict preemption principles it established in *Geier*:

[t]o the extent respondent posits that anything other than our ordinary pre-emption principles apply under these circumstances, that contention must fail in light of our conclusion last Term in *Geier v. American Honda Motor Co.*, 529 U.S. 861 (2000), that neither an express pre-emption provision nor a saving clause “bars the ordinary working of conflict pre-emption principles.” *Id.* at 869.

(*Buckman*, *supra*, 531 U.S. at p. 352 (emphasis added).)

Accordingly, the Court of Appeal majority erred in deviating from the Supreme Court’s teaching. This Court should reverse its judgment to bring California in line with *Geier* and *Buckman*, as well as the multitude of decisions that has uniformly followed the preemption principles articulated therein.

**B. The Court Of Appeal Decision Ignored The Plain Language Of The Modernization Act.**

The Modernization Act amended the FDCA to achieve, as its title states, “National Uniformity for Nonprescription Drugs.” As such, it provides for *express* preemption of all state requirements “different from or in addition to” those required under the FDCA. (See 21 U.S.C. § 379r, subd. (a), par. (2).)

The Modernization Act also includes among its “exceptions” a saving clause for state public initiatives adopted before September 1, 1997. Proposition 65 falls within this category. The saving clause states that “[t]his 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, subd. (d), par. (2) (emphasis added).) “This section,” of course, refers to § 379r, which provides for “national uniformity” of “nonprescription drugs,” *i.e.* the *express* preemption provision.

Accordingly, the plain language of the statute makes clear that the exception for state initiatives exempts them only from the newly enacted uniformity requirement imposed by section 379r, and leaves the pre-existing preemption landscape entirely undisturbed. In the Court of Appeal, the United States’ Amicus Brief explained:

Where Congress uses the ‘this section’ formulation in a savings clause, it intends to limit the application of that savings clause to one particular express preemption provision. Therefore, Congress plainly intended the exception it crafted for Proposition 65 to apply only with respect to the accompanying express federal preemption, not to conflict preemption.

(U.S. Amicus Br. at p. 29.)<sup>12</sup>

Notwithstanding that “[t]he starting point for the interpretation of a statute is its language” (*Kanter, supra*, 99 Cal.App.4th at p. 790), the majority ignored Congress’s express, unambiguous limitation to “[t]his section” in the Modernization Act, and turned instead to comments of individual legislators made during Congressional hearings or debates. (Opn. at p. 10.) This was error for several reasons.

First, these statements are not a proper source of Congressional intent in these circumstances. (See Conc. Opn. at pp. 6-8.) “When a statute is unambiguous ... its language cannot ‘be expanded or contracted by the

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<sup>12</sup> Similarly, the federal government stated in its Amicus Letter to this Court that “[a]n exception to a statutory mandate cannot exceed the breadth of that mandate.” (U.S. Dept. of Justice Amicus Letter Br., filed September 12, 2002, at p. 6; see also Conc. Opn. at p. 6 (“the scope of the saving clause coincides with the scope of the preemption clause”).)

statements of individual legislators or committees during the course of the [legislative] process.” (*Kanter, supra* 99 Cal.App.4th at p. 791 (citation omitted).)

Second, and more important, none of the legislators’ remarks make any mention of conflict preemption. Thus, as Justice Simons notes, even “without quarreling with the propriety of relying on such statements,” nothing in them supports the majority’s conclusion that Proposition 65 “not only managed to fend off the uniformity requirements [of section 379r] but had also succeeded in eliminating the narrow conflict preemption limitation the initiative had always faced.” (Conc. Opn. at pp. 6, 7.)

Finally, when conflict preemption exists on the ground of “impossibility” of dual compliance, as it does here, the question of Congressional intent does not even enter the analysis. *Florida Lime* states that rule, but the majority did not address it. (*See Florida Lime & Avocado Growers, Inc. v. Paul* (1963) 373 U.S. 132, 143-144 [83 S.Ct. 1210, 10 L.Ed.2d 248] [the conclusion that federal law preempts “state law is inescapable and requires *no inquiry into congressional design* where compliance with both federal and state regulations is a physical impossibility ...”] (emphasis added); *see also Geier, supra*, 529 U.S. at p. 884 [“[C]onflict pre-emption is different in that it turns on the identification of ‘actual conflict,’ and not on an express statement of pre-emptive intent.”].)

For all these reasons, the majority’s interpretation of the Modernization Act is flawed and unfounded. Conflict preemption applies no differently to Proposition 65 today than it did prior to enactment of the Modernization Act.

