UNITED STATES DISTRICT COURT

EASTERN DISTRICT OF CALIFORNIA

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TERRI S. O'NEAL, individually and as successor-in-interest to the Estate of BENJAMIN L. BRATT; BARRY M. BRATT, individually,

Plaintiffs,

v.

SMITHKLINE BEECHAM CORPORATION d/b/a GLAXOSMITHKLINE, a Pennsylvania Corporation; and DOES 1-50,

Defendants.

NO. CIV S-06-1063 FCD/DAD

MEMORANDUM AND ORDER

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This matter is before the court on defendant SmithKline Beecham Corporation, d/b/a GlaxoSmithKline's ("GSK") motion for summary judgment on the ground plaintiffs Terri O'Neal and Barry Bratt's ("plaintiffs") state tort claims are preempted by federal law, *i.e.*, the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 *et seq.*, and its implementing regulations, because they require warnings that directly conflict with federal law

governing the labeling and warnings for Paxil® ("Paxil"). Plaintiffs bring this action for the wrongful death of their son, Benjamin Bratt ("Benjamin"), who attempted suicide, on February 14, 1997, at the age of 13, while being treated with Paxil, an antidepressant medication manufactured and sold by GSK. Benjamin died on February 15, 1997 from injuries sustained from his suicide attempt.

The gravamen of plaintiffs' claims is that GSK should have provided, at the time of Benjamin's death, a warning that Paxil is associated with suicidality[1] in pediatric patients. GSK contends, however, that plaintiffs' state tort claims directly conflict with the FDA's-mandated labeling for Paxil in February 1997, and implementation of the warning urged by plaintiffs would have rendered Paxil's prescribing information false and misleading under federal law, as no reasonable evidence existed, at the time, to support implementation of the warning. As such, because there is a direct and actual conflict between plaintiffs' state law claims and federal law, GSK asserts plaintiffs' claims are preempted and must be dismissed.

The court heard oral argument on the motion on January 18, 2008. By this order, the court now renders its decision, granting GSK's motion in its entirety. For the reasons set forth below, the court finds that federal law preempts plaintiffs' instant action against GSK.

[1] As used by the parties, the term "suicidality" refers to suicidal thoughts and behavior.

BACKGROUND

A. FDA Regulation of Drug Labeling Generally

The Federal Drug Administration ("FDA") is responsible for enforcing the FDCA. In the FDCA, Congress broadly charged the FDA with promoting "the public health by promptly and efficiently reviewing clinical research and taking appropriate action on the marketing of regulated products," 21 U.S.C. § 393(b)(1), and with ensuring that "drugs are safe and effective," 21 U.S.C. § 393(b)(2)(B). Congress also provided the FDA with exclusive authority to enforce the FDCA, and litigants cannot enforce the FDCA through private actions. 21 U.S.C. § 337(a); Buckman Co. v. Plaintiffs' Legal Comm., 531 U.S. 341, 349 n.4 (2001).

As part of its regulatory mission, the FDA undertakes an extensive review of new drugs before they are allowed on the market. See 21 U.S.C. § 355 (outlining the New Drug Application ["NDA"], which requires, among many other things, evidence establishing whether the drug is safe and effective in its use and proposed labeling). Most prescription drugs, including Paxil, begin the regulatory approval process as a "new drug." 21 U.S.C. § 321(p). The FDA carefully reviews the NDA and identifies the actual and potential safety risks the drug poses and decides how these risks should be disclosed in the prescribing information. The FDA approves the NDA only after it concludes that a prescription drug is both "safe" and "effective" under the conditions of use specified in the proposed prescribing information. 21 C.F.R. §§ 201.56(d), 201.57 (FDA must be satisfied that the drug's labeling accurately describes its indications, dosages, administration, contraindications, warnings

and precausations, adverse reactions, interactions, and use in specific populations). The FDA must disapprove a NDA if it finds that: (1) investigations conducted to establish safety and effectiveness were not adequate; (2) the prescription drug is not safe for use under the conditions provided in the proposed labeling; or (3) the proposed labeling is false and misleading. 21 U.S.C. § 355(d); 21 C.F.R. § 314.125(b)(2), (3), (6).

As part of the approval process, manufacturers of new drugs submit to the FDA "specimens of the labeling proposed to be used for such drug." 21 U.S.C. § 355(b)(1). While there are several mandatory aspects of included drug information (see 21 C.F.R. § 201.56-57), the aspect relevant to the present case involves the "warnings" section. This section must describe "clinically significant adverse reactions (including any that are potentially fatal, are serious even if infrequent, or can be prevented or mitigated through appropriate use of the drug)." 21 C.F.R. § 201.57(c)(6)(I). Under the FDA's regulations, warnings must be included on a label "as soon as there is reasonable evidence of a casual association [of a serious hazard] with a drug." Id.[2]

The FDA communicates its decision to approve the NDA through an approval letter that sets out FDA's terms for approving both the drug and its labeling. FDA approval of a NDA is expressly conditioned on the development and use of "final printed labeling" (prescribing information) that is identical, in every

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[2] The FDA interprets the phrase "reasonable evidence of an association" to mean that "evidence exists on the basis of which experts qualified by scientific training and experience can reasonably conclude that the hazard is associated with the drug." 44 Fed. Reg. 37434, 37447 (June 26, 1979).

material respect, to the labeling that accompanies the approval letter. 21 C.F.R. § 314.105(b). Use of the FDA-approved prescribing information is mandatory and failure to comply may lead to civil and criminal enforcement. The FDCA envisions a number of remedies against violators, including in rem forfeiture, injunction, and/or criminal prosecution against the manufacturer or responsible person if a "misbranded" drug is distributed. 21 U.S.C. §§ 332(a), 333, 334(a), and 337(a). The FDA may also seek to withdraw approval of a NDA. 21 C.F.R. § 314.150(b).

