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DOCUMENT NO.	FORM	SUBJECT/TITLE	PAGES	DATE	RESTRICTION(S)
001	Fax Cover Sheet	Tort Reform [1 PAGE RELEASED IN WHOLE ON PRA RE-REVIEW 08/28/2025 JLS] - To: Brett Kavanaugh - From: Bill McCollum	1	07/26/2002	

COLLECTION TITLE:

Counsel's Office, White House

SERIES:

Kavanaugh, Brett - Subject Files

FOLDER TITLE:

Tort Reform [Folder 1]

FRC ID:

9702

RESTRICTION CODES

Presidential Records Act - [44 U.S.C. 2204(a)]

- P1 National Security Classified Information [(a)(1) of the PRA]
- P2 Relating to the appointment to Federal office [(a)(2) of the PRA]
- P3 Release would violate a Federal statute [(a)(3) of the PRA]
- P4 Release would disclose trade secrets or confidential commercial or financial information [(a)(4) of the PRA]
- P5 Release would disclose confidential advice between the President and his advisors, or between such advisors [(a)(5) of the PRA]
- P6 Release would constitute a clearly unwarranted invasion of personal privacy [(a)(6) of the PRA]

PRM. Personal record misfile defined in accordance with 44 U.S.C. 2201(3).

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- b(7) Release would disclose information compiled for law enforcement purposes [(b)(7) of the FOIA]
- b(8) Release would disclose information concerning the regulation of financial institutions [(b)(8) of the FOIA]
- b(9) Release would disclose geological or geophysical information concerning wells [(b)(9) of the FOIA]

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SUPERSEDED

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James M. Wootton
President

August 19, 2002

Brett

Dr. Glenn Hubbard
Chairman
Council of Economic Advisors
Eisenhower Executive Office Building
17th and Pennsylvania Avenue, N.W.
Washington, D.C. 20502

Dear Dr. Hubbard:

Thank you for taking the time to meet with Robert Hahn, John Schmitz and me to discuss tort reform and federalism. As you know, we very much look forward to working with you to promote both of these ideas within this Administration. We know that these issues are of great importance to President Bush who, as a former Governor and a business leader, has a unique perspective and understanding of the importance of a limited federal government that protects our liberty through the effective exercise of its Constitutionally enumerated powers

As President Bush underscored during his campaign, our civil justice system faces extraordinary problems that directly impact the national economy and our liberty. The dramatic increase in the number of lawsuits and the magnitude of jury awards have resulted in more than just direct losses to national business for liability payouts. Indeed, the current tort system imposes additional costs on the society as a whole by increasing the prices of consumer goods, discouraging technological innovation, and decreasing the supply of reasonably priced insurance. Early work by Peter Huber estimated that the economic impact of tort liability on American individuals, government organizations, and businesses is at least \$80 billion a year. (*Liability: The Legal Revolution and its Consequences* 11-14, (1990)). More recent work by the Council of Economic Advisors (CEA) estimates direct costs of nearly \$180 billion, or 1.8% of the gross domestic product (*Who Pays for Tort Liability Claims? An Economic Analysis of the U.S. Tort Liability System*, Council of Economic Advisors, April 2002, citing Tillinghast-Towers Perrin, *U.S. Tort Costs: 2000, Trends and Findings on the Costs of the U.S. Tort System*). The CEA white paper also notes that only an estimated 20% of those costs go to claimants for economic damages.

Because of the close relationship between national prosperity and a unified national marketplace our federalist system from the beginning contained the constitutional tenant that regulation of interstate commerce (as opposed to the regulation of schools or other areas that are local in nature) comes within the special authority and competence of the national government. Notably, recent U.S. Supreme Court decisions,

including *United States v. Lopez* (514 U.S. 549 (1995)) and *United States v. Morrison* (529 U.S. 598 (2000)), have signaled that the Court is prepared to enforce this "enumerated powers" approach to the Constitution and its distinction between national and state authority. Thus, the President can and should be encouraged to take thoughtful and appropriate steps to address the abuses of our civil justice system whenever those abuses burden the free flow of the goods and services in interstate commerce.

In light of these developments, Governors John Engler (Michigan) and Frank Keating (Oklahoma) convened a Federalism Symposium in Washington, D.C. on June 6, 2001, to provide a forum to discuss how to advance simultaneously the federalism agenda of the governors, the original understanding and theoretical underpinnings of federalism, and the needs of the business community. Sponsored by the U.S. Chamber of Commerce Institute for Legal Reform, the Federalism Symposium was attended by leaders in the business community, senior state officials, Bush Administration and congressional representatives, scholars, and others.

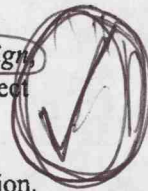
The Symposium confirmed the broad recognition by federalism experts, such as Ted Olson and Robert Bork, that Federalist principles do not require the federal government to defer to state law standards of liability that burden interstate commerce or conflict with or impede federal laws, regulation, and policies in areas where the federal government acts pursuant to an enumerated power. They and other federalism scholars identified below conclude that the Commerce Clause authorizes the federal government to remove such impediments to interstate commerce, in part by enacting preemptive statutes and regulations concerning product safety and labeling. Far from violating core tenets of federalism, federal tort reform measures that preempt the current miscellany of ill-considered, inefficient, and oftentimes judicially-imposed state policies in these areas are consistent with the proper, constitutionally-delegated role of the federal government in our system of divided power.

The attached articles and copy of the Spring 2002 *Harvard Journal of Law and Public Policy* (in which the Symposium papers were published) provide a more comprehensive discussion. They are summarized below:

- Brief of Ted Olson (now Solicitor General of the United States) to the Supreme Court on behalf of the U.S. Chamber of Commerce in *Geier v. Amer. Honda Motor Corp.* - Olson discusses how "[R]ecent developments and trends in state tort law reveal an enhanced need for vigorous enforcement of implied preemption principles and related constitutional mandates in order to shield our national economy from the increasing burdens placed upon it by unconstrained, arbitrary, inconsistent, and excessive tort verdicts and ever-expanding liability rules."
- Robert H. Bork and Daniel E. Troy, *Locating the Boundaries: The Scope of Congress's Power to Regulate Commerce*, 25 HARV. J. L. & PUB. POL'Y 849 (2002) - Bork and

Dr. Glenn Hubbard
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Page Three

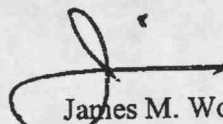
Commerce Clause's
role to prevent
efforts at state
level

- Troy examine why the Commerce Clause, from an originalist perspective, permits the federal government to establish uniform safety and labeling standards and empowers the federal government to remove impediments to interstate commerce and maintain a vibrant national economy.
- Michael W. McConnell, Book Review, *Federalism: Evaluating the Founders' Design*, U. CHI. L. REV. 1483 (1987) – McConnell's analysis finds tort reform a suitable subject for federal action because a national forum prevents a narrow "faction" within the population – such as a judge or jury confronted with an unsympathetic, out-of-state corporate defendant – from effectively crafting policies that will affect the entire nation. 
- C. Boyden Gray (former Counsel to President Bush), *Regulation and Federalism*, YALE J. REG. (1983) - Gray argues because many federal programs are "frequently inconsistent with local needs and preferences, administered by bureaucrats who are unaccountable to local citizens, and riddled with inefficiencies," federal involvement should be confined only to four areas, including products liability standards where "the combined effect of disparate state regulatory standards may intolerably burden interstate commerce."
- John Eastman, *Re-entering the Arena: Restoring a Judicial Role for Enforcing Limits on Federal Mandates*, 25 HARV. J. L. & PUB. POL'Y 931 (2002) – Eastman uses the Unfunded Mandates Reform Act (UMRA) as the basis for making two broader recommendations for incorporating constitutional considerations into Congressional deliberations. First, he proposes that Congress should consider the financial cut-offs established by UMRA as guidelines for determining limits on federal authority. Second, Eastman argues that the long-dormant non-delegation doctrine, which (in theory) prohibits the assignment of unbridled lawmaking powers to executive agencies, can also be used as a way of preventing costly federal regulations.

These analyses, along with the related Supreme Court jurisprudence, clearly support the principle that certain actions by the federal government to limit state tort liability for goods and services produced and sold in the national market do not violate the principles of federalism on which our nation was founded. On the contrary, such federal action is an essential part of the foundation of federalist theory.

We hope you find these pieces to be useful in your analysis and discussions with President Bush. If you would like to discuss any of these issues further, or have questions or comments, please do not hesitate to contact me, John or Bob.

Sincerely,



James M. Wootton
President

Only the Westlaw citation is currently available.

Court of Appeal, First District, Division 5, California.

Paul A. DOWHAL, Plaintiff and Appellant,
v.
SMITHKLINE BEECHAM CONSUMER
HEALTHCARE, etc., et al., Defendants and
Respondents.

No. A094460.

July 12, 2002.

Citizen, acting on behalf of the public, filed complaint against drug companies, seeking an injunction and alleging that companies placed nicotine delivery products in the stream of commerce without providing adequate pregnancy warning and that those acts constituted an unfair business practice. The Superior Court, San Francisco County, No. 305893, David A. Garcia, J., granted summary judgment to drug companies. Citizen appealed. The Court of Appeal, Jones, P.J., held that drug companies' obligation under state law to warn of reproductive toxicity of nicotine delivery products was exempted from both express and implied federal preemption.

Reversed.

Simons, J., filed a concurring opinion.

[1] Appeal and Error

30k0 k.

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.

[2] States 
360k0 k.

State law that conflicts with a federal statute is without effect. U.S.C.A. Const. Art. 6, cl. 2.

[3] States 
360k0 k.

Consideration of issues arising under the Supremacy

Clause starts with the assumption that the historic police powers of the States are not to be superseded by a federal act unless that is the clear and manifest purpose of Congress; accordingly, the purpose of Congress is the ultimate touchstone of pre-emption analysis. U.S.C.A. Const. Art. 6, cl. 2.

[4] States 
360k0 k.

Drug companies' obligation under state law to warn of reproductive toxicity of nicotine delivery products was exempted from both express and implied federal preemption under the Federal Food, Drug, and Cosmetic Act (FDCA) by the savings clause of the Food and Drug Administration Modernization Act of 1997. 21 U.S.C.A. § § 301 et seq.; 21 U.S.C.A. § 379r, subd. (d)(2); West's Ann.Cal.Health & Safety Code § 25249.6.

[5] States 
360k0 k.

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 the federal scheme.

San Francisco Superior Court, Hon. David A. Garcia.

Eric S. Somers, Mark N. Todzo, Todd E. Robins, Lexington Law Group, LLP, for plaintiff and appellant.

Bill Lockyer, Attorney General, Richard M. Frank, Chief Assistant Attorney General, Theodora Berger, Senior Assistant Attorney General, Craig Thompson, Supervising Deputy Attorney General, Edward G. Weil, Dennis Ragen, Susan S. Fiering, Deputy Attorneys General, Amicus Curiae on behalf of plaintiff and appellant.

James P. Bennett, Michelle B. Corash, Maria Chedid, Brooks M. Beard, Morrison & Foerster, LLP, Gene Livingston, Matthew J. Goldman, Livingston & Mattesich Law Corp., Paul D. Fogel, John E. Dittoe, Crosby, Heafey, Roach & May, for defendants and respondents.

Catherine Hanson, Astrid Meghrigian, California Medical Association, Daniel E. Troy, Chief Counsel, Lynn Whipkey Mehler, Associate Chief Counsel, Heidi P. Foster, Assistant Chief Counsel, Food and

Drug Administration, Robert D. McCallum, Jr., Assistant Attorney General, David W. Shapiro, United States Attorney, Douglass Letter, Peter R. Maier, Department of Justice, Amicus Curiae on behalf of defendants and respondents.

JONES, P.J.

*1 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). [FN1]

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 of a health professional before using this product." [FN2] 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."

*2 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."

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.

*3 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...."

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

[1] 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. [FN3] 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.

II. DISCUSSION [FN4]

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

[2][3] The supremacy clause of Article VI of the United States Constitution grants to the Congress the power to preempt state law. [FN5] 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, 112 S.Ct. 2608, 120 L.Ed.2d 407 (*Cipollone*), quoting *Maryland v. Louisiana* (1981) 451 U.S. 725, 746, 101 S.Ct. 2114, 68 L.Ed.2d 576.) 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.*)

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, 110 S.Ct. 2270, 110 L.Ed.2d 65, fn. omitted.)

*5 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

(Cite as: 2002 WL 1486578 (Cal.App. 1 Dist.))

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...."

[4] 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, 106 S.Ct. 1834, 90 L.Ed.2d 248), 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.)

*6 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. [FN6] 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, 120 S.Ct. 1913, 146 L.Ed.2d 914 (*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 clause [FN7] did not apply to the plaintiff's suit. (*Geier, supra*, 529 U.S. at pp. 867-868.) The court was then required to determine whether a saving clause contained in the Act [FN8] 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 preemption 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.)

*7 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 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,

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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.

[5] 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, 110 S.Ct. 2024, 109 L.Ed.2d 474.)

*8 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, 121 S.Ct. 1012, 148 L.Ed.2d 854 (*Buckman*); *Medtronic, Inc. v. Lohr* (1996) 518 U.S. 470, 116 S.Ct. 2240, 135 L.Ed.2d 700 (*Medtronic*); and *Freightliner Corp. v. Myrick* (1995) 514 U.S. 280, 115 S.Ct. 1483, 131 L.Ed.2d 385 (*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.

*9 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 liability [FN9] under Proposition 65. [FN10]

III. DISPOSITION

The judgment is reversed. Costs to appellant.

I concur: STEVENS, J.

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 65 [FN1] 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, 121 S.Ct. 2404, 150 L.Ed.2d 532.) 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.

*10 In *Cipollone v. Liggett Group, Inc.* (1992) 505 U.S. 504, 517, 112 S.Ct. 2608, 120 L.Ed.2d 407, 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, 115 S.Ct. 1483, 131 L.Ed.2d 385, 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, 120 S.Ct. 1913, 146 L.Ed.2d 914 (*Geier*).) This conclusion was underscored in *Medtronic, Inc. v. Lohr* (1996) 518 U.S. 470, 503, 116 S.Ct. 2240, 135 L.Ed.2d 700, 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, 121 S.Ct. 1012, 148 L.Ed.2d 854; *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. [FN2] 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 to conflict with a carefully devised regulatory scheme. (*Geier*, at pp. 873-874; *United States v. Locke* (2000) 529 U.S. 89, 106-107, 120 S.Ct. 1135, 146 L.Ed.2d 69; *American Telephone & Telegraph Co. v. Central Office Telephone, Inc.* (1998) 524 U.S. 214, 227-228, 118 S.Ct. 1956, 141 L.Ed.2d 222; *International Paper Co. v. Ouellette* (1987) 479 U.S. 481, 493-494, 107 S.Ct. 805, 93 L.Ed.2d 883; 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].)

*11 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; , 67 S.Ct. 1283, 91 L.Ed. 1585 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, 68 S.Ct. 331, 92 L.Ed. 297 [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, 32 S.Ct. 715, 56 L.Ed. 1182 [state labeling requirement held nonconflicting and valid]; cf. *McDermott v. Wisconsin* (1913) 228 U.S. 115, 131-137, 33 S.Ct. 431, 57 L.Ed. 754 [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. [FN3] 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.)

*12 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 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.

*13 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, [FN4] 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 Jeffords, like Senator Boxer, never alluded to changing the ground rules Proposition 65 faced before the Modernization Act of 1997.

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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, 120 S.Ct. 2288, 147 L.Ed.2d 352.) 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. [FN5]

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 preemption too readily in the absence of clear evidence of a conflict." (*Geier*, at p. 885.) I find no such evidence here.

*14 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 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. [FN6] 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 F.3d 807, 810; *Chemical Specialties Mfrs.*

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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, 62 Cal.Rptr.2d 368.) 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).)

*15 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.

*16 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. (1)(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. [FN7] 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 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.

*17 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. [FN8]

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

*18 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.

FN1. 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 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.

FN2. 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.

FN3. 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, 48 Cal.Rptr.2d 87, 906 P.2d 1242.) We will exercise our discretion and grant the request in this instance in order to

provide context and background for our discussion.

FN4. 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, 138 Cal.Rptr. 828.)

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, 48 Cal.Rptr.2d 87, 906 P.2d 1242.)

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, 48 Cal.Rptr.2d 87, 906 P.2d 1242.)

FN5. 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."

FN6. 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...."

FN7. 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 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.)

FN8. 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.)

FN9. 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).)

FN10. Having reached this conclusion, we need not address the other arguments that have been advanced.

FN1. 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.)

FN2. At oral argument, appellant cited *Louisiana Public Service Comm'n v. FCC* (1986) 476 U.S. 355, 106 S.Ct. 1890, 90 L.Ed.2d 369 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.

FN3. 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).)

FN4. 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.)

FN5. 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, 83 S.Ct. 1210, 10

(Cite as: 2002 WL 1486578 (Cal.App. 1 Dist.))

L.Ed.2d 248.) 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 F.2d 941, 947, 949-950 [fungicides and insecticides]; *People ex rel. Lungren v. Cotter & Co.* (1997) 53 Cal.App.4th 1373, 1393-1396, 62 Cal.Rptr.2d 368 [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.

FN6. 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.

FN7. 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."

FN8. 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.

2002 WL 1486578 (Cal.App. 1 Dist.)

END OF DOCUMENT

H

United States District Court,
C.D. California.

Flora MOTUS, Plaintiff,
v.

PFIZER INC. (Roerig Division), et al., Defendants.