**C. The Court Of Appeal Majority Improperly Disregarded FDA’s View Regarding The Preemptive Effect Of Its Own Actions.**

FDA’s position as to the preemptive effect of its nonprescription drug warning requirements on *conflicting* Proposition 65 requirements is clear: “the FDCA’s requirements with respect to drug marketing preempt any *inconsistent* requirements imposed by Proposition 65.” (U.S. Amicus Br. at p. 17 (emphasis added).) Accordingly, FDA repeatedly and explicitly directed Defendants to use only the federally-mandated warning and *prohibited* compliance with Proposition 65, because the Proposition 65 warning message as applied to the Products is inconsistent with the federal warning requirement, thwarts the federal objective of avoiding overwarning and the unnecessary significant “known” harms of smoking on pregnant women and their unborn or nursing children, and violates the FDCA’s prohibition against misbranding. (JA at 300-301, 1499-1500 [122:16-123:12], 1501 [134:2-14], 1505-1507 [141:12-143:7], 1514-1515, 1517, 1520, 1558-1563, 1568-1569, 1571, 1576 [¶ 21], 1596-1599, 1601-1605, 1607-1610, 1612-1617, 1619-1624, 1626-1630, 1634, 1638, 1640-1641, 1643-1644, 2401; Joint RJN, Ex. A).

In addition, FDA advised the Court of Appeal that to deprive Defendants of their ability to rely on FDA’s directives without “the risk of sustaining liability under a complementary state law system would plainly frustrate the objectives Congress sought to advance under the FDCA” and that, therefore, Proposition 65 “must be applied in a way that preserves the latitude necessary for the federal regulatory scheme to operate as Congress intended.” (U.S. Amicus Br. at pp. 24-25.)

FDA’s stated views regarding these conflict preemption issues should, at a minimum, be accorded significant weight. The Supreme Court

has repeatedly so held. (See, e.g., *Sprietsma*, *supra*, 123 S. Ct. at p. 529; *Geier*, *supra*, 529 U.S. at p. 883; *Medtronic*, *supra*, 518 U.S. at p. 496.)

In *Geier*, the Court stated that where, as here, “Congress has delegated to [the federal agency] authority to implement the statute; the subject matter is technical; and the relevant history and background are complex and extensive ... the agency’s own views” regarding preemption of conflicting state law “should make a difference,” because a federal agency is in the best position to understand “its own regulation and its objectives and is ‘uniquely qualified’ to comprehend the likely impact of state requirements.” (*Geier*, *supra*, 529 U.S. at p. 883 (emphasis added).) The Supreme Court therefore deferred to the Department of Transportation’s view of its own policies and objectives, as well as its determination that the state tort rule at issue would stand as an obstacle thereto.

Just last month, in *Sprietsma*, the Supreme Court underscored that the Department of Transportation’s views regarding conflict preemption of the state rule at issue in *Geier*, as conveyed to the Court in the United States’ Amicus Brief, were critical to its holding in that case:

In finding pre-emption, we expressly placed “weight upon the DOT’s interpretation of FMVSS 208’s objectives and its conclusion, as set forth in the Government’s brief, that a tort suit such as this one would “ ‘stand as an obstacle to the accomplishment and execution’ ” ‘ of those objectives ....

(*Sprietsma*, *supra*, 123 S.Ct. at p. 529.)

Similarly, in *Medtronic*, which involved the Medical Device Amendments of 1976 (“MDA”), the high court held that, “[b]ecause the 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, supra*, 518 U.S. at p. 496 (fn. and citation omitted).) “The congressional grant of authority to the agency on the matter contained within the [MDA] [] provides[s] a ‘sound basis’ for giving substantial weight to the agency’s view of the statute” and the “pre-emptive effect” of its own actions pursuant thereto. (*Id.* at p. 495-496 (citation omitted).)

As in *Geier* and *Medtronic*, Congress has delegated to FDA authority to implement the federal statute at issue.<sup>13</sup> The Court of Appeal, therefore, should have given substantial weight to FDA’s views of the preemptive effect of its own directives and objectives with respect to the Products. (*Geier, supra*, 529 U.S. at p. 883; *Medtronic, supra*, 518 U.S. at p. 495-496.) Its failure to do so was in error. Indeed, rather than accord any deference to FDA, the majority criticized the Agency for being “either unwilling or unable to recognize the limited scope of its authority” and “hinder[ing]” Defendants’ “attempts to comply with their state obligations under Proposition 65.” (Opn. at p. 15.) Unless the judgment is reversed,

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<sup>13</sup> As discussed *supra* at pp. 22-23, the FDCA specifically authorizes FDA to regulate the labeling of nonprescription drugs including appropriate warnings (21 U.S.C. §§ 331, subds. (a), (b), (k), 352, subds. (a), (f); 21 C.F.R. Part 201, Subpart C), and mandates that FDA prohibit the marketing or sale of misbranded food and drugs (see 21 U.S.C. § 331, subd. (b)). In addition, Congress delegated to FDA the authority to implement the provisions of the Modernization Act. (See, e.g., 21 U.S.C. § 379r(b)(1); compare with 21 U.S.C. § 360k(b) [MDA provision referenced by Court in *Medtronic*, 518 U.S. at p. 496.]).

Defendants and any other similarly situated entities will be forced to choose between federal or state compliance and to assume the resulting risk of prosecution and liability under one system or the other.