A prescription drug is misbranded if its labeling is false or misleading, lacks "adequate information for use," or omits material facts. 21 U.S.C. §§ 352(a), (f)(1), 321(n); 21 C.F.R. § 201.100(c)(1). Therefore, departing from the FDA-approved prescribing information, failing to include a scientifically valid warning FDA believes is necessary, or including warning information not based on scientific evidence of known risks, causes the drug labeling to be "false and misleading" and lacking "adequate directions for use" and misbranded, in violation of the FDCA. 21 U.S.C. § 352(a), (f)(1).

After approval of a NDA, the FDA continues to exercise extensive control over the safety of prescription drugs and the content of their labeling. The FDA can move to withdraw its approval of a drug if it finds that scientific data shows that the drug is unsafe for use under the conditions set forth when the application was approved. 21 U.S.C. § 355(e). Additionally, the FDA imposes comprehensive post-approval reporting requirements on manufacturers, including reports of adverse

events and all published and unpublished clinical trials on the drug. 21 C.F.R. § 314.80-81. If a manufacturer seeks NDA approval for additional indications or dosage forms (as was done for Paxil more than ten times between 1992 and 2004), then it must provide new supporting data to the FDA, including updated integrated summary of safety ("ISS") and effectiveness ("ISE"). 21 C.F.R. § 314.50(d)(5)(vi)(a). If the FDA finds that any information from a post-approval report or a new ISS report merits a change in the drug's labeling, it will request that the company make the change. If the company refuses to do so, the FDA may pursue the administrative and enforcement actions described above to secure the change.

FDA regulations also allow manufacturers to make certain changes to their drug labels. With the exception of minor editorial changes, a manufacturer must formally file a "supplement" to the NDA to effect any change in a drug's prescribing information. Two types of supplements are used for labeling changes. The first, a "Prior Approval Supplement," requires FDA's prior approval before implementation. 21 C.F.R. § 314.70(b)(2)(v). The second, a "Changes Being Effected" supplement ("CBE"), does not require prior approval but must nonetheless be submitted to the FDA for its review and final approval.[3] 21 C.F.R. § 314.70(c)(6)(iii). Among the changes

[3] If a company pursues the CBE route and immediately implements a labeling change, FDA continues to retain the right to disapprove or modify the change at any time. In the event FDA disapproves a CBE change after it is in the marketplace, the company must immediately comply with FDA's judgment and revise the label accordingly. If the company refuses, its drug is

(continued...)

that can be unilaterally made by the manufacturer using a CBE supplement are changes to "add or strengthen a contraindication, warning, precaution or adverse reaction." 21 C.F.R. § 314.70(c)(6)(iii)(A). These changes, like all warnings, remain subject to Section 201.57(c)(6)(I) and may only be added when there is reasonable evidence of an association of a serious hazard with the drug.

B. Pertinent Aspects[4] of Paxil's Regulatory History

1. FDA Review & Approval of Original Paxil NDA (1989-1992)

On November 20, 1989, SmithKline Beecham Pharmaceuticals ("SB")[5] filed a NDA for paroxetine (Paxil) seeking FDA approval for the treatment of depression in adults.[6] (Pls.' Opp'n to GSK's Stmt. of Undisputed Facts [Docket # 142-2], filed Nov. 14, 2007 ["UF"], ¶ 7.)[7] SB submitted extensive data and information

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[3](...continued)
misbranded and distribution is prohibited under the FDCA. (See Arning Decl., filed Oct. 6, 2007, ¶s 16-17.)

[4] An exhaustive description of Paxil's regulatory history is provided by GSK in its moving points and authorities (see Docket #98 at 10-21). In many respects, plaintiffs object to GSK's description. The entirety of Paxil's regulatory history, however, is not pertinent to the court's resolution of the motion, and as such, it recounts herein only that portion of the history which it finds relevant to determination of the motion. To the extent the history is repeated here, and as more fully explained below, the court overrules any evidentiary objections posed by plaintiffs.

[5] SB and GlaxoWellcome entities merged in or about December 2000 to form GSK PLC. (UF ¶ 8.) This orders refers to SB and GSK interchangeably at times.

[6] Prescription Paxil is one of a class of drugs known as selective serotonin reuptake inhibitors ("SSRIs"). (UF ¶ 6.)