No. CV 00-00298 AHM (SHx).

Dec. 12, 2000.

Wife of patient who committed suicide after taking anti-depressant drug brought suit against drug manufacturer, alleging wrongful death and negligence, strict liability, and a survival action for the pain, suffering, and losses that patient sustained while using the drug. Drug manufacturer moved for partial summary judgment. The District Court, Matz, J., held that: (1) federal law governing warning labels on drugs approved by the Food and Drug Administration (FDA) did not preempt failure-to-warn claim brought under state law by wife of patient who committed suicide after taking anti-depressants; (2) permitting state law claims for failure to warn did not conflict with the purposes and objectives of Congress by over-detering use of the medicine; and (3) wife stated claim under California law premised on strict liability based on inadequate warning.

Motion denied.

West Headnotes

[1] States ⇨18.3
360k18.3 Most Cited Cases

There are three ways in which federal law will preempt a state law, including (1) Congress explicitly defines the extent to which its enactment preempts state law, (2) state law regulates conduct in a field that Congress intended federal government to occupy exclusively, and (3) state law actually conflicts with federal law; these categories are not rigidly distinct, but may overlap.

[2] States ⇨18.3
360k18.3 Most Cited Cases

Party contending that claim is preempted bears burden of establishing preemption.

[3] Drugs and Narcotics ⇨20.1
138k20.1 Most Cited Cases

[3] States ⇨18.65
360k18.65 Most Cited Cases

Federal law governing warning labels on drugs approved by

the Food and Drug Administration (FDA) did not preempt failure-to-warn claim brought under state law by wife of patient who committed suicide after taking anti-depressants; adopting the stronger suicide warnings that wife advocated under state law would not make it impossible for drug manufacturer to comply both with wife's demands for additional warnings and with FDA's requirement that drug manufacturer use the exact labeling approved by the agency, which contained only a modest suicide warning. Federal Food, Drug, and Cosmetic Act, § 505(d, e), 21 U.S.C.A. § 355(d, e).

[4] Drugs and Narcotics ⇨20.1
138k20.1 Most Cited Cases

[4] States ⇨18.65
360k18.65 Most Cited Cases

Permitting state law claims for failure to warn of possibility of suicide as result of taking anti-depressant drug did not conflict with the purposes and objectives of Congress by over-detering use of the medicine approved by the Food and Drug Administration (FDA) or by reducing the drug label's effectiveness in communicating necessary information to doctors, and thus, state law claim was not preempted by federal drug labeling laws, where there was no persuasive evidence establishing threat of overdeterrence from strengthening suicide warning labels for the drug, and drug already contained modest warning concerning suicide. Federal Food, Drug, and Cosmetic Act, §§ 505(d), 903(b)(2)(B), 21 U.S.C.A. §§ 355(d), 393(b)(2)(B).

[5] Drugs and Narcotics ⇨18
138k18 Most Cited Cases

Under California law, wife of patient who committed suicide after taking anti-depressant drug stated claim against the drug manufacturer for strict liability premised on inadequate warning about increased possibility of suicide. *1086 George W. Murgatroyd, III, Karen Ann Barth, Baum Hedlund Aristei Guilford & Downey, Los Angeles, CA, for plaintiff.

Pierce O'Donnell, Ann M. Mortimer, Randy R. Merritt, Daniel C. Tepstein, O'Donnell & Shaeffer, Los Angeles, CA, Malcolm E. Wheeler, Amy L. Padden, James E. Hooper, Michael L. O'Donnell, Wheeler Trigg & Kennedy, Denver, CO, for defendants.

ORDER DENYING PFIZER'S MOTION FOR PARTIAL
SUMMARY JUDGMENT

MATZ, District Judge.

INTRODUCTION

Victor Motus suffered from depression. To help deal with that illness, sometime in November 1998 he began taking the drug "Zoloft," which is manufactured by defendant Pfizer Inc. ("Pfizer"). Zoloft was prescribed and supplied to Victor Motus by his internist, to whom Pfizer had provided a supply of Zoloft as a sample. For the approximately one week that he took Zoloft, Victor Motus experienced agitation, confusion and suicidal thinking. On November 12, 1998, he took his life by shooting himself.

Plaintiff Flora Motus ("Motus") was married to Victor Motus. She has brought this lawsuit, removed here from state court, seeking recovery on three claims: *1087 (1) "wrongful death/negligence"; (2) strict liability; and (3) "survival action" for the pain, suffering and losses that Victor Motus sustained while using Zoloft. Her complaint alleges, among other things, that Pfizer "negligently ... fail[ed] to adequately warn the medical community, the general public and plaintiff's decedent, Victor Motus ... of the dangers, contraindications and side effects ... of Zoloft" [Complaint, ¶ 27] and that in the United States "Zoloft was not properly labeled by defendants [FN1] ... and was not accompanied by proper warnings for safe, informed use ... [T]he labeling ... did not warn physicians in general and Decedent in particular of the dangers inherent in its use, particularly that the drug can cause the user to become violent and suicidal." Complaint, ¶ 58.

FN1. Various "DOES" are sued along with Pfizer.

Here is the suicide-related precaution that Pfizer gave:

Suicide--The possibility of a suicide attempt is inherent in depression and may persist until significant remission occurs. Close supervision of high risk patients should accompany initial drug therapy. Prescriptions for Zoloft (sertraline) should be written for the smallest quantity of capsules consistent with good patient management, in order to reduce the risk of overdose.

DSUF, ¶ 20.

Now Pfizer has moved for partial summary judgment dismissing plaintiff's "inadequate warning" claims. Pfizer seeks an order that as a matter of law it may not be held liable for its failure to include in the labeling for Zoloft a warning of the risk of suicide. Pfizer argues that under both California law and federal "conflict" preemption doctrine, plaintiff's state law claims based on Pfizer's failure to include a suicide warning in Zoloft's labeling are barred because the Food and Drug Administration ("FDA") has already considered and rejected the inclusion of such a warning in Zoloft's labeling. Motus responds that 1) although FDA did approve Pfizer's proposed labeling for Zoloft without the suicide warning, FDA did not prohibit Pfizer from adding such a warning and 2) Congress has not preempted state tort law claims for failure to warn just

because FDA has approved a manufacturer's proposed warnings.

The Court DENIES defendant's motion for partial summary judgment. As set forth in more detail below, Pfizer has failed to establish that a plaintiff is barred from asserting state law tort claims based on failure to warn of a suicide risk.

FACTS [FN2]

FN2. All the facts recited in this Order are undisputed unless otherwise noted.

A. Statutory Background

One aspect of the FDA's mission is to ensure that drugs sold in the United States are "safe and effective." 21 U.S.C. § § 355(d) and 393(b)(2)(B). To obtain FDA approval of a drug, a manufacturer must submit a New Drug Application ("NDA"). 21 U.S.C. § 355(b). NDAs must include: "full reports of investigations which have been made to show whether or not such drug is safe for use and whether such drug is effective in use ... and specimens of the labeling proposed to be used for such drug." *Id.* The FDA will disapprove an NDA if:

(1) the investigations ... do not include adequate tests ... to show whether or not such drug is safe for use ... (2) the results of such tests show that such drug is unsafe for use ... or do not show that such drug is safe for use ... (4) ... [there is] insufficient information to determine whether such drug is safe for use ... or (7) based on a fair evaluation of all material facts, [the product's] labeling is false or misleading in any particular...

21 U.S.C. § 355(d).

If FDA approves an NDA, FDA will withdraw that approval if:

*1088 clinical or other experience, tests, or other scientific data show that such drug is unsafe ... [or] that new evidence of clinical experience, not contained in such application or not available to the Secretary until after such application was approved, or tests by new methods, or tests by methods not deemed reasonably applicable when such application was approved, evaluated together with the evidence available to the Secretary when the application was approved, shows that such drug is not ... safe for use ... or that the application contains any untrue statement of a material fact.

21 U.S.C. § 355(e).

B. The Zoloft New Drug Application

On April 13, 1988, Pfizer submitted an NDA to the FDA seeking approval to market Zoloft for treatment of depression. Defendant's Statement of Uncontroverted Facts

("DSUF"), ¶ 11. Zoloft is the registered trademark and brand name in the United States for sertraline hydrochloride. DSUF, ¶ 2. Sertraline hydrochloride is one of a class of medicines commonly referred to as "selective serotonin reuptake inhibitors," or "SSRIs." *Id.*

Pursuant to Title 21 U.S.C. § 355, the statute governing New Drug Applications, Pfizer submitted 117 volumes of safety and efficacy data on Zoloft that Pfizer had developed during the preceding seven years. DSUF, ¶ 12; 21 U.S.C. § 355(b). These submissions included information about suicidality in patients given Zoloft, placebos and other drugs, although plaintiff disputes the completeness and accuracy of the information. DSUF, ¶ 13; *Opposition*, *passim*.

On November 19, 1990, FDA convened a committee of experts, the Psycho-pharmacological Drugs Advisory Committee ("PDAC"), to review the Zoloft NDA and to advise FDA regarding the medicine's safety and efficacy. DSUF, ¶ 14. As part of his presentation of safety data, one of the PDAC experts, Dr. James Knudson, addressed suicide attempts in Zoloft, placebo and active-control treated patients during the clinical studies of Zoloft. DSUF, ¶ 17. Dr. Knudson stated that:

Realizing the difficulty in interpreting data where analyses ignore differential exposure time, this table does show that disproportionate numbers of suicides do not occur among the three treatment groups. All suicide attempts appeared in depressed patients, none in the obese.

Id. At the conclusion of the meeting, the PDAC voted unanimously that the evidence Pfizer produced had shown that Zoloft "is safe when used in the treatment of depression." DSUF, ¶ 18.

On September 30, 1991, FDA issued its "approvable" letter for the Zoloft NDA. DSUF, ¶ 18. The letter stated that FDA has "proposed a number of changes to the draft labeling submitted in your July 24, 1990 amendment" and it proposed some different labeling. *Id.* The precaution section of the proposed labeling included this statement regarding suicide:

Suicide—The possibility of a suicide attempt is inherent in depression and may persist until significant remission occurs. Close supervision of high risk patients should accompany initial drug therapy. Prescriptions for Zoloft (sertraline) should be written for the smallest quantity of capsules consistent with good patient management, in order to reduce the risk of overdose.

DSUF, ¶ 20. The FDA letter instructed Pfizer to "[p]lease use the proposed text verbatim." (As was shown above, Pfizer eventually did so.) DSUF, ¶ 19. [FN3] In addition, FDA stated that final approval required Pfizer's responses to issues raised in the letter. Defendant's Motion for Partial

Summary Judgment ("Defendant's Motion"), *1089 Declaration of Martha Brumfield ("Brumfield Dec."), Exh. 3.

FN3. In addition to asserting that the data that Pfizer provided to FDA was incomplete and inaccurate, plaintiff contends that Pfizer, not FDA, drafted this language. Murgatroyd Dec., ¶ 3, Exh. A, RFA # 144.

FDA granted final approval of the Zoloft NDA on December 30, 1991. DSUF, ¶ 21. Working from a draft submitted by Pfizer, FDA also prepared a final "Summary Basis of Approval" for Zoloft. DSUF, ¶ 22; Plaintiff's *Opposition to Defendant's Motion for Partial Summary Judgment ("Opposition")*, Declaration of George Murgatroyd ("Murgatroyd Dec."), Exh. A, Response to Request for Admission Nos. 138, 139. Section 5.2.2.4.1 addressed the occurrence of suicide events in the database of tested sertraline users. DSUF, ¶ 22. That section stated that with respect to suicidality in therapeutic depression trials "[r]eview of the rates of events defined by baseline to endpoint shifts in HAMD Item 3 scores [i.e., measurement of suicidal ideation] and baseline to endpoint changes in HAMD Item 3 scores showed results favoring [Zoloft] over placebo and supported the comparability of the [Zoloft] and active control groups." DSUF, ¶ 22.

Following its approval of Zoloft for treatment of depression, FDA also approved Zoloft as safe and effective for treatment of obsessive compulsive disorder (October 25, 1996), pediatric obsessive compulsive disorder (October 10, 1997), panic disorder (July 8, 1997) and post-traumatic stress disorder (December 7, 1999). [FN4] DSUF, ¶¶ 45-48. (The latter approval was granted after Victor Motus took his life.)

FN4. The Court overrules plaintiff's FRE 402 and 403 objections to these facts. Further, at the hearing on this motion, counsel for Pfizer asserted that FDA reconsidered the issue of suicide and Zoloft on each occasion that it approved Zoloft for a new use. Pfizer's motion papers do not specify what evidence proves such reconsiderations were undertaken. The Court has reviewed the Exhibits (5-9 in Brumfield's Declaration) related to FDA's subsequent approvals of Zoloft and found only one document regarding whether FDA reconsidered the suicide issue. That document is a report, apparently prepared by Pfizer at FDA's request, detailing Pfizer's findings concerning the relation between the use of Zoloft by adults and children for obsessive compulsive disorder and suicide related behavior. Brumfield Dec., Exh. 9. The report concluded, *inter alia*, that rate of suicidal behavior

for adolescents treated with sertraline for obsessive-compulsive disorder was within the range described in normal population samples of adolescents.

C. Other SSRI's and Labeling About Suicide [FN5]

FN5. The Court overrules plaintiff's FRE 402 and 403 objections to these facts. Plaintiff's own complaint refers to the risks posed by Prozac and to an article describing the risks of Prozac, and cites a quote from Pfizer that Zoloft works "just like Prozac" with the same side effects. Complaint, ¶¶ 16-18. The evidence is also relevant to establish how the FDA handled concerns about SSRI-induced suicidal ideations.

Before and during FDA's consideration of the Zoloft NDA, FDA considered claims that other SSRIs, such as Prozac, cause suicide.

In early 1990, an article was published about Prozac that led to a much-publicized public debate about whether fluoxetine induced suicidal ideation in patients. On October 10, 1990, Sanford Block of the Church of Scientology's "Citizens Commission on Human Rights," ("CCHR") filed with FDA a petition claiming that Prozac caused suicidality and asking FDA to withdraw its approval of Prozac. DSUF, ¶ 26. On May 23, 1991, Drs. Ida Hellander and Sidney M. Wolfe of "Public Citizen Health Research Group" ("PCHRA") filed a petition asking FDA to revise Prozac's labeling and "to include a box warning [] regarding its association with intense, violent suicidal preoccupation, agitation and impulsivity in a small minority of patients." DSUF, ¶ 27.

On July 26, 1991, FDA denied the CCHR petition, stating that "[t]he data and information available at this time do not indicate that Prozac causes suicidality or violent behavior..." DSUF, ¶ 28.

On September 20, 1991, FDA convened the PDAC to further its "scientific investigation *1090 into suicidal ideation, suicidal acts, and other violent behavior reported to occur in association with the pharmacological treatment of depression." DSUF, ¶ 30. In his opening remarks to the committee meeting, Dr. Paul Leber, the then-Director of the FDA Division of Neuropharmacological Drug Products, stated that the "net effect" of "modifying antidepressant drug labeling" "might be a reduction in the use of antidepressants in the treatment of depression, and that the result might cause overall injury to the public health." DSUF, ¶ 37. "Excerpted comments" of Dr. Leber also show that he stated that "if Prozac is not more likely to induce suicidal thoughts, acts and other violent behaviors, a labeling change of the sort contemplated by some, beyond

being false and misleading, might well have a net adverse effect." *Id.* On the question whether "there is credible evidence to support a conclusion the antidepressant drugs cause the emergence and/or intensification of suicidality and/or other violent behaviors," the PDAC voted unanimously that there was no such evidence. DSUF, ¶ 39. As to the question whether "there is evidence to indicate that a particular drug or drug class poses a greater risk for the emergence and/or intensification of suicidal thoughts and acts and/or violent behaviors," the PDAC also voted unanimously that there was not. DSUF, ¶ 40.

On June 3, 1992, FDA denied the PCHRA petition because the evidence was "not sufficient to reasonably conclude that the use of Prozac is possibly associated with suicidal ideation and behavior..." DSUF, ¶ 43.

Finally, on January 2, 1997, Ms. Rosellen Meysenburg petitioned FDA to require that Prozac's suicidality warning be expanded to indicate that "people who are considered at risk for suicide and who begin to take the antidepressant drug fluoxetine hydrochloride [sic] should be carefully observed and should consider taking a sedative as well." On June 25, 1997, FDA stated: "[t]he agency has continued to monitor carefully reports of a possible connection between Prozac and increased suicidality. However, no credible scientific evidence has caused the agency to depart from its conclusion that the current Prozac labeling appropriately reflects the level of concern about Prozac and suicidality. Therefore, your petition requesting revision of the labeling for Prozac is denied." DSUF, ¶ 56.

LEGAL STANDARDS FOR A MOTION FOR SUMMARY JUDGMENT

Federal Rule of Civil Procedure 56(c) provides for summary judgment when "the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law." The moving party bears the initial burden of demonstrating the absence of a "genuine issue of material fact for trial." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 256, 106 S.Ct. 2505, 2514, 91 L.Ed.2d 202 (1986). A fact is material if it could affect the outcome of the suit under the governing substantive law. *Id.* at 248, 106 S.Ct. at 2510. The burden then shifts to the nonmoving party to establish, beyond the pleadings, that there is a genuine issue for trial. *Celotex Corp. v. Catrett*, 477 U.S. 317, 324, 106 S.Ct. 2548, 2553, 91 L.Ed.2d 265 (1986).

