

CERTIFIED FOR PUBLICATION
IN THE COURT OF APPEAL OF THE STATE OF CALIFORNIA
FIRST APPELLATE DISTRICT
DIVISION FIVE

PAUL A. DOWHAL,

Plaintiff and Appellant,

A094460

v.

**(San Francisco Super.
Ct. No. 305893)**

**SMITHKLINE BEECHAM CONSUMER
HEALTHCARE, etc., et al.,**

Defendants and Respondents.

Appellant filed an action challenging the failure of respondents to place health warnings mandated by California’s Proposition 65 on their nicotine delivery products, marketed over-the-counter as aids to stop smoking. The trial court granted summary judgment to respondents ruling that certain aspects of Proposition 65 are impliedly preempted by the Federal Food, Drug, and Cosmetic Act (FDCA) (21 U.S.C. § 301 et seq.). Because the FDCA contains a provision that expressly exempts Proposition 65 from federal preemption, we will reverse the trial court’s judgment.

I. FACTUAL AND PROCEDURAL BACKGROUND

Respondents in this action manufacture, market, and distribute over-the-counter products, such as gum and patches, that are designed to help people quit smoking through nicotine replacement therapy (the products).¹

¹ Respondents are GlaxoSmithKline Consumer Healthcare, LP, which markets Nicorette and NicoDerm CQ; McNeil Consumer Products Company and Pharmacia & Upjohn, Inc., which have marketed Nicotrol; Aventis Pharmaceuticals Inc., which is

Originally, the products were available only by prescription. However in 1993, respondents sought Federal Food and Drug Administration (FDA) approval to sell them over the counter.

One aspect of the approval process involved labeling. The FDCA includes strict labeling rules, stating that a product is deemed to be misbranded if “its labeling is false or misleading in any particular” (21 U.S.C. § 352, subd. (a).) Respondents’ application presented a complex labeling issue because the products contain nicotine, a substance recognized by the State of California to cause reproductive toxicity. (See 22 Cal. Code Regs., tit. 22, (Regs.) § 12000, subd. (c).) On the other hand, FDA officials recognized that the purpose of the products is to help individuals stop smoking, a public health goal that should not be frustrated by overwarning. As the chairman of the FDA’s nonprescription drugs advisory committee stated, “[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 underusing. . . . [¶] 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 [¶] 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.”

Partly in an effort to balance these competing concerns, the products underwent an unusually long approval process. At the conclusion of that process, the FDA approved the products for sale subject to specific labeling requirements. In each instance, the FDA mandated that the products carry the following pregnancy warning: “Nicotine can increase your baby’s heart rate; . . . if you are pregnant or nursing a baby, seek the advice

involved in the packaging of NicoDerm CQ; Alza Corporation, which manufactures NicoDerm CQ, and Costco Wholesale Corporation, Lucky Stores, Inc., Rite Aid Corporation, Safeway, Inc., and Walgreen Co., which retail Nicorette, NicoDerm CQ and/or Nicotrol.

of a health professional before using this product.”² In the course of processing supplemental new drug applications in the years that followed, the FDA told respondents they “must use,” “should . . . use,” or to “please use,” the FDA approved pregnancy warning, and that “[m]arketing the product with [labeling] that is not identical to the approved labeling text . . . may render the product misbranded and an unapproved new drug.”

Proposition 65 was approved by the voters of this state as an initiative on November 4, 1986. As is relevant here, it added section 25249.6 to the Health and Safety Code which states, “No person in the course of doing business shall knowingly and intentionally expose any individual to a chemical known to the state to cause . . . reproductive toxicity without first giving clear and reasonable warning to such individual” The regulations adopted to implement Proposition 65 state that the required warning “must clearly communicate that the chemical in question is known to the state to cause . . . birth defects or other reproductive harm.” (Regs., § 12601, subd. (a).) The regulations also describe optional safe harbor warnings that are deemed to be clear and reasonable. (Regs., § 12601, subd. (b).) One of those warning states as follows, “WARNING: This product contains a chemical known to the State of California to cause birth defects or other reproductive harm.” (Regs., § 12601, subd. (b)(4)(B).) Finally, the regulations state that the warning may be accomplished in several ways including product labeling, store signs, and public advertising. (Regs., § 12601, subds. (b)(1)(A) through (b)(1)(C).)

In January 1997, respondent McNeil asked the FDA for permission to change the label for its product Nicotrol, to add the Proposition 65 safe harbor warning that we have quoted. The FDA denied the request telling McNeil it “[m]ust use the labeling that was approved at the time of . . . approval.”

² The warnings for the various products differ in some minor respects. No party to this appeal contends the differences are relevant for purposes of this appeal.

Later that same year, the United States Congress enacted the Food and Drug Administration Modernization Act of 1997 (Modernization Act of 1997). (See 111 Stat. 2296.) The Modernization Act of 1997 added a new section to the FDCA, 21 United States Code section 379r. Subdivision (a) of section 379r states, in part, “[N]o State or political subdivision of a State may establish or continue in effect any requirement—[¶] . . . (2) that is different from or in addition to, or that is otherwise not identical with, a requirement under this Act” Section 379r also includes a narrowly focused saving clause which states, “This section shall not apply to a State requirement adopted by a State public initiative or referendum enacted prior to September 1, 1997.” (21 U.S.C. § 379r, subd. (d)(2).)

In August 1999, appellant, acting on behalf of the public, filed the complaint that is at issue in the present appeal. The complaint names respondents as defendants and contains two causes of action. First, appellant alleged respondents violated Health and Safety Code section 25249.6 because they placed products that contained nicotine into the “stream of commerce” without providing an adequate pregnancy warning as is required by Proposition 65. Second, appellant alleged those same acts (failing to provide an adequate Proposition 65 pregnancy warning) constituted an unfair business practice within the meaning of Business and Professions Code section 17200 et seq. Appellant asked the court to issue an injunction precluding respondents from offering their products for sale in California without providing an adequate Proposition 65 warning.

In November 1999, while the complaint was pending, the FDA granted permission to Novartis Consumer Health Care, Inc., (Novartis) to sell a smoking cessation product called Habitrol. Although Habitrol contains nicotine and is similar in active ingredients, indication for use, and method of administration to the products at issue in this case, Habitrol carried a different FDA approved pregnancy warning. The Habitrol warning stated as follows, “Nicotine, whether from smoking or medication, can harm your baby.” Novartis is not a party to this litigation.

When respondent SmithKline learned about the Habitrol pregnancy warning, it asked the FDA about its own warning. The FDA responded that it was “reviewing its

position as it relates to the warnings of nicotine products concerning pregnancy and breast feeding.”

In May 2000, respondents SmithKline and McNeil each wrote to the FDA, again pointing out that Habitrol carried a different pregnancy warning. Respondents also noted they were being sued by appellant who was alleging their warning was inadequate. In June 2000, the FDA responded to SmithKline that although it was reviewing its position on the pregnancy warning, SmithKline should continue to “use the current warning.”

On July 11, 2000, counsel for SmithKline wrote to the FDA seeking confirmation about the pregnancy warning that was required. The FDA responded by letter 10 days later, stating that the products “must” carry the pregnancy warning that had been specified when they were approved.

In March 2001, the FDA sent a letter to SmithKline stating that even though Habitrol carried a different warning, the instructions concerning respondents’ products remained unchanged. “[T]he agency is currently reviewing its position regarding the pregnancy/nursing warning on [over the counter] nicotine replacement products. [¶] . . . As we have stated previously, until the agency’s review is complete, all sponsors of [over the counter] nicotine replacement products should continue to use the pregnancy/nursing warning that was approved by the agency as part of their [new drug approval]. *Any additional or modified warning may render the product misbranded.*” (Italics added.)

