UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA
04-CV-2819(JMR/FLN)

Kimberly Kay Witczak	)	
	)	
v.	)	ORDER
	)	
Pfizer, Inc.	)	

Defendant, a prescription drug manufacturer, seeks summary judgment claiming federal preemption bars plaintiff's state law failure-to-warn claim. Defendant's motion is denied.

I. Background

On August 6, 2003, Timothy Michael Witczak committed suicide. His suicide occurred shortly after he began taking Zoloft, a drug manufactured by defendant. Plaintiff is Mr. Witczak's surviving spouse, and claims his suicide was caused by known side effects of Zoloft. She further claims defendant is liable for wrongful death damages because, among other things, it failed to warn of Zoloft's association with "suicidality."

Zoloft is one of a class of drugs known as Selective Serotonin Reuptake Inhibitors ("SSRIs"). Defendant initially submitted the product for Food and Drug Administration ("FDA") approval in 1988. In 1991, the FDA granted approval for the drug's use in treating adult depression. The FDA-approved label did not warn of an association between Zoloft and suicidality. Instead, the label's "Precautions" section noted suicide as an inherent risk of depression.

Since granting original approval, the FDA has reapproved Zoloft several times for treatment of other disorders. As recently as February, 2003, it approved Zoloft for treatment of Social Anxiety Disorder. During the reapprovals, the FDA never suggested that Zoloft's label was deficient for failing to warn of a link to suicidality.[1]

Claims of an association between SSRIs and suicidality have been made since the drugs were first introduced. In the past 15 years, the FDA has considered three petitions to remove Prozac, another SSRI, from the market because of the claimed association. Each petition was denied.[2]

The FDA changed its position on March 22, 2004, when it issued a Public Health Advisory recommending that all SSRIs carry a warning calling for "close observation of adult and pediatric patients treated with these agents for worsening depression or the emergence of suicidality." (Pl. Ex. 11 at 1.) Defendant complied with the FDA's recommendation. Later that year, an FDA panel issued another Public Health Advisory directing that all SSRI labels carry a "black-box warning" -- the most serious kind --

---

[1]For a more in-depth review of Zoloft's FDA-approval proceedings, see Cartwright v. Pfizer, 369 F. Supp. 2d 876 (E.D. Tex. 2005).

[2]In 2002, the FDA filed an amicus brief in a separate action. See Motus v. Pfizer, 358 F.3d 659 (9th Cir. 2004). Its brief in that case said any change in the warning to reflect a causal link between Zoloft and suicidality would create a "false and misleading" label, in violation of federal law.

warning of "increased risk of suicidality . . . in children and adolescents." (Def. Ex. EE at 1.)

II. Legal Background

Defendant moves for summary judgment, claiming plaintiff's state law failure-to-warn claim -- upon which her other claims allegedly depend -- is preempted by the federal Food, Drug, and Cosmetics Act ("FDCA"), and FDA regulations promulgated pursuant to it. There are, broadly speaking, three kinds of preemption: express preemption, field preemption, and conflict preemption.[3] Defendant claims plaintiff's case is barred by conflict preemption.

Conflict preemption can be either direct or indirect. Direct conflict (or "impossibility preemption") occurs "where it is impossible for a private party to comply with both state and federal requirements"; indirect conflict (or "obstacle preemption") exists "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, 79 (1990) (internal quotation omitted).

---

[3]Express preemption exists when Congress states a clear intent to preempt state law. See, e.g., 29 U.S.C. § 1144(a) (ERISA) ("[T]his chapter shall supersede any and all State laws insofar as they may now or hereafter relate to any employee benefit plan . . . ."). Field preemption arises when "Congress has legislated comprehensively, thus occupying an entire field of regulation and leaving no room for the States to supplement federal law." Louisiana Public Service Comm'n v. F.C.C., 476 U.S. 355, 368 (1986). Neither party suggests either express or field preemption applies here. The many express preemption cases cited in the briefs are therefore of limited relevance.