[7] Plaintiffs object to the vast majority of GSK's proffered undisputed facts, primarily on the basis of irrelevancy (continued...)

in this initial submission and in numerous amendments to the NDA throughout the following three year period. These submissions to the Paxil NDA included information describing any incidents of suicidality in patients given placebo, Paxil or active control drugs during clinical studies. (UF ¶ 9.)[8]

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[7](...continued)
(Fed. Rs. Evid. 402, 403) or improper authentication (Fed. R. Evid. 602). More specifically, plaintiffs assert their irrelevancy objections largely at GSK's proffered evidence concerning a similar SSRI, Prozac. (See Pls.' Objs. and Mtn. to Strike Evid. [Docket #151], filed Nov. 14, 2007.) Plaintiffs' objections are unavailing; GSK has amply demonstrated the multiple ways in which said evidence is relevant to this motion (see Opp'n to Mtn. to Strike [Docket #160], at 9-11), and courts considering similar motions and objections have rejected the plaintiffs' similar irrelevancy claims (see Dusek v. Pfizer, 2004 WL 2191804, at *7 (S.D. Tex. Feb. 20, 2004) (rejecting argument in Zoloft case that the court should not consider FDA's evaluation of Prozac's labeling when deciding a similar preemption motion). As to plaintiffs' authentication objections, they object to the authenticity and foundation of GSK's own documents and publicly available FDA documents. Again, plaintiffs' objections are unavailing. GSK's documents have been authenticated by Dr. Arning and a proper foundation has been laid to satisfy the business records exception to the hearsay rule. (See GSK's Opp'n to Pls.' Add'l Disputed Facts [Docket #161], filed Nov. 21, 2007, at 2-3.) As to the variety of FDA documents submitted by GSK, these documents have likewise been properly authenticated by GSK and clearly satisfy the business records exception to the hearsay rule. (Id. at 3.) Indeed, despite asserting these objections to the FDA related documents, plaintiffs themselves cite and rely upon these documents in their statement of additional disputed facts. Plaintiffs obviously cannot have it both ways.

Ultimately, where the court describes herein any fact objected to by plaintiffs on these grounds, plaintiffs' objections are overruled, and the court finds the fact undisputed. To the extent these issues are raised in plaintiffs' motion to strike evidence (Docket #151), plaintiffs' motion is denied.

[8] Despite FDA's ultimate findings to the contrary, plaintiffs contend that these initial submissions by SB, in 1989, showed a statistically significant, greater than eight fold increased risk of suicidal behavior--suicide and suicide attempts--for adult patients put on Paxil when compared to patients put on placebo (dummy) pills. Plaintiffs contend this (continued...)

In late 1990 and early 1991, two groups filed "Citizen Petitions" pursuant to 21 C.F.R. § 10.30, asking the FDA to withdraw approval of the NDA for Prozac, the only approved SSRI at the time. These petitions alternatively sought warning statements in SSRI labeling regarding an increased risk of suicide. (UF ¶s 12, 14.)

On October 3, 1990, because of the questions raised about an increased risk of suicidality in Prozac, the FDA requested data on suicidality from SB while the NDA for Paxil was under review. (UF ¶ 11 [Specifically, FDA requested SB prepare a report discussing the relationship between Paxil and "violence-ideation and suicide ideation."].) On May 10, 1991, SB submitted an analysis based on its worldwide clinical database that showed that patients randomized to Paxil therapy were at no greater risk

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[8](...continued)
information was not acted upon by the FDA because SB submitted reports that included events or conclusory statements that obscured or falsely stated the true reports. (See GSK's Resp. to Pls.' Stmt. of Add'l Disputed Facts ["ADF"], filed Nov. 21, 2007, ¶ 1-10.) More specifically, plaintiffs contend SB improperly included pre-baseline events (run-ins) as post-baseline placebo events. Pre-baseline means before a study actually begins, while potential participants are being evaluated to determine if they meet inclusion criteria as dictated by the clinical trial's protocol. Plaintiffs maintain that it was improper to have included run-in events in tabulations of post-baseline suicidal behavior events and risk rates.

This dispute between the parties does not preclude entry of summary judgment in favor of GSK on this motion for the reasons set forth more fully below. In short, to the extent plaintiffs' argument sounds in a claim of fraud, *i.e.*, that GSK defrauded the FDA in obtaining approval of Paxil, such a claim is not cognizable under Buckman v. Plaintiffs' Legal Comm., 531 U.S. 341, 348 (2001) (holding that the plaintiffs' state-law fraud-on-the-FDA claims conflict with, and are therefore impliedly pre-empted by federal law). Additionally, plaintiffs' proffered evidence does not raise a triable issue of fact that GSK was aware, at the time, of reasonable evidence of an association between Paxil and suicidality in *pediatric* patients.

for suicidal ideation or behavior than patients who were randomized to placebo or other active medication. (UF ¶ 13.)[9] On June 19, 1991, Dr. Martin Brecher, the lead FDA safety reviewer for the Paxil NDA issued his report, finding: "there is no signal in this large data base that paroxetine exposes a subset of depressed patients to additional risk for suicide, suicide attempts or suicidal ideation." (UF ¶ 15.)

In September 1991, FDA convened a Psychopharmacological Drugs Advisory Committee ("PDAC") meeting to consider further whether there was an association between SSRIs and suicide. (UF ¶ 16.) The PDAC concluded, in agreement with prior findings of the FDA itself (UF ¶s 18, 19), that no credible evidence existed to conclude that antidepressants cause the "emergence and/or intensification of suicidality and/or other violent behavior." (UF ¶ 20.)