While respondents were working with the FDA in an effort to clarify their obligation to warn, appellant filed a motion for summary adjudication. As is relevant here, appellant asked the court to rule that respondents were required under Proposition 65 to provide a pregnancy warning. Respondents opposed the motion and filed a cross-motion for summary judgment. They argued, in essence, that any obligation to warn, which they may have had under Proposition 65, was preempted by federal law.

The trial court denied appellant’s motion for summary adjudication and granted respondents’ motion for summary judgment, ruling that appellant’s Proposition 65 claims were impliedly preempted by the FDCA. The court explained its decision as follows, “Defendants have been expressly forbidden by the federal government from using the

pregnancy warnings on their products that Plaintiff contends are required by state law. [¶] Where, as here, a federal agency requires one thing in accordance with its statutory authority, and a state statute requires another, and where both requirements cannot be satisfied simultaneously, conflict preemption exists and the state requirement must yield.” In addition, the court ruled that any obligation to provide nonlabel warnings was impliedly preempted because “[r]equiring Defendants in advertising to use the same warning that FDA has expressly prohibited them from placing on their labels . . . would frustrate the purpose of the FDCA”

After the court entered judgment in favor of respondents, appellant filed the present appeal.

By letter dated August 17, 2001, while this appeal was pending, the FDA responded to a citizen’s petition appellant had filed with the agency on August 2, 2000.³ The FDA said it was “grant[ing] [appellant’s] request for a consistent pregnancy warning for all [over the counter nicotine replacement therapy] drug products that clearly and reasonably communicates all of the known harm and conveys the relative reproductive harm of smoking, use of [nicotine replacement therapy] drug products, and total abstinence from nicotine.” The FDA proposed that all nicotine replacement products, including the products at issue and Habitrol, bear the following uniform pregnancy warning: “If you are pregnant or breast-feeding, only use this medicine on the advice of your health care provider. Smoking can seriously harm your child. Try to stop smoking without using any nicotine replacement medicine. This medicine is believed to be safer than smoking. However, the risks to your child from this medicine are not fully known.” The agency denied appellant’s request that it require a warning similar to the “harm your baby” warning on Habitrol.

³ On October 4, 2001, appellant and respondents filed a joint request asking this court to take judicial notice of the August 17, 2001 letter. An appellate court can, but is not required to, take judicial notice of documents that were not presented to the trial court in the first instance. (See, e.g., *Brosterhous v. State Bar* (1995) 12 Cal.4th 315, 325.) We will exercise our discretion and grant the request in this instance in order to provide context and background for our discussion.

II. DISCUSSION⁴

Appellant contends the trial court erred when it ruled that respondents' obligation to warn under Proposition 65 was impliedly preempted by the FDCA.

The supremacy clause of Article VI of the United States Constitution grants to the Congress the power to preempt state law.⁵ It is axiomatic then that state law that conflicts with a federal statute is “without effect.” (*Cipollone v. Liggett Group, Inc.* (1992) 505 U.S. 504, 516 (*Cipollone*), quoting *Maryland v. Louisiana* (1981) 451 U.S. 725, 746.) It is equally well established that “[c]onsideration of issues arising under the Supremacy Clause ‘start[s] with the assumption that the historic police powers of the States [are] not to be superseded by . . . Federal Act unless that [is] the clear and manifest purpose of Congress.’” (*Cipollone*, at p. 516.) “Accordingly, “[t]he purpose of Congress is the ultimate touchstone” of pre-emption analysis.” (*Ibid.*)

⁴ While this appeal was being briefed, the parties filed two additional requests for judicial notice. We deferred ruling on the requests until our decision on the merits of the appeal. (Cf. *People v. Preslie* (1977) 70 Cal.App.3d 486, 493-494.)

Having now considered the requests, we rule as follows:

On July 23, 2001, appellant filed a request asking this court to take judicial notice of three documents that relate to the efforts of Novartis to gain approval of its product Habitrol. Novartis is not a party to this appeal, and Habitrol is not one of the products at issue. The documents were not presented to the trial court in the first instance. We decline to consider them. (See *Brosterhous v. State Bar*, *supra*, 12 Cal.4th at p. 325.)

On December 4, 2001, amicus the People of the State of California filed a request asking this court to judicially notice (1) a letter from the FDA to an attorney concerning a different over-the-counter product, (coal tar shampoo,) (2) a motion for summary judgment filed in a different case by a litigant who is not a party to this appeal, and (3) a letter sent in 1989 to the FDA by the President's Office of Management and Budget. None of the documents were presented to the trial court. None of them are directly relevant to issues on appeal. We decline to consider them. (See *Brosterhous v. State Bar*, *supra*, 12 Cal.4th at p. 325.)

⁵ The United States Constitution, Article VI, clause 2 states, “. . . the laws of the United States . . . shall be 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.”

The United States Supreme Court has explained that federal preemption arises in three circumstances. “First, Congress can define explicitly the extent to which its enactments pre-empt state law. [Citation.] Pre-emption fundamentally is a question of congressional intent, [citation] and when Congress has made its intent known through explicit statutory language, the courts’ task is an easy one. [¶] Second, 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. Such an intent may be inferred from a ‘scheme of federal regulation . . . so pervasive as to make reasonable the inference that Congress left no room for the States to supplement it,’ or where an Act of Congress ‘touch[es] a field in which the federal interest is so dominant that the federal system will be assumed to preclude enforcement of state laws on the same subject.’ [Citation.] Although this Court has not hesitated to draw an inference of field pre-emption where it is supported by the federal statutory and regulatory schemes, it has emphasized: ‘Where . . . the field which Congress is said to have pre-empted’ includes areas that have ‘been traditionally occupied by the States,’ congressional intent to supersede state laws must be ‘clear and manifest.’ [Citations.] [¶] Finally, state law is pre-empted to the extent that it actually conflicts with federal law. Thus, the Court has found pre-emption where it is impossible for a private party to comply with both state and federal requirements, [citation] or where state law ‘stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.’” (*English v. General Electric Co.* (1990) 496 U.S. 72, 78-79, fn. omitted.)

The first category above is described as “express preemption,” while the second and third categories fall under the rubric of “implied preemption.” (*Choate v. Champion Home Builders Co.* (10th Cir. 2000) 222 F.3d 788, 792 (*Choate*).

Here, the trial court ruled respondents’ obligation to warn under Proposition 65 was impliedly preempted under the third category. Noting that respondents were “expressly forbidden by the federal government from using the pregnancy warnings . . . required by state law,” the court concluded the requirements of both the FDA and Proposition 65 “cannot be satisfied simultaneously . . .” In addition, the court ruled that

any obligation to provide nonlabel warnings was impliedly preempted because “[r]equiring [respondents] in advertising to use the same warning that FDA has expressly prohibited them from placing on their labels . . . would frustrate the purpose of the FDCA”

We turn then, to the pivotal issue in this case: whether the trial court ruled correctly when it held that respondents’ obligation to warn under Proposition 65 was impliedly preempted by the FDCA.