Because conflict preemption is based on the presumed (rather than stated) intent of Congress, courts are advised to apply it sparingly. According to the Supreme Court, "a court should not find pre-emption too readily in the absence of clear evidence of a conflict." Geier v. American Honda Motor Co., Inc., 529 U.S. 861, 885 (2000); see also Gade v. Nat'l Solid Wastes Mgmt. Ass'n, 505 U.S. 88, 110 (1992) (Kennedy, J., concurring) ("Any conflict must be irreconcilable. The existence of a hypothetical or potential conflict is insufficient to warrant preemption of the state statute.") (internal omission and quotation omitted). Rather, a court should presume "that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress." New York State Conference of Blue Cross & Blue Shield Plans v. Travelers Ins. Co., 514 U.S. 645, 655 (1995) (internal quotation omitted). The Supreme Court has recognized "the historic primacy of state regulation of matters of health and safety." Medtronic, Inc. v. Lohr, 518 U.S. 470, 485 (1996).

III. Discussion

According to defendant, plaintiff's failure-to-warn claim conflicts both directly and indirectly with federal food and drug laws. Defendant first argues that the state law duty-to-warn requirement directly conflicts with both the FDA's requirement that it use "verbatim" the label specified by the agency, and with the

FDA's prohibition on "false and misleading" labels. Defendant alternatively argues that the failure-to-warn claim indirectly conflicts with the FDCA's goal of providing only scientifically accurate drug-label information. Defendant's contentions are without merit.

a. Direct Conflict

1. "Verbatim"

Defendant argues that if it had warned of an association between Zoloft and suicidality, it would have violated the FDA's order to use the FDA-approved warning-label language "verbatim."[4] But FDA regulations explicitly permitted defendant to unilaterally strengthen its warning label at any time without regulatory pre-approval. 21 C.F.R. § 314.70(c)(6)(iii)(A).[5] This particular regulation was promulgated precisely to allow drug-makers to quickly strengthen label warnings when evidence of new side effects are discovered. See 30 Fed. Reg. 993 (Jan. 30, 1965). Thus, as the FDA has noted, the regulation "permits the addition to the drug's labeling or advertising of information about a hazard

[4]The word "verbatim" appears only in the FDA "approvable letter" to Pfizer -- not in any of the misbranding statutes or regulations. (See Def. Ex. F at 1 ("Please use the proposed text verbatim.").)

[5]The regulation was originally codified at 21 C.F.R. § 130.9(d); it then became 21 C.F.R. § 314.8(d), before finally becoming 21 C.F.R. § 314.70(c). See 56 Fed. Reg. 59288, 59290 (Nov. 25, 1991).

without advance approval" by the FDA. 44 Fed. Reg. 37447 (June 26, 1979).

Defendant denies that § 314.70 defeats preemption because it gives manufacturers only temporary authority to strengthen their labels. The Court does not agree. The FDA's regulations do grant it the power to later disapprove a label strengthened pursuant to § 314.70. 21 C.F.R. § 314.70(c)(7). But the regulation "does not require that FDA take any action when a manufacturer" makes a change pursuant to § 314(c); if the FDA does nothing, the change remains in effect. See 56 Fed. Reg. 59290 (Nov. 25, 1991). Further, even if exercised, the power to disapprove does not retroactively make the manufacturer's strengthened label a violation of any law. Rather, if the FDA exercises its power to disapprove, the manufacturer simply stops distributing the new label. 21 C.F.R. § 314.70(c)(7).

Thus, the Court finds no absolute duty to use the FDA-approved label "verbatim." Pursuant to § 314.70(c), defendant could have strengthened its label to warn of the alleged association between Zoloft and suicidality at any time. Accordingly, it was not "impossible for [defendant] to comply with both state and federal requirements." English, 496 U.S. at 79.

2. "False and Misleading"

Defendant next asserts that a unilateral change in its warning label which suggested a link between SSRIs and suicidality would

have rendered the label "false and misleading," and in direct conflict with 21 U.S.C. § 355(e), the misbranding statute. Defendant bolsters this argument by pointing to a series of FDA pronouncements. The flaw in defendant's argument is that, as set forth below, none of the FDA's statements has the force of law. So none made it "impossible" for defendant to comply with Minnesota's failure-to-warn law.