**II. THE CONCURRING OPINION ERRED IN ITS ANALYSIS OF “ACTUAL CONFLICT.”**

**A. FDA’s Views Of Its Own Requirements, Regulations, and Policy Objectives Are Entitled To Substantial Deference.**

Although he disagreed with the majority that FDA can never preempt Proposition 65, Justice Simons nevertheless concluded that there is no “actual” State-federal conflict here. In reaching this conclusion, the concurrence, like the majority, failed to accord FDA the deference required under *Geier* and *Medtronic* (see *supra* at pp. 31-34) — even as to matters within FDA’s scientific expertise. Justice Simons’s analysis is thus predicated upon his *own view* (rather than FDA’s stated view) of the pregnancy warning language that “would seem to improve the clarity of the message to the consumer,” and what he believed the “disguise[d]” goals and objectives of FDA might *really* be. (Conc. Opn. at pp. 14-15.) Indeed, the concurrence even challenged FDA’s stated assessment of the risks posed by nicotine and by use of the Products. (See *id.* at p. 14.) Ultimately, therefore, Justice Simons’s analysis does not determine whether there is an actual conflict between Proposition 65 and FDA’s stated requirements and objectives, but whether FDA’s requirements and objectives are in his view “legitimate.” (*Id.* at pp. 14-15.)

Specifically, Justice Simons rejected FDA’s repeated and consistent statements of its position (based in part on the views of its independent scientific experts) as to each of the following key issues, and substituted his own judgment in place of FDA’s:

- FDA has determined that “[s]trengthening the warning” on Defendants’ products would likely confuse consumers, thereby “increase[ing] the risk that consumers would continue to be exposed to the much greater health risks of inhaled tobacco smoke.” (U.S. Amicus Br. at pp. 25 and 19 n. 40; see also JA at 1558-1563, Joint RJN, Ex. A at pp. 5-7.)

Nevertheless, in Justice Simons’s view, “such an addition would seem to improve the clarity of the message to the consumer.” (Conc. Opn. at p. 14)

- FDA has determined that the scientific data “do not support the conclusion that the nicotine in OTC smoking cessation products in fact causes reproductive harm.” (JA at 1559.) FDA also stated that any warning similar to the “can” or “may harm your baby” warning would constitute misbranding as it “overstates what is actually known about nicotine and its effect on the unborn child” and “is not supported by current human and animal data.” (Joint RJN, Ex. A at p. 5; see also U.S. Amicus Br. at p. 26).

Nevertheless, the concurrence finds that the record “reflect[s] the FDA’s assessment that nicotine indeed may cause harm.” (Conc. Opn. at p. 14.)

- FDA has explained that its objective in establishing the pregnancy warning for Defendants’ products and prohibiting Defendants from including a Proposition 65 warning message is to avoid overwarning and the confusion that would likely result among pregnant and nursing smokers. (See U.S. Amicus Br. at pp. 25 and 19 n.40; see also JA at 1559, Joint RJN, Ex. A at pp. 6-7.) A “pregnancy warning label that overstates the known risks of NRT products does a disservice to pregnant women struggling to avoid the known harms of smoking.” (Joint RJN, Ex. A at p. 7.)

Nevertheless, the concurrence states that, if FDA has rejected all Proposition 65 warnings, “it would appear that FDA’s concern for overwarning *disguises* its actual goal of establishing label uniformity.” (Conc. Opn. at p. 15 (emphasis added).)

- FDA has stated that it requires a scientific basis to support a material change implemented under the “[c]hanges-[b]eing-[e]ffected “regulation” (21 C.F.R. § 314.70, subd. (c)), and that Proposition 65 obligations do not satisfy that requirement. (U.S. Amicus Br. at pp. 12-13, 24-25; Joint RJN, Ex. A at pp. 5, 6-7.) Moreover, in 1997, Defendant McNeil sought approval to add the Proposition 65

warning message via the “changes being effected” regulation, but FDA rejected the warning and declared it “unacceptable.” (See JA at 1514-1515, 1517, 1520; Opn. at p. 3).

Nevertheless, the concurrence — citing no authority — concludes that “a manufacturer’s need to comply with Proposition 65 provides adequate justification for the change of label” pursuant to the “changes-being-effected” regulation. (Conc. Opn. at p. 15, n.8.)

- FDA’s letter to the California AG in 1998 communicated the Agency’s rejection of *any* warning that “state[s] categorically that the products are ‘*known* to cause reproductive harm,’” *i.e.*, *any* warning that carries the required Proposition 65 warning message. (JA 1559-1560 (emphasis added).)

Nevertheless, the concurrence concludes that “FDA’s letter to the California Attorney General, by its own terms, rejects *only* the Proposition 65 safe harbor warning.” (Conc. Opn. at p. 12 (emphasis added).)

In so doing, the concurring opinion deprived Defendants of the ability to rely on FDA’s directives as to what its own warning requirements are, what warnings it prohibits on grounds of misbranding, what objectives it seeks to achieve in imposing its requirements, and the nature of the showing required under its own regulations. Yet, under the FDCA, Congress delegated to FDA the authority to make each of these determinations and to prosecute those who do not comply with its directives. (See 21 U.S.C. §§ 301 *et seq.*; U.S. Amicus Br. at pp. 1-6.) The concurring opinion undermines FDA’s regulatory authority and improperly disrupts this carefully devised regulatory scheme. (See, e.g., *United States v. Locke* (2000) 529 U.S. 89, 106-107 [120 S.Ct. 1135, 146 L.Ed.2d 69] [courts should seek to avoid disruption of a carefully devised regulatory scheme established by federal law]; see also Conc. Opn. at pp. 3-4.)