"When the party moving for summary judgment would bear the burden of proof at trial, it must come forward with evidence which would entitle it to a directed verdict if the evidence went uncontroverted at trial. In such a case, the moving party has the initial burden of establishing the

absence of a genuine issue of fact on each issue material to its case." *C.A.R. Transportation Brokerage Co., Inc. v. Darden Restaurants, Inc.*, 213 F.3d 474, 480 (9th Cir.2000) (citations omitted). In contrast, when the non-moving party bears the burden of proving the claim or defense, the moving party can meet its burden by *1091 pointing out the absence of evidence from the non-moving party. The moving party need not disprove the other party's case. See *Celotex*, 477 U.S. at 325, 106 S.Ct. at 2554. Thus, "[s]ummary judgment for a defendant is appropriate when the plaintiff 'fails to make a showing sufficient to establish the existence of an element essential to [his] case, and on which [he] will bear the burden of proof at trial.'" *Cleveland v. Policy Management Systems Corp.*, 526 U.S. 795, 119 S.Ct. 1597, 1603, 143 L.Ed.2d 966 (1999) (citing *Celotex*, 477 U.S. at 322, 106 S.Ct. at 2552).

When the moving party meets its burden, the "adverse party may not rest upon the mere allegations or denials of the adverse party's pleadings, but the adverse party's response, by affidavits or as otherwise provided in this rule, must set forth specific facts showing that there is a genuine issue for trial." F.R.Civ.P. 56(e). Summary judgment will be entered against the non-moving party if that party does not present such specific facts. *Id.* Only admissible evidence may be considered in deciding a motion for summary judgment. *Id.*; *Beyene v. Coleman Ser. Serv., Inc.*, 854 F.2d 1179, 1181 (9th Cir.1988).

"[I]n ruling on a motion for summary judgment, the nonmoving party's evidence 'is to be believed, and all justifiable inferences are to be drawn in [that party's] favor.'" *Hunt v. Cromartie*, 526 U.S. 541, 119 S.Ct. 1545, 1551-52, 143 L.Ed.2d 731 (1999) (citing *Anderson*, 477 U.S. at 255, 106 S.Ct. at 2513). But the non-moving party must come forward with more than "the mere existence of a scintilla of evidence." *Anderson*, 477 U.S. at 252, 106 S.Ct. at 2512. Thus, "[w]here the record taken as a whole could not lead a rational trier of fact to find for the nonmoving party, there is no genuine issue for trial." *Matsushita Elec. Indus. Co., Ltd. v. Zenith Radio Corp.*, 475 U.S. 574, 587, 106 S.Ct. 1348, 1356, 89 L.Ed.2d 538 (1986) (citation omitted).

DISCUSSION

A. Federal Preemption

[1] The Supreme Court has explained that there are three ways in which federal law will preempt a state law:

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." 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."

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, or where state law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress."

English v. General Elec. Co., 496 U.S. 72, 78-79, 110 S.Ct. 2270, 2275, 110 L.Ed.2d 65 (1990) (citations omitted) (holding that nuclear fuel production employee's state law claim for intentional infliction of emotional distress was not preempted by the Energy Reorganization Act). These categories are not "rigidly distinct;" in particular, "conflict" *1092 and "field" preemption often overlap. *Id.* at 79 n. 5, 110 S.Ct. 2270.

[2] The party contending that a claim is preempted bears the burden of establishing preemption. *Jimeno v. Mobil Oil Corp.*, 66 F.3d 1514, 1526 n. 6 (9th Cir.1995). [FN6]

FN6. The Court notes that several Supreme Court cases describe a presumption against finding preemption, especially where state or local regulation of matters related to health and safety are concerned. *Hillsborough County v. Automated Medical Labs.*, 471 U.S. 707, 715, 105 S.Ct. 2371, 85 L.Ed.2d 714 (1985). Pfizer points out that cases like *Hillsborough* that employ the presumption do not address conflict preemption. The Court need not decide whether a presumption against preemption applies because the Court decides that Pfizer has not established preemption, even absent a presumption.

Pfizer makes no express or field preemption argument. Instead, Pfizer argues that "plaintiff's attempt to use state tort law to require warnings that Zolof causes suicide" conflicts with (1) FDA's various determinations regarding Zolof's and SSRI's warnings and (2) the federal statutory and regulatory objective of ensuring that labeling effectively communicates the scientific information physicians need to make informed judgments. Defendant's Motion, p. 16-17.

1. Conflict Preemption

a. Impossibility of Compliance

[3][4] In its opening motion papers, Pfizer asserts that federal law preempts plaintiffs' claims based on failure to warn because "the state law advocated by plaintiff would make it impossible for Pfizer to comply both with plaintiff's demands for additional warnings and with FDA's requirement that Pfizer use the exact labeling approved by the agency. See *Hurley v. Lederle Labs.*, 863 F.2d 1173, 1179 (5th Cir.1988)." Defendant's Motion, p. 19.

Plaintiff responds that because FDA standards for labeling are minimum standards, FDA approval of Pfizer's proposed label does not mean that state law claims based on that labeling are preempted. Opposition, p. 20, 22.

As plaintiff correctly argues, most courts have found that FDA regulations as to design and warning standards are minimum standards which do not preempt state law defective design and failure to warn claims. See, e.g., *Hill v. Searle Labs.*, 884 F.2d 1064, 1068 (8th Cir.1989) ("FDA approval is not a shield to liability ... FDA regulations are generally minimum standards of conduct unless Congress intended to preempt common law, which Congress has not done in this area."); *Kociemba v. Searle & Co.*, 680 F.Supp. 1293, 1299 (D.Minn.1988) ("The mere fact that the Cu-7 received FDA approval does not, by itself, indicate that Congress impliedly intended to preclude state tort actions against prescription drug manufacturers. This is especially true in light of the widely held view that FDA regulation of prescription drugs establishes minimum standards, both as to design and warning," citing *Graham v. Wyeth Labs.*, 666 F.Supp. 1483 (D.Kan.1987), *Brochu v. Ortho Pharmaceutical Corp.*, 642 F.2d 652 (1st Cir.1981) and *Salmon v. Parke Davis & Co.*, 520 F.2d 1359 (4th Cir.1975)); *Muzur v. Merck & Co.*, 742 F.Supp. 239, 247 (E.D.Pa.1990) ("mere compliance with FDA suggestion, or for that matter, regulation or order, does not mean that state tort law becomes irrelevant...[C]ompliance with an FDA regulation may establish that the manufacturer met the appropriate minimum standards of due care, but compliance does not necessarily absolve the manufacturer of all liability ... Manufacturers must meet state safety requirements, whether codified or embodied in the common law, in addition to satisfying initial FDA requirements"). Indeed, Pfizer cites not a single case holding that FDA prescription drug requirements preempted state law claims. [FN7]

FN7. Pfizer does however offer *Geier v. American Honda Motor Co.*, 529 U.S. 861, 120 S.Ct. 1913, 146 L.Ed.2d 914 (2000), for the proposition that even minimum standards may preempt state law tort claims. Reply, p. 5. But in *Geier*, the Supreme Court expressly found that the Department of

Transportation saw the disputed standard "not as a minimum standard, but as a way to provide a manufacturer with a range of choices among different passive restraint systems..." *Geier*, 120 S.Ct. at 1915, 1922 ("This lawsuit actually conflicts with [the safety standard]. DOT saw [the safety standard] not as a minimum standard ... In petitioners' and the dissent's view, [the safety standard] sets a minimum airbag standard ... But that was not the Secretary's view."). In any case, even if standards deemed "minimum" could conflict with state law tort suits, the warning labeling standards here do not because, as explained shortly, Pfizer has not established that federal regulations or FDA meant to prohibit Pfizer from strengthening its warnings.

*1093 So it is *Hurley* that Pfizer relies on for the proposition that an FDA determination of proper drug labeling can conflict with state law requiring additional or changed labeling. In *Hurley*, the Fifth Circuit held that federal regulations *did not* preempt the plaintiff's state law product liability claims based on the allegedly unreasonable dangerousness and inadequate warnings of a whooping cough vaccine. 863 F.2d at 1176-1177. In dicta, however, the *Hurley* Court stated that:

The defendants propose that the question of adequacy of the warning is preempted by federal law since the warning used was FDA approved ... This is the one question in this case for which the defendants' arguments on preemption are compelling ... In the area of approving warnings ... the FDA ... accepts information given by manufacturers proposing the licensing of a particular vaccine, and determines a proper warning based upon the information provided ... A state law determination on this issue should not be interjected to overrule the decision of the FDA. Such a procedure would place vaccine manufacturers in a position where they could not comply with both obligations. The FDA extensively regulates the contents and wording of these product inserts ... A manufacturer must first provide all the relevant information to the FDA, which then determines a warning it deems appropriate. The manufacturer is required to print that precise warning in its product insert ... Most important, the manufacturers cannot change the language in the product insert without FDA approval. 21 C.F.R. § 601.12. It would be patently inconsistent for a state then to hold the manufacturer liable for including that precise warning when the manufacturer would otherwise be liable for not including it ... [S]uch a case would fit one of the scenarios ... indicating preemption: the state statute actually and directly conflicts with federal law.

Hurley, 863 F.2d at 1179.

Hurley dealt with and depended on federal regulations

governing vaccines and other "biologics." The Court finds Pfizer's reliance on this language in *Hurley* misplaced. The dicta Pfizer relies on described one provision, 21 C.F.R. § 601.12, as "[m]ost important" to its statement of possible preemption. At the time *Hurley* was decided, 21 C.F.R. 601.12(b) stated that "[p]roposed changes in manufacturing methods and labeling may not become effective until notification of acceptance is received from the Director, Center for Biologics evaluation." [FN8] That provision formed the basis for the Fifth Circuit's decision that a "biologics" manufacturer could not simultaneously comply with FDA labeling requirements and a state law requiring different warnings. Neither party has indicated and nothing in the record indicates that the regulations governing "biologics" have any bearing on this case.

FN8. 21 C.F.R. § 601.12 was subsequently amended to allow certain labeling changes prior to FDA approval. 21 C.F.R. § 601.12(f)(2)(i).

The regulations that do apply here, but that did not apply in *Hurley*, militate strongly in favor of finding no conflict preemption, because they provide that Pfizer may strengthen Zolof's warnings *1094 without prior FDA approval. 21 C.F.R. § 314.70 is the federal regulation governing supplements to approved NDAs. It states that a change to labeling that "add[s] or strengthen[s] a contraindication, warning, precaution, or adverse reaction" is within the category of changes that "may be made before FDA approval." 21 C.F.R. § 314.70(c)(2)(i). Therefore, unlike in *Hurley*, here it is not true that "the manufacturers cannot change the language in the product insert without FDA approval" and is not true that a manufacturer "would otherwise be liable" for strengthening an FDA-approved warning. The FDA Commissioner's own comments support this view:

The commissioner also advises that these labeling requirements do not prohibit a manufacturer ... from warning health care professionals whenever possibly harmful adverse effects associated with the use of the drug are discovered. The addition to labeling ... of additional warnings ... is not prohibited by these regulations... In the case of an approved NDA, § 314.8(d) [now § 314.70(c)(2)(i)] permits the addition to the drug's labeling ... of information about a hazard without advance approval by the FDA ... At least one Court has held that an NDA holder may have a duty to add a warning before FDA approval of a supplemental application.

21 Federal Register 37447 (1979). There appears to be no inherent conflict between state law requiring a stronger warning for Zolof and the FDA's approval of Zolof's present warning.

In its Reply Memorandum, Pfizer supplements its argument from *Hurley* with additional "impossibility of compliance"

arguments based on a federal statute and regulations:

Since FDA has expressly and repeatedly found that there is "no credible evidence" to support an association between SSRIs and suicide any inclusion in Zolof's labeling of the warnings advocated by plaintiff would violate the statutory and regulatory prohibition against labeling that "is false or misleading in any particular." 21 U.S.C. § 355(e); 21 C.F.R. § 201.56(a)-(b). Inclusion of any such warning would violate the regulatory requirement that labeling must warn only of "[k]nown hazards and not theoretical possibilities" and must not include any "statement of differences of opinion." 21 C.F.R. § 201.57(d), 1.21(c)(1). It would violate the limitation that labeling statements are permitted "only if they are supported by scientific evidence." 44 Fed.Reg. 37434, 37441 (June 26, 1979).

Reply, p. 14-15.

First, several of the regulations cited by Pfizer do not apply to its alleged failure to warn. [FN9] It is true that 21 C.F.R. § 1.21(c)(1) states that § 1.21(a) does not "[p]ermit a statement of differences of opinion with respect to warnings..." but neither plaintiff nor defendant have asserted that plaintiff wishes to add such a statement. It is also true that 21 C.F.R. § 201.57(d) states that "[k]nown hazards and not theoretical possibilities shall be listed, e.g., if hypersensitivity to the drug has not been demonstrated, it should not be listed as a contraindication." But this language applies only to listing of "contraindications," or "those situations in which the drug should not be used because the risk of use clearly outweighs any possible benefit..." It does not apply to listings of "warnings"--which is what is at stake here and which is governed by a separate regulatory provision in § 201.57(e). Notably, Pfizer does not cite that regulation, which appears not to pose any conflict, in that it does not impose specific prohibitions. *1095 Section 201.57 delineates the "specific requirements on content and format of labeling for human prescription drugs" and subsection (e) specifically governs "warnings." In its entirety, subsection (e) states as follows:

FN9. Pfizer also cites to several comments of the FDA commissioner, which are now memorialized in the federal register, that come under the heading not of "warnings," but of "adverse reactions," a different part of prescription drug labeling that is subject to its own separate requirements. Reply, p. 15, Fed.Reg. 37453; 21 C.F.R. § 201.57(e) (governing warning labeling); 21 C.F.R. § 201.57(g) (governing adverse reaction labeling).

Under this section heading, the labeling shall describe serious adverse reactions and potential safety hazards, limitations in use imposed by them, and steps that should be taken if they occur. The labeling shall be revised to

include a warning as soon as there is reasonable evidence of an association of a serious hazard with a drug; a causal relationship need not have been proved. A specific warning relating to a use not provided for under the "Indications and Usage" section of the labeling may be required by the Food and Drug Administration if the drug is commonly prescribed for a disease or condition, and there is lack of substantial evidence of effectiveness for that disease or condition, and such usage is associated with serious risk or hazard. Special problems, particularly those that may lead to death or serious injury, may be required by the Food and Drug Administration to be placed in a prominently displayed box. The boxed warning ordinarily shall be based on clinical data, but serious animal toxicity may also be the basis of a boxed warning in the absence of clinical data. If a boxed warning is required, its location will be specified by the Food and Drug Administration. The frequency of these serious adverse reactions and, if known, the approximate mortality and morbidity rates for patients sustaining the reaction, which are important to safe and effective use of the drug, shall be expressed as provided under the "Adverse Reactions" section of the labeling.

Unlike the provision on "contraindications," which does seem to point out one type of statement that *may not* be included in the "contraindication" section of drug labeling, the provision on "warnings" very clearly lists only those statements that must be included, not statements that may *not* be included.

Although some of the federal statutory and regulatory law Pfizer cites does appear to apply to Zolof's warning label, that law does not establish conflict preemption because Pfizer has not established that plaintiff's theory of liability would require warnings that would violate federal law. It is true that prescription drug labeling may not be "false or misleading in any particular." 21 U.S.C. § 355(d); 21 C.F.R. § 201.56(b). It is also true that, as described in the federal register commentary and codified in section 201.56(a), labeling must be based on "the essential scientific information needed for the safe and effective use of the drug." 21 C.F.R. § 201.56(a); Fed Reg. 37441. But Pfizer has not attacked any specific warning as "false or misleading" or not based on "the essential scientific information needed" for safe use. Instead, Pfizer attacks plaintiff's general allegation of failure to warn. Defendant's Motion, p. 3-4. [FN10]

FN10. In fairness to Pfizer, plaintiff evidently has not yet identified the precise warning that she thinks Pfizer should have provided. As the Court stated at the hearing on this motion, this has proven vexing to the Court, too, because it would be much easier to analyze whether a supposedly necessary warning conflicted with the federal requirement if

one knew what the warning said.

The Court finds Pfizer's attack overbroad. Although certain suicide warnings could violate federal law because they were false or misleading or were not based on "the essential scientific information needed" for safe use, the Court does not think that any and every suicide-related warning that might be required under state law is necessarily false or misleading, or not based on "the essential scientific information needed" for safe use. For example, in her opposition, plaintiff discussed the SSRI warning recommended by the Medicines Control Agency, the British equivalent of the FDA: "occasionally, *1096 thoughts of suicide or self harm may occur or increase in the first few weeks of treatment with sertraline, until the antidepressant effect becomes apparent. Tell your doctor immediately if you have any distressing thoughts or experiences." Opposition, p. 23. In its Reply Memorandum, Pfizer did not refer to or attack this example of a warning. The Court has no basis to find that a restrained warning like this one is necessarily false or misleading, or not based on "the essential scientific information needed" for safe use. Therefore, the Court is not persuaded that to the extent that plaintiff's claims are based on failure to warn, they necessarily would violate federal law, regulations or policies.

Moreover, and perhaps most importantly, although FDA did not require Pfizer to include suicide-related warnings in Zolof's label, FDA has not prohibited Pfizer from doing so. On the occasions cited by Pfizer that FDA considered links between suicide and SSRIs, FDA did find that the evidence did not support requiring manufacturers to include additional suicide-related warnings. But FDA never stated that it would be impermissible to include additional warnings. This is consistent with the regulatory provision governing warning labels, 21 C.F.R. § 201.57(e), which indicates only those warnings that must be included in drug labeling, but does not prohibit any warnings.