To answer this question we focus on what we believe is the controlling statute. The Modernization Act of 1997 had many purposes, one of which was to establish “national uniformity for nonprescription drugs.” (See 111 Stat. 2374.) This goal was accomplished by adding 21 United States Code section 379r to the FDCA, subdivision (a) of which states, in part, “[N]o State or political subdivision of a State may establish or continue in effect any requirement . . . [¶] (2) that is different from or in addition to, or that is otherwise not identical with, a requirement under this Act”

The broad language preempting state laws concerning nonprescription drugs is subject to a narrow exception related to state voter initiatives. 21 United States Code section 379r, subdivision (d)(2) states, “This section shall not apply to a State requirement adopted by a State public initiative or referendum enacted prior to September 1, 1997.”

Proposition 65, by its terms, mandates warnings that are “different from” and “not identical with” those called for under the FDCA, and thus it comes within the scope of 21 United States Code section 379r, subdivision (a). However Proposition 65 was adopted by the voters of this state as a public initiative in November 1986, and therefore it comes within the saving clause set forth in 21 United States Code section 379r, subdivision (d)(2). As far as we can determine, Proposition 65 is the *only* state initiative or referendum covered by this saving clause.

These two subdivisions, read together, clearly articulate Congress’s intent. While state laws governing nonprescription drugs are generally preempted by the FDCA, Proposition 65 is not preempted.

Our reading of 21 United States Code section 379r is confirmed by the legislative history of the statute. Statements made by individual legislators can “provide evidence of Congress’[s] intent” (*Brock v. Pierce County* (1986) 476 U.S. 253, 263), and here, the Congressional Record confirms that Congress intended to exempt Proposition 65 from federal preemption. During the floor debates that led up to the enactment of the statute, Vermont Senator James Jeffords stated, “Now, the States have had authority to move into this area You have to remember they have had this authority forever, I guess, and only one State has taken it upon themselves to really do anything in this area to try and solve the problem [¶] What did we do? *We said, ‘OK, California, fine, we will not get involved with preempting you with respect to your laws that are on the books. We will allow those laws to stand. The FDA can work around that.’*” (Remarks of Sen. Jeffords, 143 Cong. Rec. S8851-01, S8857 (Sept. 5, 1997), italics added.)

During those same debates, California Senator Barbara Boxer stated, “*Finally, I want to thank Senators GREGG and JEFFORDS for working with me to ensure that California’s proposition 65 will not be preempted by the uniformity provisions of this bill.* California’s proposition 65 was passed by California voters in 1986 and requires that persons who expose others to certain levels of carcinogens or reproductive toxins give a clear and reasonable warning. [¶] Proposition 65 has successfully reduced toxic contaminants in a number of consumer products sold in California and it has even led the FDA to adopt more stringent standards from some consumer products. . . . *So I am very pleased that the FDA reform bill now being debated will exempt California’s proposition 65.*” (Remarks of Sen. Boxer, 143 Cong. Rec. S9811-04, S9843 (Sept. 24, 1997), italics added.)

The statements we have quoted reinforce our interpretation of 21 United States Code section 379r. Congress clearly did not intend to preempt Proposition 65 under the FDCA. Since “Congress has made its intent known through explicit statutory language, [our] task is an easy one.” (*English v. General Electric Co., supra*, 496 U.S. at p. 79.) The trial court erred when it ruled Proposition 65 was preempted by the FDCA.

Respondents do not dispute our interpretation of 21 United States Code section 379r. They concede that under the plain language of that statute, Proposition 65 is not expressly preempted by the FDCA.⁶ However, respondents contend the expression of legislative intent set forth in the language of the saving clause avoids *express* preemption only, and has no bearing on implied conflict preemption analysis. According to respondents, *implied* conflict preemption arises from operation of the supremacy clause and turns on the existence of an actual conflict. Here, various actions taken by the FDA prevented them from complying with Proposition 65. Because compliance with both the state Proposition 65 and federal FDA directives are a physical impossibility, Proposition 65 is *impliedly* preempted under the doctrine of implied conflict preemption. This is so despite an explicit statement of Congressional intent to the contrary.

We reject the argument. Respondents have not cited, and we are not aware of, any case that holds a court can ignore Congress’s clearly articulated and directly applicable *express* intent to preempt, (or as here, to “save” a particular state statutory scheme from preemption) based on an analysis of what Congress *impliedly* intended to do. We will not be the first.

Respondents base their argument primarily on language taken from a recent Supreme Court case, *Geier v. American Honda Motor Co.* (2000) 529 U.S. 861 (*Geier*). In *Geier*, the plaintiff was injured when the car she was driving struck a tree. She sued Honda, arguing the car was negligently designed because it lacked a driver’s side air bag. The issue on appeal was whether plaintiff’s common law tort claim was preempted by the National Traffic and Motor Vehicle Safety Act of 1966 (the Act). The court ruled first that the Act’s express preemption clause⁷ did not apply to the plaintiff’s suit. (*Geier*,

⁶ The FDA, which has filed an amicus brief, agrees with this assessment. It concedes 21 United States Code section 379r “exempts Proposition 65 from express preemption”

⁷ The express preemption clause stated, “Whenever a Federal motor vehicle safety standard established under this subchapter is in effect, no State or political subdivision of a State shall have any authority either to establish, or to continue in effect, with respect to any motor vehicle or item of motor vehicle equipment[,] any safety standard applicable to

supra, 529 U.S. at pp. 867-868.) The court was then required to determine whether a saving clause contained in the Act⁸ precluded the application of ordinary implied preemption principles. The court said it did not, explaining, “We . . . conclude that the saving clause . . . does *not* bar the ordinary working of conflict pre-emption principles. [¶] Nothing in the language of the saving clause suggests an intent to save state-law tort actions that conflict with federal regulations. The words ‘[c]ompliance’ and ‘does not exempt,’ . . . sound as if they simply bar a special kind of defense, namely, a defense that compliance with a federal standard automatically exempts a defendant from state law, whether the Federal Government meant that standard to be an absolute requirement or only a minimum one. . . . It is difficult to understand why Congress would have insisted on a compliance-with-federal-regulation precondition to the provision’s applicability had it wished the Act to ‘save’ all state-law tort actions, regardless of their potential threat to the objectives of federal safety standards promulgated under [the] Act.” (*Geier*, at pp. 869-870.)

Respondents interpret this passage as meaning that a saving clause can never preclude the application of implied preemption principles. This interpretation ignores the context of the Supreme Court’s statement. The court in *Geier* ruled that the *particular* saving clause at issue did not preclude the application of implied preemption principles. It did not purport to establish some sort of all encompassing rule. This is made clear by the court’s analysis. The court said an implied preemption analysis was *not* precluded because “[n]othing in the language of the saving clause suggest[ed] an intent to save state-law tort actions that conflict with federal regulations.” (*Geier, supra*, 529 U.S. at p. 869.) Here we are faced with precisely the opposite situation. The saving clause set forth in 21 United States Code section 379r, subdivision (d)(2), not only “suggests” an intent to

the same aspect of performance of such vehicle or item of equipment which is not identical to the Federal Standard. [Citation.]” (*Geier, supra*, 529 U.S. at p. 867.)

⁸ The saving clause at issue in *Geier* stated, “[C]ompliance with’ a federal safety standard ‘does not exempt any person from any liability under common law.’” (*Geier, supra*, 529 U.S. at p. 868.)

save some state law claims, it clearly articulates an express intent to save the precise types of claims that are issue in this case. The portion of *Geier* upon which respondents rely is not controlling.