Indeed, if adopted, the concurrence’s reasoning would render *any* federal agency governance unworkable, as it suggests that, whenever the

directives of a federal agency conflict with state law, parties receiving those directives are required essentially to second guess the agency's conclusion that its directives are necessary to further a federal objective (just as Justice Simons did here). (See Conc. Opn. at pp. 11-16.) Moreover, regulated parties are obligated continually to test those directives in the search for whether there is *any form* of conduct (or, as in this case, label) that would comply with state law without producing an enforcement action by the federal agency. (See Conc. Opn. at pp. 10-11.) Nothing short of litigation against the federal agency each time it rejected such an approach would eliminate this uncertainty. Even then, while litigation is pending, parties again would be forced to choose between federal and state compliance, with the resulting risk of prosecution and liability under one system or the other.

**B. FDA's NDA/SNDA Directives And Objectives Have Preemptive Force.**

The concurring decision rested, in part, on Justice Simons's conclusion that FDA's directives issued, and objectives established, pursuant to the drug approval process lack preemptive force. (Conc. Opn. at p. 11.) This conclusion ignores that 21 Code of Federal Regulations section 201.63, subdivision (b), mandates that a product-specific pregnancy warning established by FDA through the NDA/SNDA process "shall be used" unless FDA directs otherwise.

FDA product-specific labeling requirements are mandated through FDA directives to the specific manufacturer via NDA/SNDA approval letters like those at issue here. As described *supra* at pp. 9-19, the pregnancy warning requirement for each of the Products was formulated based on a thorough, independent, case-by-case NDA or SNDA review and

expert analysis. Because they are manufacturer-specific, these requirements are not promulgated into generally applicable regulations, and there is no requirement that FDA do so in order to legally bind manufacturers to comply. (See 21 C.F.R. § 201.63, subd. (b) [“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).].)<sup>14</sup>

Justice Simons’s conclusion also cannot be squared with: (1) *Geier*’s rejection of the argument (which much of Justice Stevens’ dissent in *Geier* addresses) that only formal rulemaking or “full-notice” objectives can have preemptive force; and (2) the First District, Division One’s contrary view in *Kanter v. Warner Lambert Co.*

**1. The concurrence improperly dismissed statements establishing FDA’s objective of avoiding overwarning on the Products as “too informal.”**

The concurrence erred in requiring a “formal regulation on overwarning,” and improperly ignored or dismissed as “entirely too informal” (Conc. Opn. at p. 11) the various statements of FDA’s objective of avoiding overwarning — some of which are identical to, and others at least as formal as, the statements of federal objective on which *Geier* found it proper to rely. (See JA at 300-301, 1514-1515, 1517, 1520, 1558-1563,

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<sup>14</sup> Failure to comply with these requirements would have put Defendants at risk of federal prosecution for misbranding under the FDCA. (21 U.S.C. §§ 331, subd. (b), 352, subds. (a), (f), 333, subd. (a)).

1596-1599, 1601-1605, 1607-1619, 1626-1628, 1638, 1640-1641, 1643-1644, 2401; Joint RJN, Ex. A.)

In *Geier*, the federal objective was expressed primarily in the United States amicus brief filed by the Solicitor General on behalf of the Department of Transportation. (See *Geier, supra*, 529 U.S. at p. 884 [“We have no reason to suspect that the Solicitor General’s representation of DOT’s views reflects anything other than ‘the agency’s fair and considered judgment on the matter.’”].) The Supreme Court also drew inferences from the regulatory history and agency commentary. (See *Geier, supra*, 529 U.S. at pp. 888, 910-911 (Stevens, J., dissenting) [conflict preemption upheld by majority “on nothing more than an *ex post* administrative litigating position and *inferences* from regulatory *history* and final *commentary*”; the majority relies “on history and regulatory commentary rather than either statutory or regulatory text”] (emphasis added).)

Indeed, much of the *Geier dissent* is devoted to criticism of the majority’s reliance on “informal” statements of a federal agency’s “*ex post* litigating position” in conducting its conflict preemption analysis. (See *Geier, supra*, 529 U.S. at pp. 888, 910-912 (Stevens, J., dissenting).) The dissent argued that finality and “formal notice-and-comment rulemaking” should be required for agency action to have preemptive force. (*Id.* at 912 (Stevens, J., dissenting); see also *id.* at pp. 910, 912 (Stevens, J., dissenting) [majority should have required “normal notice-and-comment procedures of the Administrative Procedure Act”; the Secretary should have been required to “put his pre-emptive position through formal notice-and-comment rulemaking - whether contemporaneously with the promulgation of the allegedly pre-emptive regulation or at any time that the need for pre-emption becomes apparent.”].) The majority disagreed, and held that

conflict preemption requires no such “formality” or “finality.” (See *id.* at p. 884 [neither “formal agency statement of pre-emptive intent” nor “formal agency statement identifying conflict” is required].) As discussed *supra* at pp. 31-32, *Geier* also held that a federal agency is in the best position to understand “its own regulation and its objectives and is ‘uniquely qualified’ to comprehend the likely impact of state requirements.” *Geier, supra*, 529 U.S. at 883.