Pfizer suggests that FDA *impliedly* prohibited additional suicide-related warnings, based on a comment of Dr. Paul Leber, the former Director of Neuropharmacological Drug Products, that "a labeling change of the sort contemplated by some" could be "false and misleading." Defendant's Motion, p. 10; Gaul, Dec., Exh.15. But Pfizer has not established that the labeling change "contemplated" by plaintiff's law suit is "a labeling change of the sort contemplated by some"; it is not clear just what "sort" of labeling change Leber is referring to; and, as discussed above, plaintiff has not limited herself to advocating any particular warning. Further, the Court does not agree that an excerpted comment of an FDA doctor, phrased as a hypothetical, made in ostensibly informal introductory comments to a meeting of the PDAC, and presented here

only in a footnote constitutes formal FDA prohibition of any and every strengthened suicide-related warning.

To summarize, several other courts have determined that FDA requirements are minimum standards and that FDA approval is not a shield to liability; 21 C.F.R. § 314.70(c)(2)(i) permits manufacturers to strengthen warning labels without prior FDA approval; Pfizer has not limited its attack to any specific warnings; and finally the FDA has not made any statement that Pfizer could not include a strengthened suicide warning. In light of these factors, the Court finds that Pfizer has not established that it would be impossible to comply simultaneously with FDA requirements and with a state law or decision requiring a strengthened warning.

b. Frustration of Congressional Purpose

Pfizer asserts that permitting plaintiff's state law claims for failure to warn would stand as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress:

Plaintiff seeks to require warnings that FDA has determined are not only unnecessary and unsupported by scientific data and information, but false, misleading and potentially harmful to the public. Such warnings would over deter use of the medicine, reduce the labeling's effectiveness in communicating necessary information to doctors, and impair the value of federally mandated labeling by undermining physicians' ability to rely on the labeling as scientifically based and accurate.

Defendant's Motion, p. 21.

Pfizer relies on many of the same regulations for its "frustration of purpose" argument that it relied on for its "impossibility of compliance" argument. Defendant's *1097 Motion, p. 21-22. Pfizer essentially argues that permitting a strengthened suicide warning in Zoloft's labeling would violate the federal purpose--embodied in the regulations--of ensuring that doctors act on accurate, scientifically established information. But the Court has already found that plaintiff's state law failure to warn claims do not conflict with federal statutory prohibitions and requirements because those claims do not necessarily call for false and misleading labeling or labeling not based on scientific information. The Court therefore also finds that plaintiff's state law "failure to warn" claims for relief do not necessarily conflict with the regulations' straightforward purpose of ensuring that doctors receive accurate, scientifically based information.

Pfizer also argues that permitting plaintiff to proceed with these claims would conflict with congressional purposes, because it would "overdeter" use of Zoloft. Defendant's Motion, p. 21-23. According to Pfizer, "[a]dding warnings that FDA has determined to be unsupported would give

physicians a false impression of the risks entailed in prescribing the drug, thereby deterring its use ... [and] ... would inhibit physicians from using the drug to provide their patients the available benefit..." *Id.* at 22.

At the hearing on this motion, counsel for Pfizer indicated that three sources, independent of FDA, supported this assertion. The first is "A Report of the Surgeon General on Mental Health." Declaration of Dr. Roger Lane ("Lane Dec."), Exh. 2. The Court has read the excerpt of this report that Pfizer submitted. Although it states that SSRIs are "a first-choice medication in treating depressed suicidal children and adolescents" and that "[t]he incidence of treatment related suicidal thoughts for the SSRIs is low and comparable to the rate observed for other antidepressants" it nowhere expressly addresses the issue of overdeterrence. Exh.2, p. 58,61.

Next, Pfizer's counsel referred to a statement of the American Psychiatric Association ("APA"). The Court found one exhibit in Dr. Lane's Declaration that the APA published but this document merely listed the "criteria for major depressive episode[s]" and has no relation to overdeterrence. Lane Dec., Exh.3. However, on November 28, 2000, the day after the hearing on this motion, Pfizer filed an APA "news release" to which Pfizer's counsel had referred. The "news release" concerns the FDA's denial of CCHR's petition to ban Prozac outright. It does indeed state that "our members have reported to us that the CCHR media campaign to discredit Prozac frightened many people with depression into discontinuing their medicine without first discussing it with their physicians, and discouraged others from seeking needed treatment." But the mere fact that a negative media campaign may have overdeterred prospective SSRI users does not mean that a modest warning label that Doctors could evaluate would do the same thing. Indeed, the "news release" itself states that psychiatrists routinely warn patients that antidepressants may contribute to suicidal action: "([m]any patients, however, are so depressed that they don't have the energy to act on [suicidal] thoughts," "antidepressants ... may lead to an increase in energy before it eliminates suicidal thoughts" and "[p]sychiatrists routinely alert patients and their families to this possibility...").

Third, Pfizer's counsel directed the Court's attention to the American College of Neuropsychopharmacology's Consensus Statement on Suicidal Behavior and Psychotropic Medication. Lane Dec., Exh.6. The Statement does assert that "[t]here is no evidence that antidepressants such as ... fluoxetine trigger emergent suicidal ideation over and above rates that may be associated with depression and other antidepressants." Exh.6, p. 112. However, the Statement does not explicitly address the overdeterrence issue. Moreover, it indicates that "case reports suggest that a

small minority of patients may experience *1098 emergent suicidal thoughts or evince such behavior during the pharmacological treatment of depression" and that "[p]atients should be warned that suicidal ideation may occasionally worsen in the course of treatment ... and that such an event would be a reason for immediately contacting their doctor. Applying this standard clinical practice to all patients would constitute a reasonable safeguard in the event that there are, indeed, a small minority of vulnerable patients who are at risk for emergent suicidal ideation." *Id.* at 112, 114.

In sum, the Court finds an absence of persuasive evidence establishing a threat of overdeterrence from strengthening suicide warning labeling for SSRIs. Indeed, several of the sources suggest that overdeterrence is not a concern because they recommend providing modest warnings that antidepressants may contribute to suicidal thoughts or action.

Pfizer also asserts that FDA's own rationale for rejecting strengthened suicide warnings for SSRIs was concern about overdeterrence. In support, Pfizer cites to the opening remarks to a PDAC committee meeting of Dr. Paul Leber, the then-Director of the FDA Division of Neuropharmacological Drug Products. Leber stated that:

It is very difficult for us to be Solomon-like in situations as complex and vexing as this ... We have to recognize that the 'net effect' of 'modifying antidepressant drug labeling' 'might be a reduction in the use of antidepressants in the treatment of depression, and that the result might cause overall injury to the public health ... many letters we receive ... emphasize this point. Whether they are correct or not, I am not going to speak to that, but certainly it is a concern.'

DSUF, ¶ 37; Gaul Dec., Exh. 14, p. 662-3. Further, the "Excerpted Comments" of Dr. Leber's remarks state that "if Prozac is not more likely to induce suicidal thoughts, acts and other violent behaviors, a labeling change of the sort contemplated by some, beyond being false and misleading, might well have a net adverse effect." *Id.*

The Court is not persuaded that FDA has found or has relied on a finding that strengthened suicide warnings would overdeter SSRI use. First, Leber's comments state only that strengthened suicide warnings "might" overdeter SSRI use. Leber himself states that:

[i]t is easy enough for me to understand why someone could conclude it would be constructive and in the interest of public health to inform individuals using the drug, and the practitioners, about the high rate of reporting ... [I]t is not difficult to appreciate the arguments of those who advocate what have you got to lose? Why not at least point out that some people believe there is a special linkage between Prozac and suicidal ideation.

Exh. 14, p. 663. Leber's introductory comments set out

different positions on SSRI labeling and do not discuss "whether they are correct or not." *Id.* at 662. Second, Pfizer has not established that Leber's ostensibly informal introductory comments to a committee meeting represent the formal position of the FDA.

The evidence Pfizer cites does not establish a threat of overdeterrence or a congressional purpose of preventing overdeterrence. [FN11] Thus, Pfizer has not presented surveys, statistical data or other facts. Pfizer may be correct in its assertion ... but it may not be. Potential users of Zoloft might continue to ingest it but simply be more vigilant about noticing the emergence of or an increase in suicidal ideation and more likely to call their doctor in the event of an adverse reaction.

FN11. Pfizer presents no legislative history or other evidence suggesting that in creating the FDA and enacting drug laws Congress intended to prevent or even considered overdeterrence of drug use.

*1099 Pfizer also argues, based on *Chicago and Northwestern Transportation Co. v. Kalo Brick & Tile Co.*, 450 U.S. 311, 101 S.Ct. 1124, 67 L.Ed.2d 258 (1981), that preemption is appropriate because FDA's approval of Pfizer's labeling for Zoloft and determination that Pfizer was not required to add to the label should be "entitled to considerable deference." Defendant's Motion, p. 25. In *Kalo Brick*, a shipper brought an action against a railroad to recover under state law for failure to provide adequate rail service. The railroad had abandoned a railroad line and, pursuant to the Interstate Commerce Act ("ICA"), the Interstate Commerce Commission ("ICC") had approved that abandonment. The Supreme Court held that the ICA preempted the shipper's state law claims. *Id.* at 327, 101 S.Ct. 1124. Pfizer argues that *Kalo Brick* is instructive because in both that case and here an agency was empowered to approve defendant's challenged conduct, balanced the relevant interests and then approved the conduct. Defendant's Motion, p. 24-5.

Kalo Brick is inapposite. In that case, the Supreme Court specifically held that the "findings by the Commission, made pursuant to the authority delegated by Congress, simply leave no room for further litigation over the matters respondent seeks to raise in state court." *Id.* at 327, 101 S.Ct. 1124. In accordance with that holding, the Court repeatedly emphasized the pervasive and exclusive nature of the ICA:

The [ICA] is among the most pervasive and comprehensive of federal regulatory schemes...[T]he authority of the [ICC] to regulate abandonments is exclusive ... The breadth of the Commission's statutory discretion suggests a congressional intent to limit judicial

interference ... The Act in fact spells out with considerable precision the remedies of a shipper ... Congress intended that an aggrieved shipper should seek relief in the first instance from the Commission ... It would vitiate the overarching congressional intent of creating an efficient and nationally integrated railroad system ... to permit the State of Iowa to use the threat of damages to do exactly what the Commission is empowered to excuse. A system under which each State could, through its own courts, impose on railroad carriers its own version of reasonable service requirements could hardly be more at odds with the uniformity contemplated by Congress in enacting the [ICA].

Kalo Brick, 450 U.S. at 318, 321-2, 323, 325-6, 101 S.Ct. 1124. In contrast, several courts have held that food and drug regulation and FDA determinations regarding labeling standards are not so broad or exclusive as to preempt state law claims. See *supra* at p. 10-11. Because *Kalo Brick* was based largely on the pervasive and exclusive nature of the ICA, it does not require preemption here.

In sum, the Court finds that Pfizer has failed to establish that plaintiff's state law failure to warn claims conflict with congressional purposes.

In fact, the Court notes that permitting plaintiff's state law "failure to warn" claims may complement the congressional purposes of FDA regulations. Pfizer does not dispute that the FDA and its governing statute and regulations serve the purpose of enhancing drug safety. Defendant's Motion, p. 20-21; 21 U.S.C. § 355(d) and 393(b)(2)(B). As plaintiff asserts, state law suits against drug manufacturers for defective drug design or failure to warn can serve the same public safety purpose as federal regulations by punishing perpetrators and thus preventing future harm. [FN12] *Bansener v. Smith* *1100 Lobs., 1990 WL 132579, *3 (E.D.Wis.1988). Indeed, state suits may complement the regulatory methods of promoting safety by directly flushing out more information about the risks of drugs and indirectly encouraging manufacturers to make complete risk disclosures to the FDA. *Id.* at *4 (quoting *Ferebee v. Chevron Chemical Co.*, 736 F.2d 1529, 1541-42 (D.C.Cir.1984)). [FN13]

FN12. The Court acknowledges that just because federal law and state law serve the same general purpose does not mean that no conflict can exist. Defendant's Motion, p. 20 (citing *Geier v. American Honda Motor Co.*, 529 U.S. 861, 120 S.Ct. 1913, 1923-25, 146 L.Ed.2d 914 (2000)). However, the Court has examined Pfizer's asserted bases for a conflict and has rejected them.

FN13. Plaintiff asserts that the FDA has itself acknowledged "the importance of jury verdicts and

the fact that they can help the FDA learn about the dangers of drugs." Opposition, p. 24. Plaintiff cites the following language from the FDA's denial of the CCHR petition to withdraw approval of Prozac: "On the other hand, an actual court finding of a causal relationship between Prozac and violent behavior would be relevant. In that event, the agency would be able to evaluate the scientific basis for the court's conclusion and consider whether the court's conclusion warranted a modification of its own position." Gaul Dec., Exh. 12, p. 513. FDA made this comment in response to CCHR's assertion that several lawsuits had been filed against Lilly based on Prozac's alleged causation of tardive dyskinesia. FDA's response was that mere filings are irrelevant but that actual court findings could be. Although the factual context of the comment is different from the circumstances here (e.g., different drug, different alleged adverse effect), the comment nonetheless does indicate that judicial findings based on scientific evidence may play a role in FDA determinations and could affect FDA's position on the issue of health risks.

B. Bar under California Law

[5] Pfizer argues that plaintiff's California state law strict liability inadequate warning claims are barred under the California Supreme Court case of *Carlin v. Superior Court*, 13 Cal.4th 1104, 1115, 56 Cal.Rptr.2d 162, 920 P.2d 1347 (1996). In *Carlin*, a prescription drug user brought a products liability action against a drug manufacturer for failure to warn about known or reasonably scientifically knowable dangerous propensities of a drug. Despite the defendant's argument that permitting plaintiff's strict liability claims to proceed would create a conflict with FDA labeling regulations, the Court held that plaintiff successfully stated a cause of action for strict liability premised on failure to warn. *Carlin*, 13 Cal.4th at 1113, 1118, 56 Cal.Rptr.2d 162, 920 P.2d 1347. Pfizer nevertheless relies on the following dicta from *Carlin*:

[I]n the case of an alleged "known" risk, if state-of-the-art scientific data was fully disclosed to the FDA and it determined, after review, that the pharmaceutical manufacturer was not permitted to warn—e.g., because the data was inconclusive or the risk was too speculative to justify a warning—the manufacturer could present such evidence to show that strict liability cannot apply; the FDA's conclusion that there was, in effect, no "known risk" is controlling.

Carlin, 13 Cal.4th at 1114-1115, 56 Cal.Rptr.2d 162, 920 P.2d 1347. Based on this dicta, Pfizer argues that because FDA has not found that SSRIs cause suicide, plaintiff cannot establish that Pfizer knew that SSRIs and Zoloft

cause suicide and therefore cannot make out a strict liability claim. Defendant's Motion, p. 15.

The Court rejects this argument. First, the language Pfizer relies on is only dicta and did not affect the Court's ultimate holding that plaintiff's claims *could* proceed. Second, the dicta refers only to the effect on FDA determinations on the issue of "known risks"; it does not say anything about the other possible basis that a plaintiff may, and that Motus did, assert for strict liability failure to warn claims--namely, that a manufacturer reasonably *should have known* about certain risks. Complaint, ¶ 33 ("defendants knew or should have known that their product was unsafe."). Third, the dicta does not state that an FDA determination is wholly preemptive; it instead states merely that "the manufacturer could present such evidence [of FDA's determination] to show that strict liability cannot apply," which is consistent with the California Supreme Court's statement that: "[i]n appropriate cases, FDA action or inaction, *though not *1101 dispositive*, may be admissible ... to show whether a risk was known ..." *Carlin*, 13 Cal.4th at 1114, 1115, 56 Cal.Rptr.2d 162, 920 P.2d 1347 (emphasis added). Fourth, the dicta expressly states that it applies only to those situations in which FDA "determined, after review, that the pharmaceutical manufacturer was not permitted to warn ..." The Court has already found that FDA has never determined that Pfizer was not *permitted* to strengthen the Zoloft suicide warning, but instead determined only that Pfizer was not *required* to include strengthened warnings. For these reasons, *Carlin* is inapposite. [FN14]

FN14. Plaintiff attacks *Carlin*'s dicta because it requires that "state-of-the-art scientific data concerning the alleged risk was fully disclosed to the FDA..." and plaintiff asserts that Pfizer did not disclose all risk-related data to FDA. Opposition, p. 10. It is not clear that this issue may be or need be evaluated by the Court and the Court does not reach it on this motion.

CONCLUSION

For the foregoing reasons and good cause appearing therefor, the Court DENIES defendant's motion for partial summary judgment.

IT IS SO ORDERED.

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COPY

NO. A094460

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

PAUL A. DOWHAL,
an individual,

Plaintiff and Appellant

v.

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

Defendants and Respondents.

On Appeal From A Judgment Based On An Order Granting
Motion for Summary Judgment and Denying
Cross Motion for Summary Adjudication

Superior Court of the State of California For
The County of San Francisco
Honorable David A. Garcia, Judge Presiding

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

FILED
Court of Appeal - First App. Dist.

MAR 25 2002

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By _____ DEPUTY

**AMICUS CURIAE BRIEF OF THE UNITED STATES OF AMERICA
IN SUPPORT OF DEFENDANTS/RESPONDENTS
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STATEMENT OF THE INTEREST OF THE UNITED STATES

Plaintiff-Appellant Paul Dowhal challenges the Superior Court's holding that federal law preempted a state labeling requirement for over-the-counter nicotine replacement therapy products marketed by Defendants-Respondents SmithKline Beecham, et al. The United States has a substantial interest in this Court's resolution of that issue. On the merits of the issue, the United States appears as an amicus curiae in support of Defendants because it concurs that federal law preempted a labeling requirement that Plaintiff sought to apply to Defendants under state law.