Next, respondents rely on a passage from *Geier* where the court said that the “pre-emption provision, by itself, does not foreclose (through negative implication) ‘any possibility of implied [conflict] pre-emption’” (*Geier, supra*, 529 U.S. at p. 869.) Respondents cite this language as supporting the conclusion that an implied preemption analysis is required in all cases. However, the Supreme Court’s statement must be read in the context of the case in which it was made. In *Geier*, the court was faced with a preemption clause that *did not apply* to the claim at issue. (*Id.* at pp. 867-868.) Thus, the quote, read in context, simply stands for the proposition that an *inapplicable* preemption clause does not preclude the possibility of implied conflict preemption. (See *Choate, supra*, 222 F.3d at p. 794, fn. 8 [interpreting *Geier* this same way].) Here, we are called upon to determine the effect of a clearly applicable saving clause. The quoted language from *Geier* is inapposite.

Finally, respondents rely on language from *Geier* where the court said that “conflict pre-emption is different in that it turns on the identification of ‘actual conflict,’ and not on an express statement of pre-emptive intent. [Citations.]” (*Geier, supra*, 529 U.S. at p. 884.) We have no quarrel with this language or the legal principle it describes. It simply stands for the proposition that there can be implied preemption even where Congress did not expressly articulate its intent. Here, we are faced with the very different situation where Congress has expressed its intent, clearly and specifically. The language quoted cannot reasonably be read to support the conclusion that courts may ignore Congress’s clearly articulated intent by applying an implied intent analysis.

In sum, based on our analysis of 21 United States Code section 379r, we conclude the FDCA does not preempt Proposition 65. “Just as courts may not find state measures pre-empted in the absence of clear evidence that Congress so intended, so must they give full effect to evidence that Congress considered, and sought to preserve, the States’

coordinate regulatory role in our federal scheme.” (*California v. FERC* (1990) 495 U.S. 490, 497.)

Our concurring colleague believes that Congress’s express intention to save Proposition 65 from preemption is essentially irrelevant. According to the concurrence, “[s]imply because Congress insulated Proposition 65 from the express preemption clause does not mean that conflict preemption does not apply.” (Conc. opn., p. 5.) We respectfully disagree.

The concurrence bases its argument on language contained in several recent cases that apply federal conflict preemption. (See *Buckman Co. v. Plaintiffs’ Legal Comm.* (2001) 531 U.S. 341 (*Buckman*); *Medtronic, Inc. v. Lohr* (1996) 518 U.S. 470 (*Medtronic*); and *Freightliner Corp. v. Myrick* (1995) 514 U.S. 280 (*Freightliner*)). However, none of those cases dealt with preemption in a factual context similar to that presented here. Rather, the issue in each case was the scope of federal preemption where express preemption *did not* apply. Specifically, the court in *Buckman* declined to determine whether the express preemption clause at issue was applicable. (*Buckman*, at p. 348, fn. 2.) The same is true of *Medtronic*; the court declined to determine whether an express preemption clause applied. (*Medtronic*, at p. 503.) In *Freightliner*, the court ruled the express preemption clause at issue was inapplicable. (*Freightliner*, at p. 286.) In our view, language contained in those cases is not controlling here. Unlike the courts in *Buckman*, *Medtronic*, and *Freightliner*, we are called upon to determine the effect of a directly applicable saving clause that clearly expresses Congress’s intent.

Similarly, the concurrence relies on language contained in *Nathan Kimmel, Inc. v. Dowelanco* (9th Cir. 2002) 275 F.3d 1199 (*Kimmel*) and *Choate, supra*, 222 F.3d 788. (Conc. opn., p. 2.) But once again, the court in *Kimmel* declined to determine whether the express preemption clause at issue applied, while the *Choate* court found the express preemption clause to be inapplicable. (*Kimmel*, at p. 1204; *Choate*, at p. 794.) Those cases are not persuasive where, as here, we are faced with a clearly and directly applicable saving clause.

The concurrence also suggests it would be anomalous for Congress to enact a federal law that would allow state law conflicts to exist. (Conc. opn., p. 3.) The concurrence relies on language from *Geier* where the court stated, “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.)

Considered in context, we see no reason to read the language quoted as anything more than a comment on the specific safety standard at issue in *Geier*. Moreover, we think it is apparent why Congress would allow Proposition 65 to conflict with otherwise applicable Federal law. Congress was not writing on a blank slate when it decided to impose nationwide labeling uniformity for nonprescription drugs as part of the Modernization Act of 1997. At that point, Proposition 65 had been in effect for many years, and it had proven to be highly effective. As Senator Boxer explained, Proposition 65 had “successfully reduced toxic contaminants in a number of consumer products sold in California and it [had] even led the FDA to adopt more stringent standards [for] some consumer products. . . .” (Remarks of Sen. Boxer, 143 Cong. Rec. S9811-04, S9843, Sept. 24, 1997.) We do not find it unusual that Congress would allow a longstanding and highly effective state law to remain in effect even though it might conflict with otherwise applicable federal law.

Finally, we must comment upon respondents’ argument that if at any relevant time they failed to comply with the FDA’s repeated directives to use only FDA mandated warnings, they faced sanctions for misbranding. Respondents urge that the FDA’s position has consistently made it impossible to comply with both Proposition 65 and the FDCA, and suggest it would be unfair to hold them liable under such circumstances. We need not resolve this controversy. We do observe, nevertheless, that respondents’ attempts to comply with their state obligations under Proposition 65 have been hindered by a federal bureaucracy that, at least since the enactment of the Modernization Act of 1997, was either unwilling or unable to recognize the limited scope of its authority. It

also appears that respondents were further hindered by the FDA’s admitted failure to issue “definitive advice” about what it deemed to be an appropriate warning label until its August 17, 2001 letter in response to appellant’s citizen’s petition. We must leave for another day the issue of whether respondents’ efforts to satisfy the FDA limit or preclude their liability⁹ under Proposition 65.¹⁰

III. DISPOSITION

The judgment is reversed. Costs to appellant.

Jones, P.J.

I concur:

Stevens, J.

⁹ We note that a court imposing a penalty for violating Proposition 65 must evaluate several factors including, “[t]he nature and extent of the violation,” “[w]hether the violator took good faith measures to comply with [Proposition 65],” “[t]he willfulness of the violator’s misconduct,” and “[a]ny other factor that justice may require.” (Health & Saf. Code, § 25249.7, subs. (A), (D), (E), & (G).)

¹⁰ Having reached this conclusion, we need not address the other arguments that have been advanced.

SIMONS, J., Concurring. —

I agree that the judgment must be reversed. However, I respectfully disagree with my colleagues' constitutional analysis. I cannot accept the majority's decision that Congress has excepted the requirements imposed by Proposition 65¹ not only from the express preemption clause but also from the operation of conflict preemption. I would find that Congress did no more in section 412 of the Food and Drug Administration Modernization Act of 1997 (Modernization Act of 1997) (21 U.S.C. § 379r) than save Proposition 65 from the uniformity provisions, while leaving intact the ban on actual conflicts between state and federal law. I would nevertheless reverse the judgment on the ground that no actual conflict has been demonstrated here.

I. PREEMPTION

The relatively clear language of the supremacy clause (U.S. Const., art. VI, cl. 2) has generated a considerable jurisprudence on the question of federal preemption of state law. The United States Supreme Court has noted three different categories of preemption. "State action may be foreclosed by express language in a congressional enactment [citation], by implication from the depth and breadth of a congressional scheme that occupies the legislative field [citation], or by implication because of a conflict with a congressional enactment [citation]." (*Lorillard Tobacco Co. v. Reilly* (2001) 533 U.S. 525, 541.) In the last decade, the high court has struggled with the relationship between express and conflict preemption. That is, to the extent that a federal statute expressly addresses the scope of preemption, is there any place for an implied conflict preemption rule? Since the high court's most recent pronouncements on this subject clearly answer this question in the affirmative, I believe the majority's analysis of the manufacturers' conflict preemption argument is flawed.