Ultimately, the FDA denied the citizen petitions regarding Prozac, finding that there was no "reasonable evidence of an association between the use of Prozac and suicidality." (UF ¶s 21, 22.)

Similarly, on October 5, 1992, during the PDAC panel meeting on Paxil, FDA officials presented their analyses of the Paxil NDA, including clinical trial data on safety and efficacy. (UF ¶ 24.) Dr. Thomas Laughren reported that "there was no suggestion

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[9] Plaintiffs dispute this fact, arguing that when GSK responded to the FDA's request it again, as in 1989, intentionally obscured the risks by improper inclusion of the run-in events in the post-baseline tabulations (ADF ¶s 16-20); according to plaintiffs' experts, when analyzed correctly, the net result is that the adult patients on Paxil had a statistically significant greater than eight-fold increase in suicidal behavior. (UF ¶ 13.)

here of emergence of suicidality with paroxetine." (UF ¶ 26.) The PDAC found Paxil safe and effective for use in the treatment of adult depression and voted unanimously in favor of approval. (UF ¶ 27.)

On December 29, 1992, the FDA issued an approval letter for Paxil which made clear that the approval was conditioned on the use of the FDA-approved prescribing information. (UF ¶ 29.) The original FDA-approved labeling did not include any warning or other statement indicating there was an increased risk of suicide or suicidality from Paxil. The only references to "suicide" or "suicide attempt" in the labeling appeared in the description of "a major depressive episode" and a precaution that suicide is an inherent risk in depressed patients. (UF ¶ 30.)[10]

During the period from Paxil's original approval in 1992 through January 2004, the FDA reviewed and approved at least 12 supplemental NDAs for new therapeutic indications for Paxil, and two additional NDAs for new formulations of Paxil, an oral suspension and a controlled release version of the drug. (UF ¶

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[10] Following the 1992 approval of Paxil for the treatment of adult depression, SB approved in August 1993 a clinical trial, "Study 329," involving a multi-center, double blind, placebo controlled study of paroxetine and imipramine in adolescents (ages 12 to 18 years, 11 months old) with unipolar major depression. (ADF ¶ 32.) Plaintiffs contend that beginning in 1994 through 1996, SB received reports from clinical investigators of adolescents experiencing suicidality on Paxil. (ADF ¶s 34-37.) GSK disputes these facts, arguing plaintiffs misreport the investigators' true findings (id.), and regardless, SB did not break the blind on the acute phase of the trial until *October 1997*, after Benjamin's death (UF ¶ 43). The results of this study were not submitted to the FDA until May 2003, following GSK's April 2002 application for approval of Paxil for children. For the reasons set forth below, the court finds that evidence pertaining to Study 329 does not raise a triable issue as to whether SB/GSK was aware of an association of suicidality and pediatric patients prior to February 1997.

31.) Each approval was conditioned on the verbatim use of the FDA-approved prescribing information and warnings. (UF ¶ 33.) Where required, SB and GSK submitted to the FDA ISSs, which included all available information about the safety of the drug product, including adverse events. (UF ¶ 35.) The FDA used these opportunities to review updated safety information and require certain changes to Paxil's labeling. (UF ¶ 34.) None of these reviews, however, required labeling relating to an association between Paxil and suicide or suicidality in adult or pediatric patients. (UF ¶ 39.)

2. FDA's Continued Monitoring of Paxil's Safety (1995-2003)

On June 9, 1995, in response to the FDA's request, SB submitted data and reported that studies indicated no increased suicidality associated with paroxetine or clomipramine when compared with placebo. (UF ¶ 40.)

In 1997, another citizen petition was filed with the FDA which sought to require a warning in the prescribing information for Prozac that "people who are considered at risk for suicide and who begin to take [Prozac] should be carefullly observed and should consider taking a sedative as well." On June 25, 1997, the FDA rejected the petition, explaining that it "carefully considered the issue of whether Prozac was associated with suicidal ideation and suicidality and concluded that no labeling revisions were warranted." (UF ¶s 41, 42.)

At various times between July 1999 and February 2003, in response to FDA requests or on its own, SB and/or GSK submitted

data to the FDA regarding the incidence of suicide in randomized controlled trials for Paxil. (UF ¶s 45-48.)

3. FDA Public Health Advisories, Advisory Committee Meetings and Labeling Changes for SSRIs regarding Pediatric Suicidality (2003-2004)

On May 23, 2003, GSK submitted to the FDA analyses of the reports of possible "suicide attempts" and "possibly suicide-related" events from the pediatric-only clinical trials. During the "on-therapy plus 30 days post-therapy period," there was a statistically significant difference between paroxetine and placebo when the data from all pediatric studies included in the analyses were pooled together. (UF ¶ 49.) On June 19, 2003, the FDA issued a Talk Paper, reporting that it was "reviewing reports of a possible increased risk of suicidal thinking and suicide attempts in children and adolsecents under the age of 18 treated with the drug Paxil for major depressive disorder (MDD)." The advisory stated: "Although the FDA had not completed its evaluation of the new safety data, FDA is recommending that Paxil not be used in children and adolescents for the treatment of MDD." (UF ¶ 50.) The FDA did not take any action with respect to Paxil's labeling and warnings at that time. (UF ¶ 51.)