The Food and Drug Administration ("FDA"), a component of the Department of Health and Human Services, is responsible for regulating drugs. These drugs include over-the-counter drug products, as defined by the Food, Drug, and Cosmetic Act ("FDCA" "the Act").¹ The FDCA's comprehensive scheme of drug regulation ensures that drugs are safe and effective for their intended uses. The Act specifically authorizes FDA to regulate the labeling of drug products, including appropriate warnings on over-the-counter drugs.² An over-the-counter drug is deemed misbranded under the FDCA when "[i]ts labeling is false or misleading in any particular." It is also misbranded "[u]nless its labeling bears . . . such adequate warnings against

¹ 21 U.S.C. § 301 *et seq.* The FDCA vests regulatory and enforcement authority in the Secretary of Health and Human Services. See, e.g., 21 U.S.C. §§ 371-377; § 321(d). The Secretary has delegated his authority to the Commissioner of the FDA. 21 CFR 5.10. See also 21 U.S.C. § 393 (duties and powers of the FDA).

² 21 U.S.C. § 352(a), (f); 21 CFR Part 201, Subpart C.

use . . . where its use may be dangerous to health . . . in such manner and form as are necessary for the protection of users."³

In granting summary judgment for Defendants, the trial court accepted their argument that compliance with the warning that Dowhal claimed was necessary to satisfy California law would require them to violate their product labeling duties under the FDCA. Therefore, the court determined that the FDCA preempted any California law requirement that imposed different obligations with respect to product labeling on these nicotine replacement therapy products. This Court's disposition of Dowhal's challenge to that ruling implicates FDA's interest in drug regulation.

1. STATUTORY AND REGULATORY BACKGROUND

A. THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

The FDCA prohibits the misbranding of drugs in interstate commerce and empowers FDA to regulate the labeling of drug products, including the warnings on over-the-counter drugs.⁴ Under the statute, an over-the-counter drug is misbranded where its labeling is false or misleading in any particular or if its labeling does not contain adequate warnings against any use dangerous to health.⁵ FDA's regulations establish specific requirements for over-the-counter drug product labeling. These requirements are designed to mandate warnings that reflect the known risks based on reliable scientific evidence.⁶

³21 U.S.C. §§ 352(a), 352(f).

⁴21 U.S.C. §§ 331(a), (b), (k), 352(a), (f); 21 CFR Part 201, Subpart C.

⁵21 U.S.C. §§ 352(a), 352(f).

⁶See 21 CFR 201.63(a), 201.66(c)(5)(iii)(iv)(ix).

After reviewing new drug applications ("NDAs") submitted to the agency by the individual manufacturers, FDA approved Defendants' nicotine replacement therapy products.⁷ In submitting an NDA for a specific drug product for an intended use, an applicant must provide "full reports of investigations which have been made to show whether or not such drug is safe for use and whether such drug is effective for use."⁸ An applicant must also include "adequate tests by all methods reasonably applicable to show whether or not such drug is safe for use under the conditions prescribed, recommended, or suggested in the proposed labeling."⁹ In addition, applicants must furnish "substantial evidence that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the proposed labeling."¹⁰ "Substantial evidence" must consist of adequate and well-controlled investigations, including clinical investigations by suitably qualified experts that provide a reasonable basis for concluding that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in its labeling.¹¹

Because an evaluation of a drug product's effectiveness in conjunction with FDA review of an NDA is inextricably intertwined with the proposed labeling for the product, an applicant must submit proposed labeling along with the NDA.¹² In evaluating an NDA, FDA reviews all

⁷FDA has approved other over-the-counter nicotine replacement therapy products marketed under Abbreviated New Drug Applications. 21 U.S.C. § 355(j).

⁸21 U.S.C. § 355(b)(1)(A).

⁹21 U.S.C. § 355(d).

¹⁰21 U.S.C. § 355(d)(5).

¹¹21 U.S.C. § 355(e).

¹²21 U.S.C. § 355(b)(1)(F).

the information submitted along with it to determine whether there is substantial evidence that the product will be effective and whether the benefits associated with the product outweigh any associated risks. Where the agency concludes both that the product will be effective and safe, FDA then determines how the relevant product information should be presented to the doctor. With respect to over-the-counter drugs, FDA determines how the information should be presented to the consumer in the product labeling.

Drug product labeling reflects not only the evidence submitted by the applicant in support of the NDA but also FDA's review of other relevant information. Such information may include studies completed during the drug development process, information about the chemical entity and how it acts in the body, information concerning the safety of similar drugs, and information concerning whether the drug is known to interact with any other substances. This information may also be included in the required labeling if it provides facts that a physician should know before prescribing the drug to a patient or information that a consumer should know before taking a drug.

What constitutes appropriate labeling for a drug product is not always obvious. Therefore, drug sponsors often have a dialogue with FDA about what should appear on a particular drug label. But when FDA ultimately approves an NDA, it also approves the final version of the product label. Because FDA cannot approve product labeling that would render a product misbranded, any product labeling must provide adequate directions for use and not be false or misleading.¹³

¹³21 U.S.C. § 352(a), (c), (f).

FDA Approval of Drug Product Labeling Changes

Once FDA has approved an NDA, an applicant generally may not deviate from FDA-approved product labeling without submitting an NDA supplement that provides a full explanation of the basis for the change.¹⁴ FDA permits two kinds of labeling supplements: (1) "pre-approval supplements," which require FDA approval before a change occurs; and (2) "changes being effected supplements," which may be implemented before FDA approval.¹⁵ In either case, an applicant must provide supporting information for the proposed change, or alert FDA to the existence of such information elsewhere. The supporting evidence may take several forms, including company-conducted or independent studies, published reports, and compilations of adverse events. FDA evaluates the scientific evidence pertaining to the proposed change. It then determines whether the proposed labeling change is appropriate based on such factors as the frequency of the risk of a side-effect/bad outcome, the severity of the potential risks, and the potential benefits and risks associated with the proposed warning.

Unless the proposed changes are minor, an applicant typically submits labeling changes in a pre-approval supplement. Where an applicant uses a "changes being effected" supplement, its evidentiary obligations are not reduced. Thus, although use of a "changes being effected" supplement permits a manufacturer to make labeling changes upon filing its supplement, the regulation still requires the manufacturer to "give a full explanation of the basis for the change."¹⁶ Therefore, although an applicant may implement a labeling change immediately, it must still give

¹⁴21 CFR 314.70.

¹⁵21 CFR 314.70(b),(c).

¹⁶21 CFR 314.70(c).

FDA a full explanation of the basis for the change that it has made. The more significant the proposed labeling change, the greater the explanation required. Accordingly, a drug manufacturer must have the same sound basis in scientific evidence for making a labeling change under this provision as it needs to obtain agency approval of a labeling change using the normal pre-approval supplement process.

If the agency disagrees with the changes made based on its evaluation of the evidence supporting the change, FDA notifies the company that the change is not approved. Should the company market the product using that unapproved labeling, it would violate the FDCA's prohibitions against marketing an unapproved new drug and against marketing a misbranded drug.¹⁷

Thus, in actual practice, only minor product labeling changes, like an editorial change, deletion of an ingredient affecting only the color of a drug product, or changes in the container or closure system for the drug product are generally made without FDA's prior approval. Furthermore, given the expense associated with any labeling change, manufacturers are reluctant to proceed under the provision allowing them to make a labeling change before getting FDA approval because it carries a risk that FDA will ultimately deny approval and thereby require another labeling change.

¹⁷21 U.S.C. §§ 352, 355(a).

B. THE FOOD AND DRUG ADMINISTRATION MODERNIZATION ACT

In 1997, Congress amended the FDCA by enacting the Food and Drug Administration Modernization Act ("the Modernization Act").¹⁸ These amendments to the FDCA added an express preemption provision for over-the-counter drug labeling. That provision expressly preempts any state requirement for over-the-counter drugs that is "different from, in addition to, or otherwise not identical with" an FDA requirement.¹⁹ This section also includes an exception from federal preemption for state laws adopted by public initiative or referendum enacted before September 1, 1997.²⁰

C. CALIFORNIA PROPOSITION 65

In 1986, California adopted the Safe Drinking Water and Toxic Enforcement Act, also known as Proposition 65.²¹ Under Proposition 65, in the course of doing business, persons must provide a clear and reasonable warning before exposing any individual to a chemical known to the state to cause cancer or reproductive toxicity.²² Such a warning must clearly communicate that the chemical is known to the state to cause cancer, birth defects, or other reproductive harm.²³ The regulations promulgated under Proposition 65 also provide "safe harbor" warning messages that are deemed to satisfy the requirement for a clear and reasonable warning. With

¹⁸Pub. L. No. 105-115, 111 Stat. 2296 (1997).

¹⁹21 U.S.C. § 379r(a).

²⁰21 U.S.C. § 379r(d)(2).

²¹California Health and Safety Code § 25249.5, *et seq.*

²²California Health and Safety Code § 25249.6.

²³22 California Code of Regulations § 12601(a).

respect to the nicotine therapy replacement products at issue here, that "safe harbor" warning consists of the following language: "Warning: This product contains a chemical known to the State of California to cause birth defects or other reproductive harm."²⁴ Proposition 65 also includes a statutory federal preemption exemption, which excludes from coverage exposures to chemicals for which federal law governs the warnings in a manner that preempts state authority.²⁵

Proposition 65 requires the Governor to publish a list of those chemicals known to cause cancer or reproductive harm. The Governor must cause that list to be revised at least annually to reflect additional knowledge.²⁶ Inclusion of a chemical on such a list is required where the chemical is known to the state to cause cancer or reproductive harm: (1) based upon the opinion of the state's qualified experts relying on scientifically valid testing, (2) based upon a determination by a body deemed to be authoritative by the state's qualified experts and the state's lead agency, or (3) based upon a requirement imposed by a state or federal agency that formally mandates that the chemical be labeled or identified as causing cancer or reproductive harm.²⁷

As a general matter, California has deferred to FDA's expertise concerning regulation of drug products by adopting FDA regulations for purposes of California law.²⁸ More important, California has designated FDA as one of four authoritative bodies empowered to designate

²⁴22 California Code of Regulations § 12601(b)(4)(B).

²⁵California Health and Safety Code § 25249.10(a).

²⁶California Health & Safety Code § 25249.8.

²⁷Id. California's regulation also addresses the requirements for a cognizable identification by an authoritative body of a chemical as causing reproductive toxicity. The pertinent regulation also provides for notice and public comment before a chemical may be added to the list of potentially hazardous chemicals.

²⁸California Health and Safety Code § 110111.

chemicals as reproductive toxins under Proposition 65.²⁹ Moreover, when it listed nicotine as a reproductive toxin under Proposition 65 on April 1, 1990, California relied upon FDA's action requiring a reproductive health warning to be included in the warning labeling for the prescription form of nicotine replacement therapy products as the sole basis for that listing.³⁰ Thus, California made no independent assessment of the potential reproductive toxicity of the nicotine contained in these products. Nor did it rely on a determination by any other entity deemed an authoritative body under the state's regulations.

II. STATEMENT OF THE FACTS

A. Dowhal's State Court Action

In 1998, Dowhal asked the California Attorney General to initiate an enforcement action against SmithKline Beecham and other drug manufacturers that marketed nicotine replacement therapy products in California on the ground that the warnings in their product labeling did not meet the requirements of Proposition 65. In pertinent part, FDA's approved warning for Defendants' products advised users as follows:

If pregnant or breast-feeding, ask a health professional before use. Nicotine can increase your baby's heart rate. First try to stop smoking without the [name of product].

Exh. 1 to Joint Request For Judicial Notice at 5. Beginning in 1996 and continuing through 2001, in response to specific inquiries, FDA repeatedly advised Defendants that they might be

²⁹California Health & Safety Code § 25249.8; 22 California Code of Regulations § 12306(b), (k), (l)(4). The other entities designated as authoritative bodies are the International Agency for Research on Cancer, the National Institute for Occupational Safety and Health, and the United States Environmental Protection Agency.

³⁰See J.A. 1562.

liable for selling misbranded articles if they deviated from the FDA-approved warning labeling for these nicotine replacement therapy products. See Respondents Brief at 10-14, 18-20. Furthermore, FDA gave that advice on several occasions in response to a Defendant's inquiry concerning possible use of warnings that were proposed as compliant with Proposition 65. J.A. 1499-1501, 1504-06, 1514-17, 1520-21, 1568-69, 1571, 1632-36, 2401.

In a May 6, 1998 letter to FDA, the California Attorney General questioned whether Defendants' FDA-approved product labeling satisfied the requirements of Proposition 65. In its written response, FDA advised the California Attorney General that Defendants' warning labeling clearly and accurately identified the reproductive risks associated with their nicotine replacement therapy products and therefore met the FDCA's labeling requirements. FDA also opined that Defendants' warning labeling appeared to satisfy the California Attorney General's standards with respect to Proposition 65 because the warnings were "clear and reasonable." J.A. 1558-1561. After receiving FDA's letter, the Attorney General did not initiate an enforcement action.

On August 23, 1999, Dowhal filed this action in the Superior Court of the State of California, San Francisco County. He alleged that Defendants had committed past violations as well as ongoing violations of Proposition 65 by knowingly and intentionally causing women to be exposed to nicotine through the use of their products without providing the warnings that Proposition 65 required. In addition to civil penalties and restitution, Dowhal sought to enjoin Defendants to include with their products particular warnings that significantly differed from the warnings required by FDA. Plaintiff sought an injunction requiring Defendants to use the "safe harbor" warning set forth at page 8 supra in their labeling or, alternatively, to require them to include either the following warning or a comparable one:

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.

Exh. 1 to Jt. Request For Judicial Notice at 5 (emphasis added). Defendants opposed that request because federal law controlled the contents of these warnings and preempted any state law requirements mandating inconsistent labeling that would render the products misbranded under the FDCA.

B. The Superior Court's Decision

Ruling on cross-motions for summary judgment in a March 12, 2001 order, the Superior Court concluded that Defendants were entitled to summary judgment because federal law preempted application of Proposition 65 with respect to the warnings that they used in their product labeling. J.A. 2429-2432. Applying the doctrine of conflict preemption, the trial court held that the product warnings that FDA had approved for Defendants' use in marketing their products preempted the alternative warning requirements that Dowhal asserted were mandated by Proposition 65. The Superior Court reasoned that the applicability of conflict preemption was unaffected by the express statutory preemption clause and its exception in the Modernization Act. It then concluded that conflict preemption applied because Defendants could not comply with both FDA's warnings and the warnings Dowhal claimed were mandated by Proposition 65. Furthermore, the court found conflict preemption applicable because Dowhal's proposed warnings would frustrate the federal purpose of ensuring that warnings accurately reflect the known health risks associated with drug products.

C. FDA's Disposition Of Dowhal's Citizen Petition

On August 2, 2000, one year after he filed his complaint, Dowhal filed a citizen petition with FDA asking the agency to change the warnings required in the labeling of nicotine replacement therapy products. Again, Dowhal asked FDA to require Defendants and any other manufacturers of a similar product to include a warning like the "harm your baby" warning set forth at page 11 supra.

On August 17, 2001, FDA responded to Dowhal's petition. Based on its review of the relevant information, including the information furnished by Dowhal in support of his citizen petition, FDA declined to adopt the warnings he proposed. Exh. 1 to Jt. Request for Judicial Notice. Instead, FDA asked each sponsor of a nicotine replacement therapy product to submit to the agency a labeling supplement with a new pregnancy warning containing the following wording:

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.

This warning reflected language deemed appropriate by FDA given current knowledge about the use of nicotine replacement therapy products during pregnancy. It reflected a proper balance concerning the need to warn about the harms associated with continued smoking during pregnancy, the benefits of total nicotine abstinence, the need to provide information about the known risks of nicotine replacement therapy products, and the need to provide information about the relative risks of these products in comparison to the risks of smoking. In adopting this

warning. FDA also determined that the Dowhal's proposed warning lacked sufficient support in scientific evidence.

As the FDA ultimately determined in addressing Dowhal's citizen petition, neither the "safe harbor" warning nor Dowhal's proposed "harm your baby" warning provided appropriate information concerning the nature of the risk posed by nicotine in the products. The absence of such information creates a danger that consumers may be misled about the risks associated with the products, which may result in consumer decisions concerning product use based upon an inaccurate array of information. The presentation of incomplete and misleading information in such warning labeling renders a product misbranded under the FDCA.

SUMMARY OF THE ARGUMENT

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. Therefore, under the doctrine of conflict preemption, Proposition 65 could not be applied to Defendants' warning labels if it required Defendants to use Dowhal's proposed warning labeling. Conflict preemption would also apply because state law would pose an obstacle to the accomplishment of the full purposes and objectives of a federal statute, the FDCA.

1. In rejecting Dowhal's proposed warning in the context of addressing his citizen petition on August 17, 2001, FDA determined that Proposition 65 would conflict with the FDCA if it required use of Dowhal's proposed warning labeling. Thereafter, any state requirement mandating use of labeling that differed significantly from the FDA-approved labeling would be preempted. Moreover, where a federal agency has implemented a statute that it is charged with administering, its action may also be applied to conduct that occurred before the agency

announced that decision. Therefore, FDA's construction of the FDCA's misbranding prohibition with respect to Dowhal's proposed warning labeling applies equally to Defendants' antecedent conduct.