¹ In 1986, the California voters adopted the Safe Drinking Water and Toxic Enforcement Act of 1986, also known as Proposition 65. (Health & Saf. Code, § 25249.5 et seq.)

In *Cipollone v. Liggett Group, Inc.* (1992) 505 U.S. 504, 517, the high court seemed to hold that an express preemption provision precludes the existence of implied preemption: “Congress’ enactment of a provision defining the pre-emptive reach of a statute implies that matters beyond that reach are not pre-empted.” In *Freightliner Corp. v. Myrick* (1995) 514 U.S. 280, 288, however, the court clarified its holding in *Cipollone* and held that an express preemption provision, by itself, does not foreclose, through negative implication, any possibility of implied conflict preemption. (Accord, *Geier v. American Honda Motor Co., Inc.* (2000) 529 U.S. 861, 869 (*Geier*).) This conclusion was underscored in *Medtronic, Inc. v. Lohr* (1996) 518 U.S. 470, 503, in which the high court recognized that a state statute left untouched by an express preemption clause might still be preempted under conflict preemption analysis. (See *Nathan Kimmel, Inc. v. Dowelanco* (9th Cir. 2002) 275 F.3d 1199, 1204 [“We need not determine the exact length of the preemptive shadow cast by the express language of [the statute], however, because ordinary conflict preemption principles dictate that [the plaintiff’s] state law claim is *impliedly* preempted by [the Federal Insecticide, Fungicide, and Rodenticide Act].”]; Scordato, *Federal Preemption of State Tort Claims* (2001) 35 U.C. Davis L.Rev. 1, 17-18.)

Under the preemption doctrine, a “saving” clause is a statutory provision that restricts the ambit of federal preemption. In recent years, the high court has considered the relationship between such clauses and conflict preemption and has concluded that the existence of a saving clause does not preclude “the ordinary working of conflict pre-emption principles.” (*Geier, supra*, 529 U.S. at p. 869.) In sum, in determining whether a state law is preempted by a federal provision, the current view of the United States Supreme Court is that the state law is subject to an implied conflict analysis, even if the applicable federal law contains express preemption and saving clauses. (*Buckman Co. v. Plaintiffs’ Legal Comm.* (2001) 531 U.S. 341, 352; *Geier, supra*, 529 U.S. at p. 869; see also *Nathan Kimmel, Inc. v. Dowelanco, supra*, 275 F.3d at p. 1204; *Choate v. Champion Home Builders Co.* (10 Cir. 2000) 222 F.3d 788, 794.)

The high court has acknowledged the possibility that Congress *could* insert a saving clause that eliminates conflict as well as express preemption. (*Geier, supra*, 529 U.S. at p. 872.) It is no exaggeration to say, however, that the court conveyed substantial skepticism about Congress’s interest in ever doing so: “Why, in any event, 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 [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 pre-emption principles, seeks to protect.” (*Geier*, at pp. 871-872.) “[O]ne can assume that Congress or an agency ordinarily would not intend to permit a significant conflict.” (*Id.* at p. 885.) Neither the dissenting nor the majority opinion in *Geier* cited any case in which a saving clause was so construed. Similarly, neither the parties to this appeal nor my colleagues in their majority opinion have found any such case.² The United States Supreme Court, in fact, has consistently refused to interpret a saving clause broadly when to do so would permit a state enactment

² At oral argument, appellant cited *Louisiana Public Service Comm’n v. FCC* (1986) 476 U.S. 355 as a case in which the high court found that Congress had waived conflict preemption. That case, however, dealt with very different issues than our case. In *Louisiana Public Service*, the high court faced the contention that certain orders by the Federal Communications Commission (FCC) relating to the depreciation of telephone plant and equipment preempted inconsistent state regulation. In the Communications Act of 1934, Congress granted regulatory authority to the FCC over “ ‘interstate and foreign commerce in wire and radio communication,’ [citation], while expressly denying [the FCC] ‘jurisdiction with respect to . . . intrastate communication service,’ [citation],” which was left to the states. (*Louisiana Public Service*, at p. 360.) The high court defined its task as “simply to determine where Congress *has* placed the responsibility for prescribing depreciation methods to be used by state commissions in setting rates for intrastate telephone service.” (*Id.* at p. 359.) *Louisiana Public Service* was, then, simply a statutory construction case, where Congress had created dual regulation of the telephone industry. The Communications Act of 1934 had no relevant express preemption clause or saving clause, and there was no dispute that if the FCC had jurisdiction to establish the relevant depreciation methods, the challenged state methods were in conflict and would have been preempted.

to conflict with a carefully devised regulatory scheme. (*Geier*, at pp. 873-874; *United States v. Locke* (2000) 529 U.S. 89, 106-107; *American Telephone & Telegraph Co. v. Central Office Telephone, Inc.* (1998) 524 U.S. 214, 227-228; *International Paper Co. v. Ouellette* (1987) 479 U.S. 481, 493-494; see also *Wyoming v. U.S.* (10th Cir. 2002) 279 F.3d 1214, 1234-1235 [saving clause within the National Wildlife Refuge System Improvement Act did not permit state regulation which conflicted with its purpose].)

With that framework in mind, I turn now to the federal law at issue. The Food, Drug and Cosmetic Act (FDCA) was enacted to protect the public from deleterious, adulterated and misbranded items, including over-the-counter drugs. (*United States v. Walsh* (1947) 331 U.S. 432, 434; 21 U.S.C. § 331(b).) To protect consumers from dangerous products, the FDCA requires, among other things, that drugs and devices be labeled with warnings of the risks to the user's health. (21 U.S.C. § 352(f); see generally *United States v. Sullivan* (1948) 332 U.S. 689, 696-697 [sulfathiazole tablets]; *Papike v. Tambrands, Inc.* (9th Cir. 1997) 107 F.3d 737, 739 [tampons].) Moreover, the FDCA prohibits labels on drugs and devices that are "false or misleading." (21 U.S.C. § 352(a).)

Prior to the Modernization Act of 1997, the FDCA contained no express preemption clause. States were free to require labels different from those mandated by the Food and Drug Administration so long as those warnings did not actually conflict with federal requirements. (*Savage v. Jones* (1912) 225 U.S. 501, 529-539 [state labeling requirement held nonconflicting and valid]; cf. *McDermott v. Wisconsin* (1913) 228 U.S. 115, 131-137 [state labeling requirement in conflict with federal standards held invalid].) There is no dispute that, with the enactment of the Modernization Act of 1997, Congress expressly intended to establish national uniformity for labeling of nonprescription drugs and to preempt state law with respect to labeling: "[N]o State . . . may establish or continue in effect any requirement— [¶] . . . [¶] (2) that is different from or in addition to, or that is otherwise not identical with, a requirement under [the FDCA]." (21 U.S.C. § 379r(a)(2).) The dispute in this case concerns not Congress's intent to preempt state law but its intent to *save* Proposition 65 from this preemption.