Here, FDA’s objective of avoiding overwarning was initially established by the independent medical Advisory Committee that FDA convened in 1996 to assist with the lengthy and extensive review of the scientific and medical data relating to the SNDAs filed for each of the Products. In the Advisory Committee’s report — *of which there is no mention in the concurring opinion* — the committee chair cautioned “let’s be real careful on something we want people to use more of that we don’t introduce barriers that would reduce their willingness to use the product.” (JA at 300-301.) Subsequently, FDA expressed its policy objective of avoiding overwarning on numerous occasions, including in: (1) the United States Amicus Brief filed in the Court of Appeal in 2002; (2) FDA’s 2001 response to Plaintiff’s Citizen Petition; and (3) the 1998 letter to the California AG. (See JA at 1558-1563; Joint RJN, Ex. A.)

For example, the August 17, 2001 letter responding to Plaintiff’s Citizen Petition addressed in detail the conflict between Plaintiff’s Proposition 65 demands and the Agency’s objective of encouraging pregnant smokers to quit by using Defendants’ Products. FDA stated that Plaintiff’s proposed warning “*overstates* what is actually known about nicotine and its effect on the unborn child.” (Joint RJN, Ex. A at p. 5 (emphasis added).) “The Agency is concerned that a pregnancy warning

label that *overstates* the known risks of NRT products does a disservice to pregnant women struggling to avoid the known harms of smoking.” (*Id.* at p. 7 (emphasis added).)

In the United States Amicus Brief, FDA reaffirmed the dangers that the Proposition 65 warning message posed to the federal objective and public health interests at stake:

Strengthening the warnings about the consumption of nicotine in these nicotine replacement therapy products carries an obvious risk of discouraging consumers from using the products. Such a warning would increase the risk that consumers would continue to be exposed to the much greater health risks of inhaled tobacco smoke. Given the possibility of causing such harmful consumer confusion, [Respondents] had good reason to avoid labeling changes that might render their products misbranded.

(U.S. Amicus Br. at p. 25 (emphasis added).)<sup>15</sup>

The majority in *Geier* concluded that, because the state duty advocated by the plaintiff “would have stood ‘as an obstacle to the

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<sup>15</sup> Several public health organizations and the California AG have shared FDA’s concern about overwarning on the Products and have cautioned that it would impede an important public health objective:

We agree with these organizations [including the *American Lung Association, the American Cancer Society, and the California Medical Association*] that *the public interest is poorly served by pursuing legal actions that might discourage the use of this important product as part of a smoking cessation effort*, and that an action to impose a stricter warning requirement under Proposition 65 might have that unintended consequence. We strongly believe that products that may reduce smoking should be encouraged rather than discouraged, and that an action under Proposition 65 may have an adverse public health impact.

(JA at 1528 (emphasis added).)

accomplishment and execution of” the important means-related federal objectives ..., it is pre-empted.” (*Geier, supra*, 529 U.S. at p. 881.) Contrary to Justice Simons’s view, the same is true here. FDA’s objective since the very beginning has been to reduce death and disease nationwide<sup>16</sup> by encouraging smokers — particularly pregnant women — to use Defendants’ Products to help them quit smoking if they are unable to quit on their own. Because it is FDA’s view that a Proposition 65 warning message would thwart that objective, it now is, and at all times has been, preempted.

**2. The concurrence view conflicts with the recent decision of the First District, Division One, in *Kanter v. Warner-Lambert Company*.**

According to the concurrence, “[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. at p. 11.) To the contrary, *Kanter* — decided only three weeks before the Court of Appeal decision in this case — held that FDA’s “new drug application processes” (like those at issue here) establish “federal requirement[s] with respect to labeling that can have preemptive effect.” (*Kanter, supra*, 99 Cal.App.4th at p. 794.)<sup>17</sup> There, the plaintiffs asserted breach of warranty, fraud, and unfair competition claims (among others) against the defendants based on statements appearing on the labels for an

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<sup>16</sup> “Tobacco use is the leading preventable cause of death and disease in the United States, claiming over 400,000 lives each year.” (Joint RJN, Ex. A at p. 2.)

<sup>17</sup> The petition for review of *Kanter* was denied on October 2, 2002, and the opinion was not depublished. (See *Kanter v. Care Technologies, Inc.* (2002), No. S108879, 2002 Cal. LEXIS 6376 (2002).)

OTC head lice treatment — a nonprescription drug subject to the FDA monograph system.<sup>18</sup> (*Kanter, supra*, 99 Cal.App.4th at p. 788.) The court discussed in detail the FDA new drug approval process, observing that its similarity to the FDA pre-market approval process for medical devices is “striking.” (*Id.* at pp. 793-794.) Device-specific requirements established through the FDA medical devices pre-market approval process have been held to preempt “conflicting state requirements” based on the reasoning of the Supreme Court in *Medtronic*. (*Kanter*, 99 Cal.App.4th at p. 793.)