On October 27, 2003, the FDA issued a Public Health Advisory and corresponding Talk Paper, stating that the "data do not clearly establish an association between the use of these drugs and increased suicidal thoughts or actions by pediatric patients." The Paper also provided, however, that it was "not possible at this point to rule out an increased risk of these adverse events [suicidality] for any of these drugs, including Paxil . . . ." (UF ¶ 52.) The FDA scheduled an advisory

committee meeting for February 2, 2004 to discuss the available data and pertinent regulatory actions. (UF ¶ 54.)

On February 2, 2004, an FDA advisory committee convened to discuss the possible relationship between antidepressants and suicidal thinking in pediatric patients, specifically patients 18 years of age and younger. (UF ¶ 61.) The committee ultimately recommended that the FDA reanalyze the data on pediatric use, warn the public and physicians of the possibility of suicidality in the pediatric population and change the labeling for antidepressants. (UF ¶ 64.) The committee met again in September 2004, and concluded that in the aggregate, the data reflected an increased risk of suicidality in pediatric patients and recommended that the FDA consider new class labeling changes. (UF ¶s 66, 67.)

On October 15, 2004, FDA issued a Public Health Advisory and a letter directing all manufacturers to add a "black box" warning and expanded warning statements to the labeling of all antidepressant medications describing the increased risk of suicidality in children and adolescents. (UF ¶ 68.)

On November 12, 2004, GSK submitted labeling supplements seeking to add FDA's October 15, 2004 warnings to Paxil's labeling. (Arning Decl., ¶ 56.) On January 12, 2005, FDA approved GSK's application. (Id. at ¶ 58.) On January 26, 2005, FDA notified GSK that it decided to "modify the new PI [package insert] slightly so that the language in the 'Warnings Section' of the PI more precisely mirrors the language set forth in the black box warning." (UF ¶ 70.) Specifically, the FDA stated:

> The sentence in the current "Warnings Section" of the PI that reads, "A causal role of antidepressants in inducing suicidality has been established in pediatric patients" should be excised and replaced with the following: "Antidepressants increased the risk of suicidal thinking and behavior (suicidality) in short term studies in children and adolescents with Major Depressive Disorder (MDD) and other psychiatric disorders."

(Id.) On January 26, 2005, FDA approved the labeling supplements for Paxil submitted by the company on November 12, 2004. (UF ¶ 71.)[11]

C. Undisputed Facts Regarding Benjamin Bratt's Death

Benjamin had a history of depression that predated both his suicide and his ingestion of Paxil. (UF ¶ 1.) On February 6, 1997, Paxil was prescribed for Benjamin by his nurse practitioner. (UF ¶s 2, 3.) On February 14, 1997, Benjamin attempted to commit suicide by hanging himself. (UF ¶ 4.) On February 15, 1997, Benjamin died from injuries sustained from his suicide attempt. (UF ¶ 5.)

Plaintiffs, Benjamin's parents, filed this action on April 14, 2006 in El Dorado County Superior Court. Former co-defendant McKesson Corporation (now dismissed) removed the action on the basis of diversity jurisdiction to this court on May 15, 2006. Plaintiffs' complaint asserts the following claims against GSK: (1) negligence; (2) strict products liability; (3) breach of express warranty; (4) fraud; and (5) negligent infliction of emotional distress.

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[11] Certain other changes to Paxil's labeling were conducted during 2005-2007 regarding adult suicidality. (See UF ¶s 70-91.) These facts are not pertinent to the instant motion, and thus the court does not recount that portion of Paxil's regulatory history.

STANDARD

A. Summary Judgment

The Federal Rules of Civil Procedure provide for summary judgment where "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." Fed. R. Civ. P. 56(c); see California v. Campbell, 138 F.3d 772, 780 (9th Cir. 1998). The evidence must be viewed in the light most favorable to the nonmoving party. See Lopez v. Smith, 203 F.3d 1122, 1131 (9th Cir. 2000) (en banc).

The moving party bears the initial burden of demonstrating the absence of a genuine issue of fact. See Celotex Corp. v. Catrett, 477 U.S. 317, 325 (1986). If the moving party fails to meet this burden, "the nonmoving party has no obligation to produce anything, even if the nonmoving party would have the ultimate burden of persuasion at trial." Nissan Fire & Marine Ins. Co. v. Fritz Cos., 210 F.3d 1099, 1102-03 (9th Cir. 2000). However, if the nonmoving party has the burden of proof at trial, the moving party only needs to show "that there is an absence of evidence to support the nonmoving party's case." Celotex Corp., 477 U.S. at 325.

Once the moving party has met its burden of proof, the nonmoving party must produce evidence on which a reasonable trier of fact could find in its favor viewing the record as a whole in light of the evidentiary burden the law places on that party. See Triton Energy Corp. v. Square D Co., 68 F.3d 1216, 1221 (9th Cir. 1995). The nonmoving party cannot simply rest on its

allegations without any significant probative evidence tending to support the complaint. See Nissan Fire & Marine, 210 F.3d at 1107. Instead, through admissible evidence the nonmoving party "must set forth specific facts showing that there is a genuine issue for trial." Fed. R. Civ. P. 56(e).