Congress carved out of the express preemption clause an exception for certain state initiatives: “*Except as provided in subsection . . . (d),*” no state may impose requirements that differ from, add to, or are not identical to federal requirements. (21 U.S.C. § 379r(a), italics added.) Section 379r(d), in turn, provides: “This section shall not apply to a State requirement adopted by a State public initiative or referendum enacted prior to September 1, 1997.” Proposition 65 comes within this exception and is apparently the only state initiative to qualify.³ There is no doubt that this saving clause permits California, when acting pursuant to Proposition 65, to require label warnings that differ from, add to, or are otherwise not identical to the label requirements imposed under the FDCA. I cannot accept, however, the majority’s conclusion that this saving clause further permits California to impose labeling requirements that actually conflict with federal requirements.

My colleagues conclude that because it is clear that Congress enacted an express preemption clause (creating uniformity) and then expressly saved Proposition 65 from the uniformity requirements, it is inappropriate to search for an implied legislative intent to retain actual conflict preemption. They say: “Respondents have not cited, and we are not aware of, any case that holds a court can ignore Congress’s clearly articulated and directly applicable *express* intent to preempt, (or as here, to ‘save’ a particular state statutory scheme from preemption) based on an analysis of what Congress *impliedly* intended to do. We will not be the first.” (Maj. opn., *ante*, at p. 11.)

This analysis seems to ignore the post-*Cipollone* decisions discussed above. Simply because Congress insulated Proposition 65 from the express preemption clause does not mean that conflict preemption does not apply. Of course, under *Geier*, Congress could express an intent to reverse the normal operation of the supremacy clause and permit conflicting state law to reign supreme, a prospect the high court viewed as

³ Other states may apply for an exemption from uniform labeling, but such an exemption is conditioned on the absence of an actual conflict with federal law. (21 U.S.C. § 379r(b)(1)(B).)

unlikely. But the majority does not rely on any textual analysis of either the preemption or the saving clause (21 U.S.C. § 379r) to indicate such a congressional intent.

Certainly nothing in the saving clause warrants a conclusion that Congress wished to bypass the conflict preemption doctrine. In my view, the scope of the saving clause coincides with the scope of the preemption clause. That is, the express preemption clause imposes “national uniformity for nonprescription drugs” (21 U.S.C. § 379r; Pub.L. No. 105-115 (Nov. 21, 1997) 111 Stat. 2296, § 412), and the saving clause creates an exception for California, acting through Proposition 65. As a matter of logic, the saving clause for Proposition 65 does nothing more than serve as a shield, protecting Proposition 65 from the effects of the uniformity provisions of the Modernization Act of 1997. The majority points to no language in the two clauses, and I find none, that permits California to act so as to frustrate any statutory purpose other than uniformity. (See *United States v. Locke, supra*, 529 U.S. at p. 106.) In my view, Proposition 65 remains limited by the doctrine of conflict preemption and may not interfere with the congressional purpose expressed in the FDCA of protecting the consumer from dangerous or misbranded products.

This interpretation of the saving clause does not render it ineffectual. To the contrary, unlike any other state, California (when acting pursuant to Proposition 65) is entitled to adopt warnings different from as well as additional to those required by federal law. Unlike other states, the only limitation California faces is that these warnings may not actually conflict with the FDCA. Proposition 65 is saved by being left precisely where it was before the uniform labeling law of the Modernization Act of 1997 took effect, allowed to impose different, but not conflicting requirements.

My colleagues rely on the comments of Senators Boxer and Jeffords to support their interpretation. Without quarreling with the propriety of relying on such statements, I believe these particular remarks provide little support to their construction. In the portion of Senator Boxer’s remarks emphasized by the majority, she is quoted as thanking other Senators “*for working with me to ensure that California’s proposition 65 will not be preempted by the uniformity provisions of this bill*” and “*So I am very pleased*

that the FDA reform bill now being debated will exempt California's proposition 65." (Remarks of Sen. Boxer, 143 Cong.Rec. S9811-04, S9843 (Sept. 24, 1997); maj. opn., *ante*, p. 10.) These remarks do not suggest that Senator Boxer believed she had not only managed to fend off the uniformity requirements but had *also succeeded* in eliminating the narrow conflict preemption limitation the initiative had always faced. In fact, in remarks between the ones quoted by my colleagues, Senator Boxer lauds the accomplishments of the proposition: "Proposition 65 has successfully reduced toxic contaminants in a number of consumer products sold in California and it has even led the FDA to adopt more stringent standards for some consumer products." (Remarks of Sen. Boxer, at p. S9843.) These hardly sound like the words of someone who thought it was necessary to change the legal landscape under which the proposition had been functioning.

The remarks of Senator Jeffords must be considered in context. He and Senator Kennedy apparently disagreed about the uniformity provisions relating to the labeling or packaging of *cosmetics*. On September 5, 1997, when the quoted remarks were made (see maj. opn., *ante*, p. 10), this provision as it was then worded,⁴ concerned Senator Kennedy because it precluded states from enacting legislation to protect their citizens. He described California as being "grandfathered in" (that is protected from the *upcoming* regulatory change) and sought a similar status for Massachusetts and other states. (Remarks of Sen. Kennedy, 143 Cong.Rec. S8851-01, S8860 (Sept. 5, 1997).) Though they preceded the comments of Senator Kennedy, the remarks of Senator Jeffords seem responsive to that concern: i.e., only California had acted in the past to deal with cosmetics and therefore it had received special protection from *future* preemption. (Remarks of Sen. Jeffords, 143 Cong.Rec. S8851-01, S8857 (Sept. 5, 1997).) Senator

⁴ This provision was apparently redrafted before the senate proceedings on September 24, 1997, to permit states to enact legislation unless the FDA had already acted in that specific area. This "compromise" was satisfactory to Senator Kennedy. (Remarks of Sen. Kennedy, 143 Cong.Rec. S9811-04, *supra*, at p. 9818.)

Jeffords, like Senator Boxer, never alluded to changing the ground rules Proposition 65 faced before the Modernization Act of 1997.

II. PROPOSITION 65 IS NOT PREEMPTED

Having concluded that the doctrine of conflict preemption applies despite the existence of the saving clause, I now turn to the determinative question whether Proposition 65 actually conflicts with federal law. The long-established rule is that an actual conflict between state and federal law will be found either where it is impossible for a private party to comply with both state and federal standards or where under the circumstances of a particular case the challenged state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress. (*Crosby v. National Foreign Trade Council* (2000) 530 U.S. 363, 372-373.) As I see it, the principal question requiring analysis here is the latter—whether federal purposes would be thwarted by requiring Proposition 65 compliant language on either packaging labels or point of sale signs.⁵

⁵ The doctrine of conflict preemption is also triggered when compliance with both state and federal law is impossible because one requires what the other prohibits. (*Florida Avocado Growers v. Paul* (1963) 373 U.S. 132, 142-143.) Here, the trial court concluded that such a conflict existed in this case, resting its conclusion on the difference between plaintiff’s proposed warnings and the federal requirements. I disagree with that conclusion. The FDCA and its implementing regulations require particular warning labels on the package for over-the-counter products. (21 U.S.C. § 352(f); 21 C.F.R. §§ 201.60, 201.66 (2001).) Even if one were to conclude that Proposition 65 requires a warning that contradicts the federal requirements (a conclusion I do not draw), the state law does not mandate that the warning appear on the package label. Proposition 65 requires “clear and reasonable warning” of chemicals known to cause cancer or reproductive toxicity. (Health & Saf. Code, § 25249.6.) A “[w]arning” . . . need not be provided separately to each exposed individual and may be provided by general methods such as labels on consumer products, inclusion of notices in mailings to water customers, posting of notices, placing notices in public news media, and the like . . .” (Health & Saf. Code, § 25249.11, subd. (f).) The “safe harbor” regulations provide that the warning may be placed either on the product label *or* on a sign posted at the retail outlet in a visible place specifying the products containing chemicals that are known to the state to cause cancer, birth defects, or reproductive harm. (Cal. Code. Regs., tit. 22, § 12601, subds. (b)(1)(A), (b)(1)(B), (b)(3).) Thus, Proposition 65 can be complied with by using point of sale signs. (*Chemical Specialties Mfrs. Ass’n, Inc. v. Allenby* (9th Cir. 1992) 958