*Medtronic* contrasts generic with device-specific federal requirements and explains that there is greater concern for protecting the device-specific from conflicting state requirements, because they are established when the federal government has “weighed the competing interests relevant to the particular requirement in question, reached an unambiguous conclusion about how those competing considerations should be resolved in a particular case or set of cases, and implemented that conclusion via a specific mandate on manufacturers or producers.” (*Kanter, supra*, 99 Cal.App.4th at p. 793 [citing *Medtronic, supra*, 518 U.S. at p. 501].)

Adopting the reasoning of the analogous medical devices authorities, *Kanter* concluded that, even though the monograph system “does not

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<sup>18</sup> One system used by FDA for evaluating whether OTC drugs are safe and effective is the creation of an expert advisory review panel that evaluates a category of products for its safety and effectiveness, reviews its labeling, and advises FDA on the promulgation of “monographs” establishing conditions under which particular “categories” of OTC drugs can be marketed and recognized as not misbranded. (See *Kanter, supra*, 99 Cal.App.4th at p. 786; 21 C.F.R. §§ 330.1, 330.10, subd. (a), 330.14, subd. (a).) These monograph regulations include warning language and other labeling requirements. (See *id.*)

require each manufacturer to submit its label for approval,” it nevertheless is sufficiently specific to “establish[] a federal requirement regarding labeling that can preempt conflicting state requirements.” (*Kanter, supra*, 99 Cal.App.4th at p. 794.)<sup>19</sup> This conclusion applies with even greater force here, because FDA’s warning directives as to each of the Products were indeed based on a product-specific (and unusually thorough and lengthy) review in which each manufacturer was required to (and did) submit its label for approval.

**C. The Concurrence Erred In Concluding That Defendants Could Place Proposition 65 Warnings On Point-Of-Sale Signs Without Violating Federal Law.**

Justice Simons’s “actual conflict” analysis addressed only the “frustration of purpose” form of conflict preemption: “As I see it, the principal question requiring analysis here is ... whether *federal purposes* would be thwarted by requiring Proposition 65 compliant language on either packaging labels or point of sale signs.” (Conc. Opn. at p. 8 (emphasis added).) Any attempt to circumvent FDA’s requirements by using, in point-of-sale advertising, a warning that FDA has determined is unsupported, inaccurate, overstated, and prohibited would frustrate FDA’s federal objective of encouraging pregnant smokers to use the Products so as to reduce the thousands of unnecessary infant deaths and birth defects caused by maternal smoking each year. Indeed, Justice Simons did not deny that, whether placed on the label affixed to a product or on a point-of-

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<sup>19</sup> After concluding that the state claims at issue were *expressly* preempted under the Modernization Act, *Kanter* stated that it was “unnecessary” to reach the question of actual conflict/impossibility under the doctrine of conflict preemption. (*Kanter, supra*, 99 Cal.App.4th at p. 797.)

sale sign, a state warning that undermines a federal objective would be nullified by conflict preemption. Justice Simons nonetheless concluded — incorrectly — that a Proposition 65 warning message is not preempted under the “frustration of purpose” doctrine because FDA’s objective of avoiding unnecessary harm caused by maternal smoking, in his view, is insufficiently “formal” and not “legitimate.” (Conc. Opn. at pp. 11, 14; see *supra* at pp. 34-37, 38-42.)

As to the “impossibility” form of conflict preemption, the concurrence rejected Defendants’ position that it is, and always has been, impossible for them to use a Proposition 65 warning message on the Products without risk of federal prosecution. In Justice Simons’s view, “[e]ven if one were to conclude that Proposition 65 requires a warning that contradicts the federal requirements ... state law does not mandate that the warning appear on the package label,” and Proposition 65 therefore “can be complied with by using point of sale signs.” (Conc. Opn. at p. 8 n.5.)

Justice Simons was mistaken. Surely state law cannot require Defendants to communicate to consumers in advertising the very same information that FDA has directed they *must not* communicate through product labeling because it has judged that information to be inaccurate and detrimental to public health. (See *Geier, supra*, 529 U.S. at pp. 873-874 [“a case of impossibility” conflict preemption is one in “which state law penalizes what federal law requires”].) To do so would subvert FDA’s authority and, in any event, would not immunize Defendants from federal prosecution as the concurrence suggests. Rather, it would subject Defendants to an additional federal enforcement action for false advertising under the authority of the Federal Trade Commission (“FTC”).

The FTC has jurisdiction over product advertising.<sup>20</sup> Section 5 of the Federal Trade Commission Act declares that “deceptive acts or practices in or affecting commerce ... [are] unlawful.” (15 U.S.C. § 45.) The FTC has authority to prosecute for deceptive practices where there is lack of substantiation for a statement made about a product. (*FTC Policy Statement Regarding Advertising Substantiation* (1983), 1984 FTC LEXIS 6, at \*433 [“[F]ailure to possess and rely upon a reasonable basis for objective claims constitutes an unfair and deceptive act or practice in violation of Section 5.”].)<sup>21</sup> When that statement in advertising concerns product safety, the FTC requires “scrupulous accuracy.” (*FTC Statement of Enforcement Policy Against Deceptive Acts or Practices, Letter to Congressman John D. Dingell* (Oct. 14, 1983), 1984 FTC LEXIS 71, at \*172 (*Enforcement Policy Statement*) [reproduced as appendix to *In re Cliffdale Assocs., Inc.* (1984) 103 F.T.C. 110, Docket No. 9156, 1984 FTC LEXIS 71, at \*166-192 (Mar. 23, 1984)].)