B. Conflict Preemption

The United States Constitution and federal laws and treaties "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." U.S. Const. Art. VI, Cl. 2. In applying this standard, the United States Supreme Court has recognized three types of federal preemption of state law. First is express preemption, where Congress states explicitly the preemptive effect of its legislation on state law. English v. General Electric Co., 496 U.S. 72, 78-79 (1990). Second is field preemption, where Congress intends for federal law to occupy exclusively an entire field of regulation. Id. at 79. Third is conflict preemption, the type of preemption advocated by GSK in this case. 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." Sprietsma v. Mercury Marine, 537 U.S. 51, 64 (2002) (internal quotations and citations omitted); see also Witczak v. Pfizer, Inc., 377 F. Supp. 2d 726, 728 (D. Minn. 2005) (discussing the two forms of conflict

preemption, direct and indirect). Conflict preemption can arise even when the conflict does not stem directly from federal statutory language. Regulations promulgated pursuant to federal statutory authority "have no less pre-emptive effect than federal statutes." Fidelity Federal Savings and Loan Ass'n v. de la Cuesta, 458 U.S. 141, 153 (1982).

However, because states are themselves independent sovereigns within the federal system, there is a general presumption that Congress does not cavalierly preempt state law causes of action. Building and Const. Trades Council of Metro. Dist. v. Assoc. Builders and Contractors of Mass./RI, Inc., 507 U.S. 218, 224 (1993) ("Consideration under the Supremacy Clause starts with the basic assumption that Congress did not intend to displace state law.") Thus, conflict preemption applies only if the need for it is clear. Geier v. Am. Honda Motor Co., Inc., 529 U.S. 861, 885 (2000) ("a court should not find preemption too readily in the absence of clear evidence of a conflict").

ANALYSIS

Under these preemption principles, plaintiffs may not force GSK to choose between avoiding state tort liability and complying with federal law. Geier, 529 U.S. at 873. Nor may plaintiffs pursue claims that hinder the "full purposes and objectives of Congress," Capital Cities Cable, Inc. v. Crisp, 467 U.S. 691, 699 (1984) (internal quotations and citations omitted), or "frustrate the purposes" of "statutorily authorized agency regulations," City of New York v. FCC, 486 U.S. 57, 63-64 (1988). Here, the court does not reach this latter "obstacle preemption" theory,

because it finds a direct conflict of law and thus bases its decision on a finding of "impossibility preemption."

A direct conflict of law exists in this case because GSK could not have been in compliance with federal law in February 1997 and have included the suicidality warning plaintiffs urge. In other words, had GSK included the warning that plaintiffs insist upon, GSK would have risked misbranding Paxil in violation of the FDCA. Therein the lies the actual and direct conflict presented in this case--comply with federal law and be held liable under state law tort claims, or, to avoid state tort liability, add a warning without reasonable evidence and violate federal law.

As the court will explain below, GSK and plaintiffs agree on one critical point: GSK could not have changed the Paxil labeling to include a warning of a potential association of suicidality in pediatrics taking Paxil absent "reasonable evidence" of an association. 21 C.F.R. § 201.57(c)(6)(I). The court cannot find, however, on the evidence proffered by plaintiffs, that such evidence existed *prior to* Benjamin's death in February 1997. In fact, the evidence submitted by GSK suggests the contrary. Clearly, plaintiffs' state law claims conflict directly with the FDA-mandated labeling and warning for Paxil, at the relevant time. Had GSK included the warning plaintiffs urge, contrary to the FDA's approvals and absent reasonable evidence available at the time, it would have misbranded the drug in violation of the FDCA. Thus, plaintiffs' claims are preempted.

Before addressing these findings, the court notes preliminarily that in reaching its decision it does not rely on

the preemption opinions of the FDA, as either expressed in the various amicus briefs submitted by GSK in support of its motion[12] or as stated in the 2006, so-called "Preemption Preamble."[13] Since this is a case of conflict preemption, no formal statement

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[12] In their motion to strike evidence (Docket #151), plaintiffs also seek to exclude all amicus briefs filed by GSK in support of its motion. The submitted amicus briefs were filed by the FDA in other failure to warn litigation relating to SSRIs. While the court does not rely on these briefs in reaching its decision herein, it does not strike the evidence as requested by plaintiffs. Plaintiffs' primary objection on hearsay grounds is unpersuasive. Courts routinely consider amicus briefs filed in other litigation. See e.g. In re Bextra and Celebrex Mktg. Sales Practices & Prod. Liab. Litig., 2006 WL 2374742, at *5 (N.D. Cal. Aug. 16, 2006); Witczak v. Pfizer, Inc., 377 F. Supp. 2d 726, 730 n. 6 (D. Minn. 2005). Moreover, even if the amicus briefs were considered hearsay evidence, the briefs fall under the public records exception to the hearsay rule. Fed. R. Evid. 803(8). The briefs also do not need to be purely factual to be admissible. See e.g. Breech Aircraft Corp. v. Rainey, 488 U.S. 153, 170 (1988); Gilbrook v. City of Westminster, 177 F.3d 839, 858-59 (9th Cir. 1999). Finally, plaintiffs assert a number of other bases for exclusion of these briefs, none of which the court finds persuasive. (See Opp'n to Mtn. to Strike at 6-9.) As a result of these findings, the court denies plaintiffs' motion to strike evidence (Docket #151) in its entirety.