A. The *Motus* Amicus Brief

Defendant proffers the FDA's amicus brief in Motus v. Pfizer in support of its position. 358 F.3d 659 (9th Cir. 2004) brief available at 2002 WL 32303084.[6] There, the FDA -- which has since modified its own position -- avers that it would have deemed any warning of a causal link between Zoloft and suicidality to be false and misleading. (Brief at p. 14.) These assertions do not preempt state law.

The FDA is authorized to promulgate regulations which have the preemptive force of law, so long as the regulations are properly adopted and in accord with its statutory authority. E.g. City of New York v. F.C.C., 486 U.S. 57, 63-64 (1988). And an agency's interpretations of its own regulations are ordinarily entitled to great deference. See generally Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc., 467 U.S. 837 (1984).

[6]Plaintiff moved to strike evidence of the Motus brief. Defendant also brought a motion to strike evidence of certain FDA statements. Both motions were denied at the hearing.

The Court, however, declines to treat statements from a single FDA legal brief as declarations afforded the preemptive force of law. First, the propositions defendant cites from the Motus brief were not even addressed or considered by the Motus court itself. See Motus, 358 F.3d at 661 (affirming district court's holding that plaintiff could not establish causality without reaching the preemption issue). Second, the FDA has since distanced itself from the substance of the Motus brief by recommending labeling changes that, in fact, reflect concerns about the association between SSRIs and suicidality. Thus, the Court has "reason to suspect that the [Motus brief's] interpretation does not reflect the agency's fair and considered judgment on the matter in question." Auer v. Robbins, 519 U.S. 452, 462 (1997).

Furthermore, even if the Court credited the Motus brief as an attempt by the FDA to articulate an official agency position, it would still fail to preempt plaintiff's claim. This is because the FDA has no authority to declare, ipse dixit, that a label is false and misleading. Rather, the government must initiate an enforcement action to establish that the drug is in fact misbranded. See 21 U.S.C. §§ 331-37, 352. For all of these reasons, the statements in the Motus brief are insufficient to preempt plaintiff's failure-to-warn claim.

B. The Reapprovals

Defendant next suggests the FDA would have regarded any unilateral label change to be "false and misleading" by pointing to the FDA's frequent reapproval of Zoloft without any changes to its warnings or its label. This suggestion fails to recognize that "FDA regulations are generally minimum standards of conduct" unless Congress has expressed clear intent to preempt state common law, which it has not done here. Hill v. Searle Laboratories, 884 F.2d 1064, 1068 (8th Cir. 1989); see also Wells v. Ortho Pharm. Corp., 788 F.2d 741, 746 (11th Cir. 1986) ("An FDA determination that a warning is not necessary may be sufficient for federal regulatory purposes but still not be sufficient for state tort law purposes."). As a result, rather than acting as a mandate, the reapprovals merely confirmed the minimum labeling requirements. They do not prove that a label strengthened pursuant to § 314.70(c)(6)(iii)(A) would necessarily be "false and misleading."

In sum, Pfizer's claim of direct conflict rests on its own assumptions of what the FDA would have done if defendant had unilaterally strengthened its warning label. The validity and authority of state law, however, does not depend on speculative hypotheticals. See Gade, 505 U.S. at 110 (Kennedy, J., concurring). The Court cannot find that defendant has established a direct conflict.

b. Indirect Conflict

Defendant also claims that complying with Minnesota's duty-to-warn regime would have created an indirect conflict. It claims any warning of a possible link between Zoloft and suicidality would have frustrated Congress's goal of ensuring the scientific validity of drug label information. Specifically, defendant posits that failure-to-warn laws pressure drug manufacturers to paper their labels with unsubstantiated warnings in order to avoid lawsuits. Defendant claims this undercuts the FDA's mission to provide only scientifically valid warnings, and over-deters the use of efficacious drugs. The Court considers this a public policy argument gone awry.