What constitutes a sufficient obstacle to the fulfillment of Congress's objectives so as to create a conflict is "a matter of judgment, to be informed by examining the federal statute as a whole and identifying its purpose and intended effects." (*Crosby v. National Foreign Trade Council*, *supra*, 530 U.S. at p. 373.) Consideration must also be given to whether state law is an obstacle to the goals expressed in the administrative regulations issued by the agency charged with implementing the federal statute. (*Geier*, *supra*, 529 U.S. at pp. 874-886 [state tort lawsuit held preempted by vehicle safety regulation issued by the federal Department of Transportation].) In my judgment, Proposition 65 poses no obstacle to the purposes and intended effects of the FDCA or its implementing regulations. *Geier* instructs that "a court should not find pre-emption too readily in the absence of clear evidence of a conflict." (*Geier*, at p. 885.) I find no such evidence here.

As already indicated, a principal purpose of the FDCA is to protect consumers from dangerous products by requiring warnings of the risks to the user's health. (21 U.S.C. § 352(f).) Proposition 65 has the same objective, to give adequate warning to consumers. (Health & Saf. Code, § 25249.6.) Compliance with Proposition 65 would not frustrate the full-notice objective of the FDCA. (Cf. *Chemical Specialties Mfrs. Ass'n, Inc. v. Allenby*, *supra*, 958 F.2d at p. 950 [no conflict between Proposition 65 and Federal Hazardous Substances Act].)

Of course, the newly-added congressional purpose of establishing national uniformity in the labeling of nonprescription drugs (21 U.S.C. § 379r) would be thwarted by state-imposed warnings that are different from the warnings required by the FDCA. But Congress has excepted Proposition 65 from the uniform labeling requirement. (21 U.S.C. § 379r(a), (d)(2).) By expressly allowing California, through Proposition 65, to require labeling that differs from or adds to the labeling required by the FDCA, Congress has nullified any argument that its goal of uniformity would be thwarted by enforcement

F.2d 941, 947, 949-950 [fungicides and insecticides]; *People ex rel. Lungren v. Cotter & Co.* (1997) 53 Cal.App.4th 1373, 1393-1396 [paint].) And these "signs do not constitute labeling." (*Chemical Specialties Mfrs. Ass'n*, at p. 947.) Complying with both Proposition 65 and the federal requirements is not physically impossible.

of Proposition 65. Past assertions by the Food and Drug Administration (FDA) notwithstanding, the mere fact that a proposed warning differs from or adds to the its mandated warning cannot render the product “misbranded.”

Another purpose of the FDCA is to protect consumers by ensuring that the labels on drugs and devices are not “false or misleading.” (21 U.S.C. § 352(a).) To that end, the FDA regulations require that labeling on over-the-counter drugs be “clear and truthful in all respects.” (21 C.F.R. § 330.10(a)(4)(v) (2001).) Labeling must include warnings expressed “in such terms as to render them likely to be read and understood by the ordinary individual, including individuals of low comprehension, under customary conditions of purchase and use.” (*Ibid.*) There is nothing in Proposition 65 inconsistent with that federal objective. Proposition 65 requires a “clear and reasonable” message when a product contains a chemical known to cause cancer or birth defects or reproductive harm. (Health & Saf. Code, § 25249.6.) Under state regulations implementing Proposition 65, for consumer products that contain a chemical known to the state to cause reproductive toxicity, a warning in the following language is deemed clear and reasonable: “WARNING: This product contains a chemical known to the State of California to cause birth defects or other reproductive harm.” (Cal. Code Regs., tit. 22, § 12601, subd. (b)(4)(B).) The state regulations require that the message be displayed so that it “is likely to be read and understood by an ordinary individual under customary conditions of purchase or use.” (Cal. Code Regs., tit. 22, § 12601, subd. (b)(3).)

In a lawsuit filed under Proposition 65, a plaintiff is not required to persuade the court that a particularly worded warning is appropriate.⁶ Rather, a plaintiff’s burden is to demonstrate that a defendant’s warning fails to comply with that law’s requirements. For this reason, respondents’ preemption defense can succeed only if all possible consumer product warnings that would satisfy Proposition 65 actually conflict with the federal standards. (*Comm. of Dental Amalgam Mfrs. & Distribs. v. Stratton* (9th Cir. 1996) 92

⁶ In fact, in the complaint filed by appellant in this case, he suggests no specific warning requirement. In a contemporaneously filed motion for a preliminary injunction, however, he did propose one.

F.3d 807, 810; *Chemical Specialties Mfrs. Ass'n, Inc. v. Allenby*, *supra*, 958 F.2d at p. 943; *People ex rel. Lungren v. Cotter & Co.*, *supra*, 53 Cal.App.4th at p. 1393.) The state regulations implementing Proposition 65 provide that warnings other than the safe harbor warnings are not precluded as long as the message clearly conveys that the chemical in question is known to cause cancer or birth defects or reproductive harm. (Cal. Code Regs., tit. 22, § 12601, subd. (a).)

The respondents argue, however, that the warning prescribed by the FDA for nicotine replacement therapy (NRT) products establishes a ceiling as well as a floor and that the FDA has prohibited any Proposition 65 warning. This argument is premised on the notion that all possible Proposition 65 warnings would interfere with the FDA's stated policy against overwarning consumers about the risks inherent in NRT products, because this overwarning would discourage consumers from trying to stop smoking.

Respondents have not presented any formal FDA regulation on overwarning. Respondents point to a variety of less formal sources, which, they contend, establish its determination that Proposition 65 warnings constitute overwarning: (1) numerous letters exchanged between the FDA and the respondents, from 1996 through 2001, in which it rejected requests to permit the addition of certain supplemental warnings on NRT products; (2) a letter from the FDA to the California Attorney General, dated June 5, 1998, in which it rejected a request to compel the respondents to add the Proposition 65 safe harbor warning to their products; and (3) the August 17, 2001 FDA response to appellant's citizen petition (the Response), denying appellant's request to add a particular Proposition 65 warning to the products. Respondents' contention is unavailing.

The correspondence between the FDA and respondents was entirely too informal to establish a policy that would justify invoking the supremacy clause to invalidate a state law. The FDA letters seem to be nothing more than a formulaic response directing the manufacturers not to act while a review of the issue was conducted. In fact, in its *amicus curiae* brief, the FDA acknowledges that the correspondence between it and the manufacturers did not constitute a formal directive or set out a definitive FDA policy on proper warnings.

The FDA's letter to the California Attorney General, by its own terms, rejects only the Proposition 65 safe harbor warning. Moreover, the stated rationale for this conclusion, that the data justifies a warning only that nicotine may increase fetal heart rate, was specifically disavowed by it in the August 2001 Response.