[13] In 2006, the FDA issued its most recent labeling rule; in the preamble to the rule, it explained the implications of its labeling regulations on products liability claims, expressly finding that: "under existing preemption principles, FDA approval of labeling under the act, whether it be in the old or new format, preempts conflicting or contrary State law." 71 Fed. Reg. 3922, 3934 (Jan. 24, 2006). In making this finding, the FDA provided certain examples of when it believes state laws are preempted, with one situation specifically pertinent to this case: "FDA believes that State laws conflict with and stand as an obstacle to achievement of the full objectives and purposes of Federal law when they purport to compel a firm to include in labeling or advertising a statement that FDA has considered and found scientifically unsubstantiated. In such cases, including the statement in the labeling or advertising would render the drug misbranded under the act (21 U.S.C. § 352(a) and (f))." 71 Fed. Reg. 3922, 3935. More specifically, the FDA found that claims that a drug sponsor breached an obligation to warn by failing to include contraindications or warnings that are not supported by evidence that meets the standards set forth in this rule are preempted. Id. at 3936.

of Congressional intent to preempt is necessary, nor is a statement of agency intent required. Geier, 529 U.S. at 884; see also Pennsylvania Employees Benefit Trust Fund v. Zeneca, Inc., 2007 WL 2376312, at *6 (3rd Cir. Aug. 17, 2007) (recognizing that conflict preemption arises absent an "express congressional command"). Thus, consideration of the preemption views of the FDA is not necessary to resolution of the motion. As such, the court does not discuss herein the parties' various and lengthy arguments in favor and against paying deference to the FDA's views on whether cases such as this one are preempted by federal law. Instead, this court's decision is driven by the facts of this case, which point to only one conclusion--that at the relevant time, GSK could not have complied with both federal and state law requirements for the warning at issue. See accord Dobbs v. Wyeth Pharma., 2008 WL 169021, at *13 (W.D. Okla. Jan. 17, 2008) (declining to pay deference to the "relatively broad scope of preemption set forth in the Preamble and *amicus* briefs filed [by the FDA] since 2000" since the particular facts of that case "present[ed] a narrower issue").

A. FDA-Mandated Labeling and Warnings for Paxil Pre-February 1997

Federal law requires GSK to follow FDA's labeling and to use the FDA-approved labeling verbatim. 21 U.S.C. § 314.105(b). If GSK departs from these federal requirements and inserts unsubstantiated warnings, the drug labeling will be false and/or misleading, and the company could be subjected to enforcement actions. See 21 U.S.C. § 352(a), (f).

Here, plaintiffs do not dispute that prior to February 1997, the FDA did not require that SB/GSK warn of an increased risk of suicidality in patients taking Paxil, adult or adolescent. While Paxil's NDA was under review during 1989 through 1992, the FDA considered whether any credible evidence existed to find that antidepressants cause the emergence and/or intensification of suicidiality and/or violent behavior, and concluded that no such evidence existed. (UF ¶ 20.) Ultimately, the FDA denied two citizen petitions directed at Prozac, a similar SSRI to Paxil, on the basis of this conclusion. (UF ¶s 21, 22.) Similarly, the PDAC panel on Paxil specifically concluded that "there is no suggestion here of emergence of suicidality with paroxetine." (UF ¶ 26.) The panel found Paxil safe and effective for use in the treatment of adult depression and voted unanimously in favor of approval. (UF ¶ 27.) The original FDA-approved labeling, which SB/GSK was mandated to use (UF ¶ 29), did not include any warning or other statement indicating there was an increased risk of suicide or suicidality from Paxil. The only references to "suicide" or "suicide attempt" in the labeling appeared in the description of "major depressive episode" and a precaution that suicide is an inherent risk in depressed patients. (UF ¶ 30.)

Prior to February 1997, the FDA considered two supplemental NDAs for new therapeutic indications for Paxil (for obsessive compulsive disorder and panic disorder), ultimately approving these NDAs. Again, the FDA's approval was conditioned on the verbatim use of the FDA-approved prescribing information and warnings; like the initial approval, the required labeling did not require any warning relating to an association between Paxil

and suicide or suicidality in adult or pediatric patients. (See UF ¶s 31, 33-34, 39.)

It was not until June 2003, *six years* after Benjamin's death, that the FDA first recognized "a possible increased risk of suicidal thinking and suicide attempts in children and adolescents under the age of 18 treated with the drug Paxil for major depressive disorder (MDD)." (UF ¶ 50.) In an advisory issued June 19, 2003, the FDA recommended that Paxil not be used in children and adolescents for the treatment of MDD. (Id.) The FDA did not take any action with respect to Paxil's labeling and warnings at that time. (UF ¶ 51.)

The FDA continued to study the issue (UF ¶ 52), commissioning an advisory committee to meet in February 2004 to discuss the possible relationship between antidepressants and suicidal thinking in pediatric patients. (UF ¶ 61.) Following that meeting and in conformance with the committee's final recommendations of September 2004 for class-wide labeling changes, on October 15, 2004, the FDA issued a Public Health Advisory and letter directing all manufacturers to add a "black box" warning and expanded warning statements to the labeling of all antidepressant medications describing the increased risk of suicidality in children and adolescents. (UF ¶ 68.) Thus, it was not until over *seven* years after Benjamin's death that the FDA required labeling changes to warn of the risk plaintiffs assert SB/GSK should have implemented prior to February 1997.