Moreover, just as the doctrine of primary jurisdiction allows a trial court to rely upon an agency explanation issued after the filing of a lawsuit, this Court now may properly rely on FDA's application of the FDCA's misbranding provision in the agency's August 17, 2001 determination in order to affirm the Superior Court's grant of summary judgment for Defendants. Furthermore, FDA's determination concerning appropriate warning labeling reflects the agency's application of its unrivaled expertise to the relevant data. Because Congress has entrusted FDA to make any necessary judgments concerning what labeling provides the warnings necessary to avoid misbranding a product, a state court should defer to FDA's assessment and apply it in a way that assures the proper functioning of a comprehensive federal regulatory plan.

Conflict preemption also applies here because requiring Defendants to use Dowhal's proposed warning labeling to meet their duties under Proposition 65 would pose an obstacle to the accomplishment of the full purposes and objectives of Congress. State law must be applied here in a way that preserves the latitude necessary for the federal regulatory scheme to operate as Congress intended. FDA repeatedly cautioned the Defendants against changing their warning labeling unless they had an adequate factual basis to do so. Tellingly, Defendants had no new facts to present to FDA to support different warning labeling. Under these circumstances, applying Proposition 65 to require Defendants to use Dowhal's proposed warning labeling would thwart attainment of the goals Congress sought to achieve under the FDCA.

2. Plaintiff erroneously contends that the Modernization Act exempts Proposition 65 from displacement under conflict preemption principles. The Superior Court correctly held that the Modernization Act affects only express preemption, not conflict preemption.

ARGUMENT

I. THE FDCA PREEMPTS THE ENFORCEMENT OF PROPOSITION 65 AS A STATE LAW BECAUSE IT WOULD CONFLICT WITH THE REQUIREMENTS OF FEDERAL LAW AND POSE AN OBSTACLE TO ACCOMPLISHING THE OBJECTIVES OF THIS FEDERAL STATUTE.

To assure adherence to the Supremacy Clause of the United States Constitution, federal law preempts enforcement of state law in certain circumstances.³¹ Thus, federal law preempts state law where Congress has expressed a clear intent that a federal statute have that effect. Even absent explicit preemption language in a statute, federal law preempts state law where Congress has clearly intended to legislate comprehensively and thereby precluded the states from supplementing federal law. Finally, federal law preempts state law where compliance with both federal and state law is impossible or where state law poses an obstacle to accomplishing the full purposes and objectives of Congress as expressed in a statute.³²

By enacting the FDCA, Congress established a comprehensive scheme of drug regulation. That regulatory plan promotes the important interest of protecting consumers from unsafe drugs. To advance that interest, the FDCA operates to ensure that drugs on the market are safe and effective. Thus, the FDCA prohibits the sale of misbranded drugs,³³ which it identifies as drugs

³¹U.S. Const. art. VI, cl. 2.

³²United States v. Locke, 529 U.S. 89, 109 (2000); Geier v. American Honda Motor Co., 529 U.S. 861, 873 (2000); Capital Cities Cable, Inc. v. Crisp, 467 U.S. 691, 698-99 (1984).

³³See 21 U.S.C. § 331(b).

that lack adequate warnings.³⁴ Given the comprehensive nature of drug regulation under this federal law, any state regulation must be compatible with the regulatory plan established under the FDCA.

Here, conflict preemption applies because requiring Defendants to use Dowhal's proposed warning labeling to meet their duties under Proposition 65 would conflict with federal law and pose an obstacle to accomplishing Congress's full purposes and objectives.³⁵

A. Application Of Proposition 65 To Require Defendants To Use Dowhal's Proposed Warnings Would Make It Impossible For Them To Comply With Both Federal and State Law.

In support of the agency's role in assuring that misbranded drugs are not sold, Congress gave FDA authority to regulate the labeling of drug products. FDA's authority includes the power to require appropriate warnings on over-the-counter drugs and prohibit the sale of misbranded drug products.³⁶ Under the Act, an over-the-counter drug is deemed misbranded when "[i]ts labeling is false or misleading in any particular" or "[u]nless its labeling bears . . . such adequate warnings against use . . . where its use may be dangerous to health . . . in such

³⁴See 21 U.S.C. § 352(a) ("A drug or device shall be deemed to be misbranded if its labeling is false or misleading in any particular.") See also 21 U.S.C. § 352(f) (a drug or device shall be deemed to be misbranded "unless its labeling bears (1) adequate directions for use; and (2) such adequate warnings against use in those pathological conditions. . . where its use may be dangerous to health . . . in such manner and form, as are necessary for the protection of users").

³⁵English v. General Electric Co., 496 U.S. 72, 78-79 (1990). See also Geier v. American Honda Motor Co., 529 U.S. at 873; Laurence H. Tribe, American Constitutional Law, § 6-25 at 481 n. 14 (2d ed. 1988) (conflict preemption applies even "where Congress did not necessarily intend preemption . . . [if] the particular state law conflicts directly with federal law or stands as an obstacle to the accomplishment of federal objectives.").

³⁶21 U.S.C. § 352(a), (f); 21 C.F.R. Part 201, Subpart C.

manner and form as are necessary for the protection of users."³⁷ To constitute an adequate warning, a warning must in FDA's view be clear and truthful in all respects, not be misleading in any particular respect, and accurately communicate both the benefit-to-risk ratio and the proper use of the product in terms likely to be read and understood by the ordinary person.³⁸

**1. FDA's Action On Dowhal's Citizen Petition Showed That The FDCA
Preempted Compelled Use Of Dowhal's Proposed Warning Labeling
Under Proposition 65.**

Under the FDCA, manufacturers of drug products may not make changes to product labeling previously approved by FDA unless those changes are accurate and not misleading. Therefore, to the extent that state law would require a manufacturer to use product labeling that misbrands a drug product, the FDCA preempts state law under the doctrine of conflict preemption.

It cannot be reasonably disputed here that the FDCA's requirements with respect to drug marketing preempt any inconsistent requirements imposed by Proposition 65. Thus, the critical question is whether the FDCA's prohibition against the sale of misbranded drugs conflicted with the warning labeling that Dowhal claimed was required by that state law.

In determining whether Dowhal's proposed warning labeling was prohibited under the FDCA, the analysis must start from the proposition that an agency's reasonable judgment with

³⁷21 U.S.C. §§ 352(a), 352(f).

³⁸See 21 C.F.R. § 330.10(a)(4)(iii), (v). See also 21 U.S.C. § 355(d), which conditions FDA's approval of a new drug application upon the presentation of adequate tests to show the safety of the drug under the conditions prescribed, recommended, or suggested in the proposed labeling and upon the agency's finding that the labeling for the drug is not "false or misleading in any particular."

respect to the meaning of its own statute is entitled to judicial deference.³⁹ Therefore, any reasonable agency determination as to what constitutes misbranding under the FDCA will ordinarily be controlling.

Here, FDA ultimately rejected Dowhal's proposed warning labeling as inconsistent with the FDCA's prohibition against misbranding. In its August 17, 2001 letter, FDA addressed Dowhal's citizen petition requesting the agency to require under the FDCA the same warning that he claimed Proposition 65 required. Exh. 1 to Jt. Request for Judicial Notice. In that letter, FDA also established a new pregnancy warning for nicotine replacement therapy products. That warning differed materially from the warning Dowhal sought. In formulating the new labeling requirement, FDA sought to fashion a warning that clearly and reasonably communicated all the known risks associated with these products as well as the relative reproductive risks associated with smoking in comparison to total abstinence from nicotine in any form. Exh. 1 to Jt. Request for Judicial Notice at 6-8.

Tellingly, FDA considered and rejected Dowhal's proposed Proposition 65-compliant warning labeling. 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. As the agency's August 17, 2001 determination made clear, use of Dowhal's proposed warning labeling would render the Defendants' products misbranded because

³⁹Chevron U.S.A. Inc. v. Natural Resources Defense Council, Inc., 467 U.S. 837, 842-45 (1984).

that warning overstated the known risks of product use by equating the hazards posed by small amounts of nicotine delivered by means other than through inhaled smoke with the risks of smoking,⁴⁰ Exh. 1 to Joint Request For Judicial Notice at 6-8. Accordingly, if Proposition 65 required Defendants to use Dowhal's warning labeling, that state law would conflict with the FDCA and would yield to federal law under the doctrine of conflict preemption.

2. The Preemptive Effect Of FDA's Disposition Of The Citizen
Petition Also Governs The Application Of Proposition 65
To Defendants' Conduct Before FDA Issued Its Determination.

FDA's August 17, 2001 construction of the FDCA's misbranding prohibition with respect to Dowhal's proposed warning labeling also applies to the Defendants' conduct before that date. Where an agency has construed a statute that it is charged with administering, the agency's construction may also be applied to conduct that occurred before the agency announced that construction.⁴¹ In Smiley v. Citibank (South Dakota), N.A., which also involved a federal statute that preempted state law, the Supreme Court held that a regulation setting forth the Comptroller of the Currency's construction of the National Bank Act was entitled to deference. More important, the Court explained that the Comptroller's construction merited deference even though that construction would apply to conduct that predated the issuance of the regulation containing the agency's construction. The Court concluded that applying the new statutory construction to

⁴⁰Cigarettes must carry one of four Surgeon General warnings. 15 U.S.C. § 1333(a)(1). One of the permissible warnings states: "Smoking By Pregnant Women May Result in Fetal Injury, Premature Birth, and Low Birth Weight." That warning, which closely resembles the warning Dowhal sought, does not differentiate the known harmful effects associated with cigarette smoking from the potential risks of nicotine replacement products. Those risks are not yet scientifically substantiated.

⁴¹Smiley v. Citibank (South Dakota), N.A., 517 U.S. 735, 744 n. 3 (1996).

conduct completed before the regulation's issuance did not pose a risk of giving the regulation invalid retroactive effect. At least where an agency's construction filled a gap where there had been no contrary agency guidance, "it would be absurd to ignore the agency's current authoritative pronouncement of what the statute means."⁴²

The same rule should govern here. Before FDA's disposition of Dowhal's citizen petition, the agency had not issued definitive advice concerning whether use of Dowhal's proposed warning labeling would render Defendants' products misbranded under the FDCA. Given FDA's August 17, 2001 determination, the agency's rejection of Dowhal's proposed warning labeling constitutes the agency's authoritative assessment of the relevant evidence. It also represents this federal agency's authoritative interpretation and application of the FDCA with respect to that warning labeling. In accordance with the Supreme Court's admonition in Smiley that it would be absurd to disregard an agency's current authoritative application of its governing statute in these circumstances, this Court should apply FDA's construction of the FDCA's requirements to the Defendants' adherence to the FDA-approved product labeling before August 17, 2001.

Although FDA may not have issued a formal directive until it acted on Dowhal's citizen petition, the agency's action on the petition did not reflect a new position by FDA concerning the application of the FDCA to Dowhal's proposed warning labeling. In fact, FDA repeatedly advised Defendants that such a warning could misbrand their products. Thus, the agency's formal determination confirmed the statute's applicability to Dowhal's proposed warning labeling based on the agency's review of all the relevant data. The determination showed the conflict between the FDCA's misbranding prohibition and any state law that required use of Dowhal's

⁴²517 U.S. at 744 n. 3.

proposed warning labeling. Where such a conflict exists between federal and state law, federal law preempts state law even with respect to transactions that have already been completed before the agency's determination confirming the conflict.⁴³

Moreover, judicial application of FDA's August 17, 2001 statutory construction to the Defendants' conduct before that date closely parallels the doctrine of primary jurisdiction. Where the issues presented fall within an agency's specialized expertise and involve "technical and intricate questions of fact and policy that Congress assigned to a specific agency," the doctrine of primary jurisdiction permits a trial court to consider an agency explanation provided after the commencement of a lawsuit.⁴⁴

FDA has now determined in a final agency action that use of Dowhal's proposed warning labeling would render these products misbranded. For the same reason that a trial court should rely upon an agency explanation issued after the filing of a lawsuit under the doctrine of primary jurisdiction, "it would be absurd to ignore the agency's current authoritative pronouncement of what the statute means" to resolve a question concerning whether use of Dowhal's proposed warnings would make Defendants' products misbranded under the FDCA.⁴⁵ Therefore, this Court may affirm the Superior Court's grant of summary judgment for Defendants based upon FDA's action on Dowhal's citizen petition.

⁴³See Medtronic, Inc. v. Lohr, 518 U.S. 470 (1996). Given the pendency of Dowhal's citizen petition before FDA and the fact his petition presented the same questions his lawsuit raised, the Superior Court could have stayed the action pending FDA's disposition of the citizen petition either at the request of a party or sua sponte.

⁴⁴See Wise v. Pacific Gas & Electric Co., 77 Cal. App. 4th 287, 295-96 (1999); Farmers Insurance Exchange v. Superior Court, 2 Cal. 4th 377, 380 (1992).

⁴⁵Smiley v. Citibank (South Dakota, N.A.), 517 U.S. at 744 n. 3.

FDA's August 17, 2001 determination also merits deference from a state court with respect to conduct that preceded the determination for another reason. That determination reflects a regulatory decision based upon this federal agency's application of a statute it is charged with administering. The determination necessarily involves applying the agency's expertise to the data relevant to deciding what warning label is appropriate for these products. In Chicago and North Western Transportation Company v. Kalo Brick and Tile Company,⁴⁶ the Supreme Court concluded that the ICC's judgment was entitled to deference in a state court because Congress had entrusted the agency with responsibility for making such judgments. The Court explained that, because "the judgment as to what constitutes reasonableness belongs exclusively to the Commission," it would frustrate Congressional intent as expressed in a federal statute "to permit the State of Iowa to use the threat of damages to require a carrier to do exactly what the Commission is empowered to excuse."⁴⁷ Here, where Congress has entrusted FDA to make any necessary judgments concerning what labeling provides the warnings necessary to keep a product from being misbranded, a state court must also defer to FDA's assessment.

Furthermore, especially where a party may challenge a federal agency's determination in federal court under the Administrative Procedure Act after exhausting available administrative remedies, that party may not bypass that judicial remedy by challenging the agency's determination indirectly by bringing an action under state law.⁴⁸ Tellingly, where judicial review

⁴⁶450 U.S. 311, 325-26 (1981).

⁴⁷450 U.S. at 325-26. See also Deford v. Soo Line Railroad Co., 867 F.2d 1080, 1089 (8th Cir. 1989).

⁴⁸See 5 U.S.C. § 701 *et seq.*

is available under the federal system, review under state law is unavailable even where the agency did not make its determination until after the initiation of the state court action.⁴⁹

To be sure, where the evidence bearing upon what warning labeling is appropriate has changed significantly over time, that change may affect whether FDA's determination concerning appropriate labeling may be fairly applied to prior conduct. Thus, if the FDA here had relied heavily on new facts to conclude that Dowhal's proposed warning labeling would render these products misbranded, it might bear on the acceptability of the labeling before those facts came to the agency's attention. Here, however, there is no suggestion that any significant evidentiary change occurred from the time Dowhal filed this suit until the agency's disposition of his citizen petition. Therefore, there can be no suggestion that Dowhal's proposed warning was at some earlier time compliant with the FDCA.

**B. Application Of Proposition 65 To Require Dowhal's Proposed Warnings
Would Frustrate Attaining The FDCA's Objectives.**

The discussion above also shows that conflict preemption applies here because requiring Defendants to use Dowhal's proposed warning labeling to meet their duties under Proposition 65 would pose an obstacle to accomplishing Congress's full purposes and objectives.⁵⁰ As previously noted, by enacting the FDCA, Congress established a comprehensive regulatory plan

⁴⁹Chicago and Northwestern Transportation Co. v. Kalo Brick & Tile Co., 450 U.S. at 326.

⁵⁰English v. General Electric Co., 496 U.S. at 78-79. See also Geier v. American Honda Motor Co., 529 U.S. at 873; Laurence H. Tribe, American Constitutional Law, § 6-25 at 481 n. 14 (2d ed. 1988).

designed to ensure the safety and effectiveness of drugs. Congress gave FDA plenary authority to regulate the labeling of drug products.⁵¹

State law must be applied in a way that preserves the latitude necessary for the federal regulatory scheme to operate as Congress intended.⁵² As we have previously discussed, a drug manufacturer's use of the "changes being effected" supplement is generally limited to circumstances involving noncontroversial labeling changes. 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. FDA's regulation does not allow a drug manufacturer to file such a submission without an adequate factual foundation. Moreover, standing alone, the fact that state law requires use of a particular warning cannot not constitute the necessary factual predicate.

Furthermore, FDA responded to specific inquiries from Defendants during the 1997-2001 period by advising them that they might be liable for selling misbranded drug products if they deviated from the FDA-approved warning labeling for these nicotine replacement therapy products. See Respondents Brief at 10-14, 18-20. Moreover, FDA gave that advice on several occasions in response to a Defendant's inquiry concerning possible use of warnings that were proposed as compliant with Proposition 65. J.A. 1499-1501, 1504-06, 1514-17, 1520-21,

⁵¹21 U.S.C. § 352(a), (f); 21 CFR Part 201, Subpart C.

⁵²Buckman Co. v. Plaintiffs' Legal Committee, 531 U.S. 341, 347-48 (2001).

1568-69, 1571, 1632-36, 2401. Depriving Defendants of their ability to heed this advice without the risk of sustaining liability under a complementary state law system would plainly frustrate the objectives Congress sought to advance under the FDCA.⁵³

In light of the nature of their particular products, these Defendants had another valid reason for hesitancy in adopting Plaintiffs proposed warnings based on their concern over liability for misbranding. With many drug products, strengthening the warnings on product labeling may carry only a moderate risk of causing confusion among consumers about whether to use a product. Here, nicotine, the ingredient in Defendants' products that made them subject to Proposition 65, is also present in cigarettes. Consumers use Defendants' products solely to assist their efforts to discontinue the use of cigarettes and thereby avoid further exposure to the serious health hazards posed by inhaled tobacco smoke.