The FTC’s *Enforcement Policy Statement* also states that “[FTC] will find deception if there is a representation, omission or practice that is likely to mislead the consumer acting reasonably in the circumstances, to

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<sup>20</sup> The FDCA and Federal Trade Commission Act provide overlapping authority for FDA and the FTC to regulate OTC drug marketing. (See *Sandoz Pharms. Corp. v. Richardson-Vicks, Inc.* (3d Cir. 1990) 902 F.2d 222, 226-227.) “The FTC’s authority derives from its power to regulate any false or deceptive advertising ..., even in the OTC drug industry.” (*Id.*) To address this overlapping authority, “FDA and the FTC agreed to a division of regulatory authority: the FDA regulates the labeling of OTC drugs while the FTC monitors the advertising for these drugs.” (*Id.* at p. 227.)

<sup>21</sup> Reproduced as appendix to *In re Thompson Med. Co.* (1984) 104 F.T.C. 648, Docket No. 9149, 1984 FTC LEXIS 6, at \*431-441 (Nov. 23, 1984), *aff’d*, 791 F.2d 189 (D.C. Cir. 1986), *cert. denied*, 479 U.S. 1086 (1987).

the consumer's detriment." (*Enforcement Policy Statement*, 1984 FTC LEXIS 71, at \*170.) Including a warning message that is "overstated," "inaccurate," and "unsubstantiated" in advertising could mislead pregnant/nursing consumers to their detriment (and the detriment of their unborn or nursing children) because it will discourage some pregnant consumers from using the Products, and they will continue smoking instead. (See also *Commission Statement of Policy on the Scope of the Consumer Unfairness Jurisdiction, Letter to Congressmen Ford and Danforth* (Dec. 17, 1980), 1984 FTC LEXIS 2, at \*305-309 [reproduced as appendix to *In re Int'l Harvester Co.* (1984) 104 F.T.C. 949, Docket No. 9147, 1984 FTC LEXIS 2, at \*298-316 (Dec. 21, 1984) (unfairness doctrine applies where there is an unjustified consumer injury, the injury is outweighed by any countervailing benefits to consumers or competition, and consumers are not able to avoid injury)].)

It is particularly significant that, in evaluating whether there has been a violation of the Federal Trade Commission Act, FTC, as a matter of practice, defers to the judgment of FDA as to the accuracy of any warning used by Defendants in advertising. (See, e.g., *Removatron Int'l Corp. v. FTC* (1st Cir. 1989) 884 F.2d 1489, No. 88-2245, 1989 U.S. App. LEXIS 13594 (Sept. 11, 1989) [affirming FTC finding of violation based in part on FDA evaluation]; *In re Thompson Med.*, 1984 FTC LEXIS 6, at \*165 (¶ 241) [acknowledging need for regulatory harmony and uniform standards; same level of scientific evidence required by FDA for OTC labels is required by FTC for OTC product advertising]; *In re Sterling Drug, Inc.* (1983) 102 F.T.C. 395, Docket No. 8919, 1983 FTC LEXIS 65, (July 5, 1983) [claim found to be unsubstantiated based in part on FDA determinations], *aff'd*, 741 F.2d 1146 (9th Cir. 1984), *cert. denied*, 470 U.S.

1084 (1985); James M. Serafino, *Developing Standards for Health Claims - the FDA and the FTC*, 47 Food & Drug L.J. 335, 337 (1992) [“Despite the primary responsibility of the FTC to regulate advertising of products regulated by the FDA, the FTC has traditionally used the expertise of the FDA in evaluating advertising claims for OTC drugs ....”].)

In short, to the extent that FDA may lack direct or full jurisdiction over point-of-sale advertising, enforcement responsibility will rest with the FTC. This does not eliminate the conflict that exists between State and federal law or make simultaneous compliance possible.

### CONCLUSION

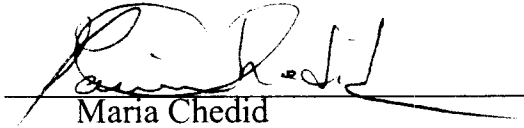
For all the foregoing reasons, Defendants respectfully request that this Court reverse the judgment of the Court of Appeal, and thereby affirm the judgment of the trial court.

Dated: January 21, 2003

Respectfully submitted,


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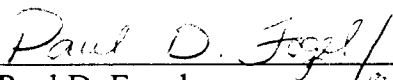
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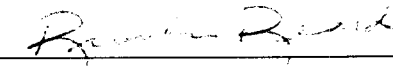
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## CERTIFICATION OF LENGTH OF BRIEF

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) and Exhibit A attached to this brief contain 13,954 words.

Dated: January 21, 2003

  
\_\_\_\_\_  
Brooks M. Beard

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

Executed at San Francisco, California, this 21st day of January, 2003.