It is obvious that state failure-to-warn laws do not pressure manufacturers to include false or invalid warnings. Instead, they give drug manufacturers every incentive to warn of real, known risks as soon as they are discovered -- even before any FDA action. This does not conflict with the FDCA's purposes and objectives. To the contrary, FDA regulations allow drug manufacturers to strengthen warning labels "in the interest of drug safety" at any time without FDA pre-approval precisely so that new warnings can be "placed into effect at the earliest possible time" and "to enable

prompt adoption of such changes." 30 Fed. Reg. 993 (Jan. 30, 1965).[7]

This regulation underscores the crucial flaw in defendant's argument: Congress certainly did not intend to bar drug companies from protecting the public when enacting the FDCA; its goal was to protect the public. See, e.g., F.D.A. v. Brown & Williamson Tobacco Corp., 529 U.S. 120 (2000) ("The labeling requirements currently imposed by the FDCA . . . require the FDA to regulate the labeling of drugs and devices to protect the safety of consumers."); United States v. Sullivan, 332 U.S. 689, 696 (1948) ("[T]he Act as a whole was designed primarily to protect consumers from dangerous products."). Any contrary interpretation of Congress's intent is perverse.

The FDA itself vindicated Congress's protective intent when it issued its March 22, 2004, Public Health Advisory, recommending that SSRI labels be modified to reflect potential suicide risks. The FDA noted in the Advisory that it had "not concluded that [SSRI side effects] are a precursor to either worsening of depression or the emergence of suicidal impulses," but it still recommended the label change to alleviate "concern." (Pl. Ex. 11 at 1.) In other words: "Safety first."

---

[7]Prior to 1965, FDA regulations prohibited drug companies from strengthening their warnings without prior regulatory approval. See Caraker v. Sandoz Pharm. Corp., 172 F. Supp. 2d 1018, 1034-35 (S.D. Ill 2001) (citing 25 Fed. Reg. 12,592, 12,595 (Dec 9, 1960)).

State consumer-protection law compliments, rather than frustrates, the FDA's protective regime. This is especially apparent when one considers that prescription drugs were once marketed primarily to trained health care providers -- sophisticated and discerning intermediaries. Today, on the other hand, pill-rolling apothecaries and the mortar and pestle have disappeared. They have been replaced by drug manufacturers who urge the use of their drugs in mass-market print and television advertisements targeted directly at the public. Defendant, for example, advertises the drug involved in this case by personifying it as a happy, bouncing-oval cartoon character.

This new drug-marketing environment calls out for enhanced consumer protection. But defendant urges the Court to find Congress intended to obviate the very state laws that provide remedies to consumers harmed by dangerous products and deceptive marketing. The Court finds this proposition untenable in the absence of a clear and compelling Congressional statement. See Bates v. Dow Agrisciences LLC, 125 S. Ct. 1788, 1802 (2005) ("If Congress had intended to deprive injured parties of a long available form of compensation, it surely would have expressed that intent more clearly.").

Defendant's extended argument -- that too many warnings will dilute the effectiveness of warnings in general, and thereby under-deter the use of dangerous drugs -- is similarly unavailing. Drug

companies' pursuit of the public is sufficient to deter them from recklessly warning of unsubstantiated associations between their products and dire risks to health. State law need not be preempted to accomplish this.

Finally, defendant's argument that it should not be exposed to fifty-one separate tort-law regimes also rings hollow. Most mass merchants in this nation's economy sustain this burden as a cost of doing business. If Congress intends to create a class of protected businesses, it has the means and ability to do so. The Court finds no proof that it has done so here.

IV. Conclusion

Defendant's preemption argument has a surface appeal: Should it face state law liability for a failure to warn even though its label fully complied with federal law? But the argument fails upon scrutiny. Federal labeling laws are minimum standards; they do not necessarily shield manufacturers from state law liability. The primary purpose of both the FDCA and the FDA's regulatory scheme is to protect the public. State-law protections reinforce and enhance this objective.

Defendant's preemption argument ultimately fails because Congress has not expressed a specific intent to preempt state consumer-protection laws in the area of prescription-drug labeling. In the absence of Congress's express statement, defendant must overcome the presumption against implying Congressional preemptive

intent. It has not done so. As a result, plaintiff's state law claims remain viable.

Accordingly, for all of the foregoing reasons, IT IS ORDERED that:

1. Defendant's motion for summary judgment [Docket No. 15] is denied.

2. The motions to strike [Docket Nos. 66 & 97] are denied.

Dated: July 20, 2005

s/ James M. Rosenbaum
JAMES M. ROSENBAUM
United States Chief District Judge