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, Defendants had good reason to avoid labeling changes that might render their products misbranded.

⁵³Based on the particular wording of the agency's communications to certain Defendants, FDA may have in some instances preempted application of Proposition 65 at least as to Proposition 65-compliant warnings that FDA considered and rejected for purposes of compliance with the FDCA. But because preemption applies to all the Defendants in this suit for their actions during entire time period at issue for the reasons set forth elsewhere in this brief, this Court need not consider the applicability of preemption based on FDA's specific communications to particular Defendants.

The California Attorney General nevertheless asserts (Br. 33-35) that FDA's treatment of warning labeling requirements for Habitrol, another nicotine replacement therapy product marketed by a company that is not a party in this case, Novartis Consumer Health, Inc., shows that Defendants' use of Dowhal's proposed warning labeling would not cause them to misbrand their products. The Attorney General chiefly relies upon the fact that, when FDA approved the warning labeling for Habitrol in 1999, that warning labeling included the "harm your baby" warning Dowhal advocates under Proposition 65.

To begin with, this argument ignores the fact that, for FDA's regulatory purposes, every new drug is unique even if its formulation includes ingredients similar to or even identical to another drug product. FDA must evaluate each application based upon the submissions made by the applicant and all other relevant evidence that is available to the agency when it reviews the application. Thus, each NDA approval is manufacturer-specific. Accordingly, it does not necessarily follow that, because FDA has approved a label for one product, its approval for that product represents de facto approval for the identical warning for all similar products.

Furthermore, soon after FDA issued the approval for Habitrol, the agency determined that the scientific evidence regarding the potential harms from the use of the product did not, in fact, support the use of that warning. FDA's determination rendered this product misbranded. But in the exercise of its administrative discretion, FDA withheld pursuit of an enforcement action for misbranding against Habitrol's sponsor while the agency determined what language an appropriate warning should contain. Tellingly, after the agency addressed Dowhal's citizen petition, FDA instructed Habitrol's sponsor to submit an NDA Supplement containing the same labeling that the agency had approved in its August 17, 2001 determination. In so doing, FDA

brought these products under a uniform labeling regime, but not a regime requiring the use of the "harm your baby" warning.

In any event, as our argument above shows, state law here conflicts with the FDCA to the extent that Proposition 65 requires Defendants to use Dowhal's proposed warning labeling. Therefore, this Court need not decide whether Proposition 65 may require a drug manufacturer to make a significant change in warning labeling where that manufacturer lacks adequate evidence to justify a labeling change under the federal regulatory plan created by the FDCA. Likewise, the Court also need not decide whether California law may require a drug manufacturer to make a significant change in warning labeling where FDA has explicitly cautioned the manufacturer against making an unwarranted change in warning labeling.

II. THE MODERNIZATION ACT DOES NOT AFFECT THE APPLICATION OF CONFLICT PREEMPTION HERE.

Dowhal contends (Br. at 21-29) that the Modernization Act exempts Proposition 65 from displacement under conflict preemption principles. But the Superior Court correctly held that the Modernization Act affects only express preemption, not conflict preemption.

The Modernization Act added to the FDCA an express preemption provision for over-the-counter drug labeling. That provision expressly preempts any state requirement regarding over-the-counter drugs that is "different from, in addition to, or otherwise not identical with" an FDA requirement.³⁴ That provision, however, also includes an exception from such federal

³⁴21 U.S.C. § 379r(a).

preemption for state laws adopted by public initiative or referendum enacted prior to September 1, 1997, a classification that includes Proposition 65.⁵⁵

A statutory provision that excludes a state law from the ordinary impact of express preemption does not affect conflict preemption. In Geier v. American Honda Company, the Supreme Court held that, even where Congress uses a savings clause to exempt a particular state law from the impact of express preemption, conflict preemption still applies where a conflict exists between state law and federal law that frustrates attaining a federal objective or makes it impossible for persons to comply with the both federal and state law.⁵⁶ In Geier, the Court cautioned against giving broad effect to such savings clauses where doing so would upset the careful regulatory scheme established by federal law. In reaching that result, the Court emphasized that "[c]onflict preemption turns on the identification of actual conflict, and not on an express statement of preemptive intent."⁵⁷

Similarly, in Buckman Company v. Plaintiffs' Legal Committee,⁵⁸ which also involved the FDCA, the Court held that conflict preemption applied notwithstanding an express preemption provision that also contained a savings clause. There, plaintiffs asserted that another express preemption provision in the FDCA did not preempt their state law claims alleging fraud on the agency.⁵⁹ Reaffirming its analysis in Geier, the Court observed that "[n]either an express

⁵⁵21 U.S.C. § 379r(d)(2).

⁵⁶529 U.S. 861, 870.

⁵⁷529 U.S. at 884.

⁵⁸531 U.S. 341 (2001).

⁵⁹Sec 21 U.S.C. § 360k(a), in the Medical Device Amendments, Pub. L. No. 94-295, 90 Stat. 539 (1976).

preemption provision nor a savings clause bars the ordinary working of conflict preemption principles."⁶⁰

Furthermore, the particular language of the Modernization Act's exemption from express preemption confirms that the exemption does not affect conflict preemption. Section 21 U.S.C. § 379r(d)(2) exempts Proposition 65 from express preemption by virtue of its language that "this section shall not apply to a state requirement." (emphasis added) "This section" refers to the statutory provision entitled National Uniformity for Non Prescription Drugs, which sets forth the federal preemption provision.⁶¹ 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.⁶² 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.

The California Attorney General also contends (Amicus Br. at 33-35) that the Modernization Act eliminated FDA's authority to prohibit Defendants from using Dowhal's proposed warning. Here, he suggests that any refusal by FDA to permit Defendants to use that

⁶⁰531 U.S. at 352. The express preemption language and savings clause in 21 U.S.C. § 360k for medical devices, is similar to the Modernization Act's express preemption provision and its savings clause, which Dowhal relies on here. See also Freightliner Corporation v. Myrick, 514 U.S. 280 (1995) (implied preemption may apply despite presence of express preemption clause).

⁶¹See 21 U.S.C. § 379r(a).

⁶²United States v. Locke, 529 U.S. 89, 106 (2000); Morales v. Trans World Airlines, Inc., 504 U.S. 374, 385 (1992); AT&T Co. v. Central Office Telephone, Inc., 524 U.S. 214, 227-28 (1998).

PCL XL error

Subsystem: IMAGE

Error: MissingData

Operator: ReadImage

Position: 724

FRAMEWORK FOR A COMPENSATION PROGRAM FOR PRESCRIPTION DRUG INJURIES

Trial lawyers and other advocates of the current tort liability system for prescription drug injuries claim that the threat of potentially massive liability gives manufacturers an essential incentive to optimize their product quality and risk-management practices while simultaneously compensating individuals who have suffered injuries as a result of inadequacies in those practices. The purported incentive provided by the tort system, however, directly conflicts with the risk management analysis undertaken by FDA in its approval of new drugs and in its postmarket surveillance of drugs already in the marketplace. FDA's decision to approve a new drug represents the agency's determination that, based on current scientific knowledge, the benefits of the new drug product to the public health outweigh its risks. The approval decision is made with full knowledge of the fact that *all drugs* pose some risk to some portion of the patient population, and that further study and experience will, over time, provide additional information about risks both known and unknown at the time the drug is approved.

In reality, however, every new piece of safety information provided to the public by FDA and drug manufacturers after a new drug is approved and in use provides opportunistic trial lawyers with a marketing opportunity for a new class action. The costs of defending those state law tort suits -- and the ad hoc decisions of non-expert judges and inexperienced juries in those actions -- often create incentives that are inconsistent with the FDA's expert determination regarding the benefit to public health of individual drugs and the Agency's programs for overseeing and managing the unavoidable risks of prescription drugs. For example, State law verdicts (or the threat of such verdicts) in "failure to warn" tort suits create overwhelming incentives for manufacturers to expand and, consequently, complicate their prescription drug labeling, which directly conflicts with recent FDA efforts to streamline and simplify such labeling, which the agency has undertaken after extensive study of the problem of information overload on drug labels. In short, the current tort system constitutes a shadow regulatory regime that frustrates, conflicts with, and ultimately threatens to undermine the comprehensive regulatory system crafted by the FDA in the exercise of its unique expertise in regulating pharmaceuticals for the protection of public health.

Despite these conflicts, Federal regulators and courts have been reluctant to preempt State law tort claims -- no doubt out of concern that preemption would deprive injured persons of compensation for drug-related injuries. In similar situations, however, Congress has responded by displacing tort liability and providing an alternative compensation regime. For example, when lawsuits threatened the supply and availability of childhood vaccines, Congress passed the National Childhood Vaccine Injury Act of 1986, which eliminated counterproductive litigation while providing an administrative system for compensating those injured by the inherent and inevitable risks of vaccines.

Similarly, sound public policy now demands the elimination of the tort system's ongoing interference with the FDA's management of new drug approval and adverse event surveillance programs designed to protect the public health. At the same time, FDA, Congress, industry and the public must ensure that those who are injured by prescription drugs are fairly compensated. In addition to frustrating FDA's public health objectives as noted above, the current tort system

is unacceptably slow, expensive, and inefficient, with an enormous amount of compensation dollars diverted to lawyers, experts and other administrative costs. Even worse, a number of factors, including public perceptions of "big business" generally and the pharmaceutical industry specifically, the complexity of the legal and factual issues involved, and the varying leverage wielded by trial lawyers based upon the "inventory" of claimants they have been able to amass, frequently make the results of drug tort litigation fundamentally unfair to defendants and plaintiffs alike. These cases have become a crapshoot for plaintiffs, whose outcome depends not so much on the merits of the parties' respective claims as on substantively irrelevant factors, such as where suit was brought and who represents the plaintiffs. Thus, a new system is needed to spread the risk of pharmaceutical-related injuries among all those benefiting from prescription drugs and to provide swift, predictable, reasonable and fair compensation with maximum efficiency. To protect the public health for all Americans and to assure fair and efficient resolution of claims for drug-related injuries, we must find a better way.

Overview of Program

A tort replacement initiative in the prescription drug field would, like the Vaccine Act, substitute a "no-fault" reimbursement program covering certain injuries caused by prescription drugs for the existing tort/product liability system. Once in effect, the program would apply prospectively to future claims for prescription-related injury, regardless of when the drug was first prescribed or the injuries first began to develop.. Such a program would effectively eliminate the specter of "bet the company" mass tort litigation in which, despite the best efforts of scientists and regulators, an approved drug product is determined to have previously unknown or unpredictable adverse consequences when administered to the population at large. Coverage could be provided through a trust fund for those who could demonstrate the requisite injury caused by an FDA-approved prescription drug, provided that the drug was taken pursuant to and consistent with a prescription issued to the claimant by a qualified (or purportedly qualified) physician.

The program would allow claimants to recover economic damages (lost earnings and medical care expenses) from the fund consistent with established guidelines, place caps on the recovery of damages for death and non-economic damages, prohibit recovery of punitive and exemplary damages, and permit the recovery of only reasonable attorneys fees and costs. The program would be secondarily liable, and would not pay for items or services covered by collateral sources, such as federal and state benefit plans and private insurance. Moreover, the program could be designed to allow it to seek contribution from responsible third parties (*e.g.*, a physician/administrator who commits malpractice). Compensation awards would be paid from a trust fund that could be financed with a small levy on all prescription drugs covered by the program.

As noted above, FDA approval of a prescription drug as safe and effective represents the Agency's determination that the benefits of the drug product to patient populations outweigh the attendant risks. Some risks, however, remain in the use of all prescription drugs. Some of these risks, ranging from the minor side effects of many prescription drugs to the frequently significant impact of chemotherapy drugs on patients who might die absent treatment, are necessarily attendant upon use of the drug product. They are disclosed in labeling when their incidence has been demonstrated to be sufficiently connected to administration of the drug that FDA deems

their disclosure appropriate to protecting the public health. The tort system theoretically bars recovery for those effects as a risk assumed by the patient (although in specific cases, plaintiffs have prevailed). The program, similarly, would not provide recovery for such effects.

Other prescription drug injuries, whether labeled or not, are so far removed from the benefits of the product that an individual drug user could not reasonably expect such an injury attendant to the benefit of the product. The best example is the severe adverse reaction that may occur in a small number of users of a drug who cannot be identified. The program would be designed to allow recovery for such injuries, even where the existing tort system might not.

Framework of Program

1. Prescription Drugs to Be Covered: Coverage would extend to all prescription drugs approved by FDA and issued through an authorized prescription written in the United States and trust territories or for Armed Forces members serving abroad and their dependents. The limitation to United States drugs is justified by importation and reimportation limitations placed on prescription drugs by the Prescription Drug Marketing Act and FDA's recent concerns regarding the scope of the personal use exemption to the importation and reimportation limitations.

2. Uses to Be Covered: Coverage would extend to all uses of an eligible prescription drug. Thus, the program would include both off-label use and allegations of erroneous prescribing or dosage.

(a) Attempting to exclude off-label uses would render the program ineffective for a large number of claims that currently clog the tort system.

(b) In addition, FDA's current labeling regulations require specific warnings related to common off-label uses where there is lack of substantial evidence of effectiveness of the use and association of the use with clinically significant risk or hazard.

(c) Regarding medication errors, the Fund would be authorized to pursue contribution claims from physicians or prescribers to the extent the Fund pays benefits for doctor or prescriber error.

3. Claimant Eligibility: The claim may be denied upon demonstration of use without a prescription issued to the claimant, use by the patient inconsistent with label or physician instructions and warnings, and/or misrepresentation by the patient to the prescriber concerning the existence of conditions material to determining whether the drug is contraindicated.

(a) As part of the petition process, the Claimant would bear the initial burden of providing the prescription and averring as to proper use and lack of material misrepresentation.

(b) The initial burden on the petitioner could also be satisfied by requiring a standardized affidavit from the prescribing physician as to existence and necessity of prescription and appropriate instruction of and disclosure to the patient.

(c) The Fund could challenge the claim based on medical records and other evidence, but would bear the burden of persuasion.

4. Parties to be Covered: The Program would cover manufacturers, health care providers, and pharmacists, with the Fund able to pursue contribution claims against providers and pharmacists for prescribing errors. Such broad coverage would prevent diversion of disproportionate tort burdens to health care providers and pharmacists.

5. Injuries to be Covered: The program would include, subject to determination of causation as noted below, all injuries except those within the known risks identified on the labeling at the time the prescription was issued that are so likely to manifest themselves as part of the benefits of the product that their occurrence should reasonably be expected.

(a) To control administrative costs and prevent the system from being overloaded by trivial or frivolous claims, consideration could be given to establishing an injury threshold for compensable claims under the system. Injuries falling below the seriousness threshold would not be compensated.

(b) As noted below, specific determination of those injuries (and their magnitude) that are sufficiently known and likely to occur could be tied to FDA's determinations of risk as reflected in its labeling decisions. Caps on damages for wrongful death or pain and suffering, similar to the \$250,000 cap for each contained in the Vaccine Act, would be included.

(c) Over time, experience with the administration of the system may provide a basis for establishing schedules setting compensation amounts for certain injuries. Such schedules could apply presumptively, with claimants free to offer evidence demonstrating that the scheduled compensation would be insufficient and inappropriate under the circumstances and that, subject to applicable caps, a higher compensation amount should be awarded.

(d) Claims alleging fear of future injury based on exposure (i.e., medical monitoring claims) would not be covered unless FDA determines medical monitoring is warranted based upon experience with a particular drug

(e) Punitive damages would be unavailable under the system.

(f) Under the broad preemption of pharmaceutical-related claims associated with the system, there would be no provision for residual common law or statutory claims for medical monitoring, punitive damages, or liability in excess of awarded amounts.

6. Determination of Causation: Over time, FDA would make drug-by-drug determinations of the types and magnitude of injuries that would be entitled to the rebuttable presumption of causation. These determinations would be made as part of FDA's labeling or approval decisions, and would be reviewed periodically based on adverse event reports, additional information requested or received from the manufacturer or other sources, and experience to date of petition determinations.

(a) All other injuries would be subject to proof of causality by preponderance of evidence.

(b) FDA's labeling requirements, both proposed and current, require that labeling categorize adverse reactions by frequency (most frequent, less frequent, and rare) and severity. These determinations could provide the basis for distinguishing between known adverse reactions whose occurrence and magnitude can reasonably be expected from use of the product (those that are most frequent or least severe and should therefore be excluded from coverage) and the known but unpredictable severe adverse reaction.

(c) As the entity ultimately responsible for the risk-benefit determination that permits marketing of a pharmaceutical product, FDA is in the best position to ultimately decide which risks inherent in the product are part of the trade-off for the product's benefits, and which are so out of proportion to the benefits that a claimant should be compensated.

7. Administration of Program: Under enabling legislation, the Secretary of Health and Human Services would promulgate regulations establishing a system for the efficient and expeditious determination of petitions, which might include, at the Secretary's discretion, contracting with outside parties experienced in the adjustment of medical claims to make an initial determination of eligibility and amount of award, subject to de novo review by a Special Master and APA review by a district court, thus combining private sector, administrative and judicial resources.

8. Funding of Program: Funding would be based on a tax on wholesale sales of each prescription drug.

(a) Adjustments should be considered as cost information is developed or to address other inequities (*e.g.*, adjustments to impose equal tax burdens on manufacturers of "brand name" and "generic" products that present identical risk factors).