Mila Benedict  
\_\_\_\_\_  
(typed)

*Mila Benedict*  
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(signature)

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

Executed at San Francisco, California, this 21st day of January, 2003.

Mila Benedict  
\_\_\_\_\_  
(typed)

*Mila Benedict*  
\_\_\_\_\_  
(Signature)

**PROOF OF PERSONAL SERVICE**

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

Executed at San Francisco, California, this 21st day of January, 2003.

Mila Benedict  
\_\_\_\_\_  
(typed)

*Mila Benedict*  
\_\_\_\_\_  
(signature)

[The words appearing in this Exhibit have been included in the total word count in Defendants' Certification of Length of Brief]

**EXHIBIT A**

**ABBREVIATED CHRONOLOGY OF  
STATE, FEDERAL, AND PARTY ACTION**

Date	FDA/OTHER ACTION	JA No.
2/9/96	Pursuant to SNDA regulations, FDA mandates "can increase heart rate" warning language for Nicorette.	1596-1599
4/19/96	During SNDA process, FDA medical Advisory Committee states that, unlike with other products, the federal objective is to avoid overwarning and to encourage <i>more</i> use of Defendants' Products given their purpose.	300-301
8/2/96	Pursuant to SNDA regulations, FDA mandates same warning language for NicoDerm.	1601-1605
1/6/97	McNeil seeks approval of addition of Proposition 65 "safe harbor" warning via "changes being effected" supplement pursuant to 21 C.F.R. § 314.70, subd. (c).	1514-1515
5/20/97	FDA rejects McNeil's "changes being effected" application to add a Proposition 65 warning, stating that such warning is "unacceptable."	1517-1518 1520-1521
3/20/98	Plaintiff serves his 60-day Notice under Proposition 65.	1523
5/6/98	AG corresponds with FDA regarding Proposition 65 as it relates to the Products.	1525-1526

Date	FDA/OTHER ACTION	JA No.
6/5/98	FDA Deputy Center Director Lumpkin informs AG that <i>any</i> warning on Defendants' Products that communicates the Proposition 65 <i>message</i> ("known" to cause "birth defects or other reproductive harm") would be inaccurate, because it is scientifically unsupported.	1558-1561
7/10/98	AG informs Plaintiff that, in this case, FDA's action pursuant to the FDCA preempts Proposition 65, and that an enforcement action against Defendants is unwarranted and contrary to public health.	1528-1535
8/23/99	Plaintiff files Complaint.	1-11
11/12/99	Habitrol receives FDA OTC sale approval on November 12, 1999, and subsequently appears on the market with "harm your baby" warning.	2267-2270
12/2/99	Defendant SmithKline immediately submits a FOIA request to FDA seeking basis for "harm your baby" Habitrol warning to determine if there is new science available.	1653
1/12/00	Pursuant to SNDA regulations, FDA informs SmithKline that it is "reviewing its position" concerning the required pregnancy warning, and instructs SmithKline to continue using the same warning on the Products until review is complete.	1614
2/16/00	Pursuant to SNDA regulations, FDA again informs SmithKline that it is "reviewing its position" concerning the required pregnancy warning, and instructs SmithKline to continue using same warning on the Products until review is complete.	1624

Date	FDA/OTHER ACTION	JA No.
2/16/00	Pursuant to SNDA regulations, FDA mandates same warning language for NicoDerm Clear as for other NicoDerm and Nicorette products.	1626-1630
5/10/00	Defendants write to FDA seeking direction as to warning requirements given the ongoing litigation, the different warning on Habitrol, and FDA's pending review of the warning.	1657-1659 1662-1664
6/20/00	Pursuant to SNDA regulations, FDA responds by saying that it is reviewing its position and again instructs Defendants to keep using the warning mandated in their respective SNDA approval letters.	1634
7/11/00	SmithKline again writes to FDA seeking direction.	1568-1569
7/21/00	FDA responds that Defendants "must" continue using only the warning mandated in the Defendants' respective SNDA approval letters until FDA's review is complete.	1571
8/1/00	Plaintiff files a Citizen Petition with FDA, seeking the "can harm your baby" or "similar" warning on all NRT products.	1150-1156
9/25/00	Pursuant to SNDA regulations, FDA mandates same warning language for Nicorette Orange as that mandated for previous Nicorette products.	1640-1644
12/22/00	In a letter to FDA, AG's office states that it is reversing its position regarding FDCA preemption of Proposition 65.	1544-1556
2/27/01	SmithKline again writes to FDA seeking direction.	

Date	FDA/OTHER ACTION	JA No.
3/2/01	FDA responds that Defendants must use the warning approved for their respective SNDAs; “[a]ny additional or modified warning may render the product misbranded.”	2401
8/17/01	FDA responds to Plaintiff’s Citizen Petition by rejecting the “can harm your baby” and any “similar” warning, because such warnings are inaccurate and overstated; a new uniform warning for all NRT products will require a statement that the “risks” posed by the Products are “not” known.	Ex. A to Joint RJN
3/22/02	United States Amicus Brief filed in Court of Appeal. Addressing each of the key issues in this case, FDA confirms that a Proposition 65 warning message would conflict with FDA’s requirements and health objectives and would render the Products misbranded.	