The Response makes no determination that all Proposition 65 warnings conflict with an FDA policy on overwarning. It expresses a concern about any warning that discourages consumer use of NRT products. The FDA determined that consumers might be misled by a warning that contains the phrase “[n]icotine . . . *can harm* your baby.” Its criticism was directed, however, only at the specific warning proposed by appellant in his citizen petition, which was patterned after the Habitrol warning [“If pregnant or breast-feeding, ask a health professional before use. Nicotine, whether from smoking or medication, can harm your baby. First try to stop smoking without the patch.”]. In the FDA's view, the Habitrol warning urged by appellant exaggerates the certainty and dimension of the harm by equating the harm resulting from NRT products with the harm resulting from smoking. Nothing in the Response provides “clear evidence” that the FDA would find all warnings that comply with Proposition 65 to be insufficient or confusing.

It seems more consistent with the language of the Response to view the FDA's concern about overwarning as a corollary of its objective of ensuring clear and accurate labeling. (21 U.S.C. § 352(a); 21 C.F.R. § 330.10(a)(4)(v) (2001).) In its Response, the FDA recognized the particular problems posed by NRT products when fashioning an adequate statement of the risks to the user: “NRT drug products pose significant challenges as compared to other [over-the-counter] drugs as they are indicated to break the addiction to smoking, a condition that is known to cause harm. When determining the proper labeling for these products, the [FDA] is faced with the difficult task of relaying the relative risks of the potential harm from NRT products versus the known harm caused by the continued use of tobacco products. [¶] . . . [¶] . . . The complexity of the data regarding exposure to nicotine during pregnancy and the relative risks of

smoking versus use of NRT products are not easily translated to consumer friendly language on an [over-the-counter] package.”

To be sure, a warning imposed by Proposition 65 that is *inaccurate* and misstates the risks of an over-the-counter drug would violate federal standards and be preempted. The manufacturers assert that any Proposition 65 warning would be false because NRT products are not truly “known” to cause reproductive harm. But this argument misstates the nature of the Proposition 65 warning. Proposition 65 does not require warnings about the harm of using particular products; the Proposition 65 warning is that the product contains a *chemical* known to cause reproductive harm. There is no dispute that the NRT products contain nicotine and that nicotine is linked to reproductive harm. California law explicitly recognizes a causative relationship (Cal. Code Regs., tit. 22, § 12000, subd. (c)), and, as evidenced by this record, California relied upon information obtained from the FDA as a basis for listing nicotine as a reproductive toxin. (See Cal. Code Regs., tit. 22, §§ 12000, subd. (a), 12306, subd. (l)(4).) Even in its most recent communiqué, based on current data, the FDA continues to recognize a causative connection between nicotine and reproductive harm, although it is unable to quantify the precise contribution of nicotine to reproductive toxicity.⁷ In its Response, the FDA explained: “[C]hronic nicotine exposure may represent some risk in humans for embryo-fetal lethality While smoking has clearly been associated with fetal harm, the contribution of nicotine has not been clearly delineated. . . . [¶] . . . [¶] . . . [C]igarette smoking results in the exposure of the fetus to a number of harmful substances, and it is impossible to ascertain the exact contribution of nicotine to the harm caused by smoking.”

The FDA’s recognition of the possibility of harm from nicotine is further evidenced in the newly-mandated label announced by the FDA in its Response: “**If you**

⁷ When classified as prescription products, NRT products contained the following FDA-mandated label identifying nicotine as a “mediator” in reproductive harm: “Cigarette smoking during pregnancy is associated with an increased risk of spontaneous abortion, low birth weight infants and perinatal mortality. Nicotine and carbon monoxide are considered the most likely mediators of this outcome.”

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.” (Boldface type in original.) The admonition that consumers should try to avoid using the product and use the product only with a doctor’s advice, together with the statement that the risks of NRT products are not fully known, reflect the FDA’s assessment that nicotine indeed may cause harm.

There is no apparent reason why the new FDA-mandated warning could not be supplemented with the simple insertion, after the first sentence of that warning, of a statement, consistent with Proposition 65, acknowledging the risk that nicotine may cause fetal harm. This supplemental information about nicotine would in no way undermine the congressional goal of protecting consumers from unknown risks. And an accurate statement would certainly not violate the goal of truthful labeling. If anything, such an addition would seem to improve the clarity of the message to the consumer by revealing the reasons for the label’s admonitions.

In appropriate circumstances, it may be true that overwarning (or underwarning) of the risks could render a package label “false or misleading.” However, in the circumstances here, *when applied to Proposition 65*, there appears to be no basis for the FDA to reject accurate, easily understood supplemental warnings about nicotine simply because the warnings have the potential to discourage the use of an NRT product. Nothing in the FDCA reflects a congressional intent to *limit* clear and accurate warnings of health risks so that consumers might be more inclined to take advantage of certain beneficial products. (*Motus v. Pfizer, Inc.* (C.D.Cal. 2000) 127 F.Supp.2d 1085, 1098 & fn. 11.) To the contrary, Congress has expressly allowed California to add its own supplemental warnings through Proposition 65. The FDA has no legitimate reason, within the scope of its authority to implement the FDCA, to soften the warning about nicotine any more than it has legitimate reason to soften warnings on other risky over-the-counter drugs that may have health benefits.

It is worth noting that the FDA’s own regulations allow a *manufacturer* to add or strengthen a warning label without waiting for prior FDA approval. (21 C.F.R. § 314.70(c)(2)(i) (2001).) Contrary to the assertion of the FDA in its amicus curiae brief, a preapproval label supplement is not confined to minor editorial changes. In fact, the regulations allow minor editorial changes to be made without any FDA approval at all. (21 C.F.R. § 314.70(d)(3) (2001).) The implication from the regulations is that additional warnings to the consumer by the manufacturer are too important to defer until after the approval process is complete. It is difficult to understand, then, how the addition of warnings mandated by Proposition 65 would frustrate federal full-notice objectives when warnings voluntarily affixed would not.⁸

Respondents may, of course, be correct and the Response may have been intended to state an FDA policy on overwarning that would bar any modification of its proposed warning. The disquiet expressed in that document about the phrase “can harm your baby” may reflect a broad-based concern that would equally ban compliance with Proposition 65 regardless of the language of the warning in its entirety. If so, then it would appear that the FDA’s concern for overwarning disguises the its actual goal of establishing label uniformity. In its Response, the FDA concluded that labeling of NRT products should be “consistent” and “uniform” and, while manufacturers “may also consider a different warning, they will have to provide data to support alternative wording.” That pronouncement flies in the face of the saving clause (21 U.S.C. § 379r(d)(2)), by which Congress has given its imprimatur to different or supplemental warnings required by Proposition 65. The FDA recognized the difficulty of achieving the goal of a clear statement of the risks of NRT products but failed to perceive that it is in

⁸ The FDA emphasizes that a manufacturer is required to explain the “basis” for a preapproval change in label. (21 C.F.R. § 314.70(c) (2001).) It argues that the fact that a manufacturer is required by Proposition 65 to add warnings would not provide a satisfactory *scientific* explanation of the basis for the change of label. The argument is not persuasive. In light of the saving clause enacted by Congress expressly allowing the different or supplemental warnings called for by Proposition 65, a manufacturer’s need to comply with Proposition 65 provides adequate justification for the change of label.

precisely this type of situation that the Congressional desire to permit variance needs to be honored.

In summary, I would conclude that Proposition 65 is not saved from any actual conflict with federal labeling standards. However, no actual conflict exists. Compliance with both Proposition 65 and federal regulations would not be physically impossible, nor would compliance with Proposition 65 interfere with congressional or FDA purposes. I concur in the majority's decision that the judgment must be reversed.

SIMONS, J.

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