(b) Implementing legislation should provide for consideration of the feasibility of the use of risk rating after a set period of years.

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Baker & Hostetler LLP

Fax

To: Brett Kavanaugh**From:** Bill McCollum**Fax:** 202-456-5104**Pages:** 15 including cover**Phone:****Date:** July 26, 2002**Re:** Tort reform**CC:**

☐ **Urgent** ☐ **For Review** ☐ **Please Comment** ☐ **Please Reply** ☐ **Please Recycle**

• Comments:

As we discussed on the phone yesterday there may be real opportunity in working out the tort provisions of the terrorism insurance legislation to put in the bill at least the Lexecon fix from H.R.860 if not that whole bill. Following for your use are copies of the Chamber talking points for Lexecon, a summary of H.R.860 and a copy of the bill. Representing the Institute for Legal Reform of the Chamber I will do anything I can to help you set the stage to accomplish this. Please give me a call as this develops and tell me what I need to do. I have offices at Baker & Hostetler LLP both in Washington and Orlando. Subject to need in D.C. I will be in Florida much of the next month and may be reached at 407-649-4050 or through my assistant or voice mail in D.C. at 202-861-1797.

will M.



The Need for H.R. 860

Section 1407 of the Judicial Code, 28 U.S.C. § 1407, permits federal cases involving "one or more common questions of fact" to be consolidated in a single court for "pretrial proceedings . . . for the convenience of parties and witnesses and [to] promote the just and efficient conduct of such actions." Consolidation is authorized only upon approval of a 7 member judicial panel appointed by the Chief Justice of the United States (the "Multidistrict Panel").

Judges handling consolidated pretrial proceedings ("transferee judges") often believe that maintaining consolidation through trial would equally advantage parties and witnesses and promote justice and efficiency. However, the Supreme Court's decision in Lexecon v. Milberg, Weiss et al, 118 S.Ct. 956 (1998), interpreted Section 1407 to foreclose transferee judges from maintaining consolidation through trial and to require remand of such cases to the separate courts in which they were initiated. That decision overturned 30 years of prior practice and created a situation described by the Chairman of the Multidistrict panel as "cumbersome, repetitive, costly, time consuming, inefficient and a wasteful utilization of judicial and litigant resources."

H.R. 860, Section 2, responded to the concerns of the judiciary over Lexecon and adopted ameliorative language proposed by the Judicial Conference and the Administrative Office of the United States Courts. H.R. 860 would amend Section 1407 to permit a transferee judge to maintain consolidation for trial purposes in his/her own court or another convenient district "in the interest of justice and for the convenience of the parties and witnesses." H.R. 860 would thus remove the barrier to judicial fairness and efficiency created by Lexecon and the existing language of Section 1407.

H.R. 860 was passed without dissent on suspension of rules by the House of Representatives on March 14, 2001. It is, however, languishing in the Senate Judiciary Committee because of controversy over the unrelated provisions of Section 3 of the bill which address mass disaster litigation. As a result, transferee courts administering consolidated pretrial proceedings remain under mandate to splinter them by remand before trial with attendant hardships to litigants and the judiciary. It is imperative to break the logjam and proceed with the enactment of Section 2 of H.R. 860 as promptly as possible.

H.R.860

Sponsor: Rep Sensenbrenner, F. James, Jr.(introduced 3/6/2001)

Latest Major Action: 3/15/2001 Referred to Senate committee

Title: To amend title 28, United States Code, to allow a judge to whom a case is transferred to retain jurisdiction over certain multidistrict litigation cases for trial, and to provide for Federal jurisdiction of certain multiparty, multiforum civil actions.

SUMMARY AS OF:

3/14/2001--Passed House, amended. (There are 2 other summaries [</cgi-bin/bdquerytr/z?d107:HR00860:@@D&summl&>](/cgi-bin/bdquerytr/z?d107:HR00860:@@D&summl&>))

Multidistrict, Multiparty, Multiforum Trial Jurisdiction Act of 2001 - Amends the Federal judicial code to allow a civil action transferred for coordinated or consolidated pretrial proceedings (multidistrict litigation) to be transferred to the transferee or other district for trial purposes in the interest of justice and for the convenience of the parties and witnesses. Directs that any such action transferred for trial purposes be remanded to the district court from which it was transferred for the determination of compensatory damages, unless the court also finds that the action should be retained for the determination of compensatory damages for the convenience of the parties and witnesses and in the interests of justice.

Grants Federal district courts original jurisdiction over civil actions arising out of a single accident that results in the death or injury of 25 or more natural persons, provided the injury has resulted in damages which exceed \$150,000 per person and minimal diversity of citizenship (as prescribed in this Act) exists. Directs the district court to abstain from hearing any such action in which: (1) the substantial majority of all plaintiffs are citizens of a single State of which the primary defendants are also citizens; and (2) the claims asserted will be governed primarily by the laws of that State. Permits any person with a claim arising from such an accident to intervene as a party plaintiff, even if that person could not have brought an action in district court as an original matter. Requires a federal district court in which such an action is pending to notify the judicial panel on multidistrict litigation. Authorizes venue for such action in any district in which a defendant resides or in which a substantial part of the accident occurred.

Permits a district court to retain such actions for the determination of liability and punitive damages. Calls for remand of determinations of damages other than punitive damages, including the possibility of remand to State courts in which actions were originally filed, unless the Federal court finds that it would serve the convenience of parties and witnesses and the interests of justice to retain the action for the determination of such damages as well.

Permits removal of actions which could have been brought in district court under the above provisions from State to U.S. district courts. Authorizes removal before trial within 30 days of a defendant's becoming a party to a suit under this Act, or at a later time with leave of the district court. Establishes a presumption in favor of discretionary remand to State courts for damages determinations after rulings on liability.

Authorizes nationwide service of process and, upon a showing of good cause, nationwide service of subpoenas with regard to actions under this Act.

107TH CONGRESS
1ST SESSION

H. R. 860

AN ACT

To amend title 28, United States Code, to allow a judge to whom a case is transferred to retain jurisdiction over certain multidistrict litigation cases for trial, and to provide for Federal jurisdiction of certain multiparty, multiform civil actions.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the "Multidistrict,
5 Multiparty, Multiforum Trial Jurisdiction Act of 2001".

6 **SEC. 2. MULTIDISTRICT LITIGATION.**

7 Section 1407 of title 28, United States Code, is
8 amended—

9 (1) in the third sentence of subsection (a), by
10 inserting "or ordered transferred to the transferee
11 or other district under subsection (i)" after "termi-
12 nated"; and

13 (2) by adding at the end the following new sub-
14 section:

15 "(i)(1) Subject to paragraph (2) and except as pro-
16 vided in subsection (j), any action transferred under this
17 section by the panel may be transferred for trial purposes,
18 by the judge or judges of the transferee district to whom
19 the action was assigned, to the transferee or other district
20 in the interest of justice and for the convenience of the
21 parties and witnesses.

22 "(2) Any action transferred for trial purposes under
23 paragraph (1) shall be remanded by the panel for the de-
24 termination of compensatory damages to the district court
25 from which it was transferred, unless the court to which

3

1 the action has been transferred for trial purposes also
2 finds, for the convenience of the parties and witnesses and
3 in the interests of justice, that the action should be re-
4 tained for the determination of compensatory damages.”.

5 **SEC. 3. MULTIPARTY, MULTIFORUM JURISDICTION OF DIS-**
6 **TRICT COURTS.**

7 (a) **BASIS OF JURISDICTION.—**

8 (1) **IN GENERAL.**—Chapter 85 of title 28,
9 United States Code, is amended by adding at the
10 end the following new section:

11 **“§ 1369. Multiparty, multiform jurisdiction**

12 “(a) **IN GENERAL.**—The district courts shall have
13 original jurisdiction of any civil action involving minimal
14 diversity between adverse parties that arises from a single
15 accident, where at least 25 natural persons have either
16 died or incurred injury in the accident at a discrete loca-
17 tion and, in the case of injury, the injury has resulted in
18 damages which exceed \$150,000 per person, exclusive of
19 interest and costs, if—

20 “(1) a defendant resides in a State and a sub-
21 stantial part of the accident took place in another
22 State or other location, regardless of whether that
23 defendant is also a resident of the State where a
24 substantial part of the accident took place;

1 “(2) any two defendants reside in different
2 States, regardless of whether such defendants are
3 also residents of the same State or States; or

4 “(3) substantial parts of the accident took place
5 in different States.

6 “(b) LIMITATION OF JURISDICTION OF DISTRICT
7 COURTS.—The district court shall abstain from hearing
8 any civil action described in subsection (a) in which—

9 “(1) the substantial majority of all plaintiffs
10 are citizens of a single State of which the primary
11 defendants are also citizens; and

12 “(2) the claims asserted will be governed pri-
13 marily by the laws of that State.

14 “(c) SPECIAL RULES AND DEFINITIONS.—For pur-
15 poses of this section—

16 “(1) minimal diversity exists between adverse
17 parties if any party is a citizen of a State and any
18 adverse party is a citizen of another State, a citizen
19 or subject of a foreign state, or a foreign state as
20 defined in section 1603(a) of this title;

21 “(2) a corporation is deemed to be a citizen of
22 any State, and a citizen or subject of any foreign
23 state, in which it is incorporated or has its principal
24 place of business, and is deemed to be a resident of

1 any State in which it is incorporated or licensed to
2 do business or is doing business;

3 “(3) the term ‘injury’ means—

4 “(A) physical harm to a natural person;
5 and

6 “(B) physical damage to or destruction of
7 tangible property, but only if physical harm de-
8 scribed in subparagraph (A) exists;

9 “(4) the term ‘accident’ means a sudden acci-
10 dent, or a natural event culminating in an accident,
11 that results in death or injury incurred at a discrete
12 location by at least 25 natural persons; and

13 “(5) the term ‘State’ includes the District of
14 Columbia, the Commonwealth of Puerto Rico, and
15 any territory or possession of the United States.

16 “(d) INTERVENING PARTIES.—In any action in a dis-
17 trict court which is or could have been brought, in whole
18 or in part, under this section, any person with a claim
19 arising from the accident described in subsection (a) shall
20 be permitted to intervene as a party plaintiff in the action,
21 even if that person could not have brought an action in
22 a district court as an original matter.

23 “(e) NOTIFICATION OF JUDICIAL PANEL ON MULTI-
24 DISTRICT LITIGATION.—A district court in which an ac-
25 tion under this section is pending shall promptly notify

1 the judicial panel on multidistrict litigation of the pend-
2 ency of the action.”.

3 (2) CONFORMING AMENDMENT.—The table of
4 sections at the beginning of chapter 85 of title 28,
5 United States Code, is amended by adding at the
6 end the following new item:

“1369. Multiparty, multiform jurisdiction.”.

7 (b) VENUE.—Section 1391 of title 28, United States
8 Code, is amended by adding at the end the following:

9 “(g) A civil action in which jurisdiction of the district
10 court is based upon section 1369 of this title may be
11 brought in any district in which any defendant resides or
12 in which a substantial part of the accident giving rise to
13 the action took place.”.

14 (c) MULTIDISTRICT LITIGATION.—Section 1407 of
15 title 28, United States Code, as amended by section 2 of
16 this Act, is further amended by adding at the end the fol-
17 lowing:

18 “(j)(1) In actions transferred under this section when
19 jurisdiction is or could have been based, in whole or in
20 part, on section 1369 of this title, the transferee district
21 court may, notwithstanding any other provision of this
22 section, retain actions so transferred for the determination
23 of liability and punitive damages. An action retained for
24 the determination of liability shall be remanded to the dis-
25 trict court from which the action was transferred, or to

1 the State court from which the action was removed, for
2 the determination of damages, other than punitive dam-
3 ages, unless the court finds, for the convenience of parties
4 and witnesses and in the interest of justice, that the action
5 should be retained for the determination of damages.

6 “(2) Any remand under paragraph (1) shall not be
7 effective until 60 days after the transferee court has
8 issued an order determining liability and has certified its
9 intention to remand some or all of the transferred actions
10 for the determination of damages. An appeal with respect
11 to the liability determination of the transferee court may
12 be taken during that 60-day period to the court of appeals
13 with appellate jurisdiction over the transferee court. In the
14 event a party files such an appeal, the remand shall not
15 be effective until the appeal has been finally disposed of.
16 Once the remand has become effective, the liability deter-
17 mination shall not be subject to further review by appeal
18 or otherwise.

19 “(3) An appeal with respect to determination of puni-
20 tive damages by the transferee court may be taken, during
21 the 60-day period beginning on the date the order making
22 the determination is issued, to the court of appeals with
23 jurisdiction over the transferee court.

1 “(4) Any decision under this subsection concerning
2 remand for the determination of damages shall not be re-
3 viewable by appeal or otherwise.

4 “(5) Nothing in this subsection shall restrict the au-
5 thority of the transferee court to transfer or dismiss an
6 action on the ground of inconvenient forum.”.

7 (d) REMOVAL OF ACTIONS.—Section 1441 of title 28,
8 United States Code, is amended—

9 (1) in subsection (e) by striking “(e) The court
10 to which such civil action is removed” and inserting
11 “(f) The court to which a civil action is removed
12 under this section”; and

13 (2) by inserting after subsection (d) the fol-
14 lowing new subsection:

15 “(e)(1) Notwithstanding the provisions of subsection
16 (b) of this section, a defendant in a civil action in a State
17 court may remove the action to the district court of the
18 United States for the district and division embracing the
19 place where the action is pending if—

20 “(A) the action could have been brought in a
21 United States district court under section 1369 of
22 this title; or

23 “(B) the defendant is a party to an action
24 which is or could have been brought, in whole or in
25 part, under section 1369 in a United States district

1 court and arises from the same accident as the ac-
2 tion in State court, even if the action to be removed
3 could not have been brought in a district court as
4 an original matter.

5 The removal of an action under this subsection shall be
6 made in accordance with section 1446 of this title, except
7 that a notice of removal may also be filed before trial of
8 the action in State court within 30 days after the date
9 on which the defendant first becomes a party to an action
10 under section 1369 in a United States district court that
11 arises from the same accident as the action in State court,
12 or at a later time with leave of the district court.

13 “(2) Whenever an action is removed under this sub-
14 section and the district court to which it is removed or
15 transferred under section 1407(j) has made a liability de-
16 termination requiring further proceedings as to damages,
17 the district court shall remand the action to the State
18 court from which it had been removed for the determina-
19 tion of damages, unless the court finds that, for the con-
20 venience of parties and witnesses and in the interest of
21 justice, the action should be retained for the determination
22 of damages.

23 “(3) Any remand under paragraph (2) shall not be
24 effective until 60 days after the district court has issued
25 an order determining liability and has certified its inten-

1 tion to remand the removed action for the determination
2 of damages. An appeal with respect to the liability deter-
3 mination of the district court may be taken during that
4 60-day period to the court of appeals with appellate juris-
5 diction over the district court. In the event a party files
6 such an appeal, the remand shall not be effective until the
7 appeal has been finally disposed of. Once the remand has
8 become effective, the liability determination shall not be
9 subject to further review by appeal or otherwise.

10 “(4) Any decision under this subsection concerning
11 remand for the determination of damages shall not be re-
12 viewable by appeal or otherwise.

13 “(5) An action removed under this subsection shall
14 be deemed to be an action under section 1369 and an ac-
15 tion in which jurisdiction is based on section 1369 of this
16 title for purposes of this section and sections 1407, 1697,
17 and 1785 of this title.

18 “(6) Nothing in this subsection shall restrict the au-
19 thority of the district court to transfer or dismiss an ac-
20 tion on the ground of inconvenient forum.”.

21 (c) SERVICE OF PROCESS.—

22 (1) OTHER THAN SUBPOENAS.—(A) Chapter
23 113 of title 28, United States Code, is amended by
24 adding at the end the following new section:

1 **"§ 1697. Service in multiparty, multiform actions**

2 "When the jurisdiction of the district court is based
3 in whole or in part upon section 1369 of this title, process,
4 other than subpoenas, may be served at any place within
5 the United States, or anywhere outside the United States
6 if otherwise permitted by law."

7 (B) The table of sections at the beginning of
8 chapter 113 of title 28, United States Code, is
9 amended by adding at the end the following new
10 item:

"1697. Service in multiparty, multiform actions."

11 (2) SERVICE OF SUBPOENAS.—(A) Chapter 117
12 of title 28, United States Code, is amended by add-
13 ing at the end the following new section:

14 **"§ 1785. Subpoenas in multiparty, multiform actions**

15 "When the jurisdiction of the district court is based
16 in whole or in part upon section 1369 of this title, a sub-
17 poena for attendance at a hearing or trial may, if author-
18 ized by the court upon motion for good cause shown, and
19 upon such terms and conditions as the court may impose,
20 be served at any place within the United States, or any-
21 where outside the United States if otherwise permitted by
22 law."

23 (B) The table of sections at the beginning of
24 chapter 117 of title 28, United States Code, is

12

1 amended by adding at the end the following new
2 item:

"1785. Subpoenas in multiparty, multiforum actions."

3 **SEC. 4. EFFECTIVE DATE.**

4 (a) SECTION 2.—The amendments made by section
5 2 shall apply to any civil action pending on or brought
6 on or after the date of the enactment of this Act.

7 (b) SECTION 3.—The amendments made by section
8 3 shall apply to a civil action if the accident giving rise
9 to the cause of action occurred on or after the 90th day
10 after the date of the enactment of this Act.

Passed the House of Representatives March 14,
2001.

Attest:

Clerk.