Thus, the record indicates that the type of warning which plaintiffs claim SB/GSK should have included in its Paxil label had been considered and rejected by the FDA because such a

warning was not supported by reasonable evidence at the time of Benjamin's death. A state law determination, to the contrary, that such a warning was required creates a conflict between federal and state law and imposes inconsistent federal and state obligations, thus warranting a finding of preemption.

A number of other courts have found similarly. For example, in Tucker v. SmithKline Beecham Corp., 2007 WL 2726259, at *10 (S.D. Ind. Sept. 19, 2007) , the court held that "[b]ecause [plaintiff's] state law [failure-to-warn] claims seeking to impose liability on GSK represent an obstacle to the FDA's efforts to ensure the proper use of Paxil, [the] claims are preempted;" see also Sykes v. Glaxo-SmithKline, 484 F. Supp. 2d 289, 318 (E.D. Pa. 2007) (holding the plaintiffs' failure-to-warn claims, regarding certain pediatric vaccines, conflict with the FDCA, because the warnings "[were] not scientifically supported and would have been false and misleading under federal law"); accord Dobbs v. Wyeth Pharmaceuticals, 2008 WL 169021, at *13 (Jan. 17, 2008) (same Effexor); Colacicco v. Apotex, Inc., 432 F. Supp. 2d 514 (E.D. Pa. 2006) (same Paxil); Dusek v. Pfizer, Inc., 2004 WL 3191804, at *8-10 (S.D. Tex. Feb. 20, 2004) (same Zoloft); Needleman v. Pfizer, Inc., 2004 WL 1773697, at *5 (N.D. Tex. Aug. 6, 2004) (same Zoloft); Ehlis v. Shire Richwood, Inc., 233 F. Supp. 2d 1189, 1197 (D.N.D. 2002) (same Adderall); In re Bextra and Celebrex Mktg. Sales Pracs. & Prods. Liab. Litig., 2006 WL 2374742, at *9 (N.D. Cal. Aug. 16, 2006) (same Celebrex);

Conte v. Wyeth, Inc., 2006 WL 2692469, at *6 (Cal. Sup. Ct. Sept. 14, 2006) (same metroclopramide).[14]

Here, plaintiffs assert claims based on the failure to include a warning unsubstantiated by reasonable evidence, and thus, create a direct conflict with federal law. Because plaintiffs assert claims based on a type of warning which the FDA considered and rejected due to lack of reasonable evidence during the relevant time period, this case presents the precise conflict that courts have previously identified.

Nevertheless, plaintiffs maintain that the FDA did not appreciate the necessity for a suicidality warning earlier because SB obscured or falsely stated its data submitted to the

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[14] The court acknowledges that there are other lower courts (although none of these cases involved Paxil specifically) which have declined to find preemption in prescription drug cases. (See GSK's Mem. of P. & A. at 26 n. 14 [citing cases].) Primarily, these courts reason that FDA drug labeling requirements impose only "minimum standards" that may be supplemented by state law, and therefore the state laws do not conflict with federal law. The conclusion that FDA labeling requirements are merely minimum standards emphasizes the FDA regulations permitting a drug manufacturer to add warnings to its label without prior FDA approval. However, for the reasons set forth below, this court does not find that argument persuasive because these courts (like plaintiffs here) fail to acknowledge the significance of the other regulations which only require such additions to a warning if "reasonable evidence" of an association of a hazard with the drug exists. See Cartwright v. Pfizer, Inc. 369 F. Supp. 2d 876 (E.D. Tex. 2005). Where such evidence is not present, as is the case here, there can be a finding of impossibility preemption because state law may require precisely what federal law does not. Moreover, even some of the courts that have found no preemption on a theoretical level have acknowledged that where the *facts* demonstrate that the FDA actually considered and rejected a similar warning, conflict preemption, via "impossibility preemption," may be found. See e.g. Kelly v. Wyeth, 2007 WL 1302589 (Mass. Sup. 2007); Perry v. Novartis Pharma. Corp., 456 F. Supp. 2d 678 (E.D. Pa. 2006). Such are the facts in this case, which warrant a preemption holding.

FDA in 1989 and 1991. According to plaintiffs, when analyzed correctly, without including pre-baseline run-in events as if they were post-baseline events, the net result is that patients on Paxil have a statistically significant greater than eight-fold increase in suicidal behavior. (ADF ¶s 1-11, 16-20.) According to plaintiffs' experts, Drs. Glenmullen and Grimson, when properly viewed, there are two overall conclusions that can be drawn from the Paxil data regarding suicidality submitted in 1989 and 1991: (1) a patient treated with Paxil is at between three to nine times greater risk of suicidality than if treated with a placebo and this is a statistically (beyond chance) association; and (2) if a Paxil treated patient experiences suicidality, then more likely than not (68% to 89%) the suicidality is attributable to Paxil. (Id.) Thus, plaintiffs contend that a warning regarding suicidality should have been included in the Paxil label from the outset.

Plaintiffs acknowledge that this early data pertained to adults only. However, they contend that even with respect to the pediatric population specifically, SB/GSK was aware of the need for a suicidality warning prior to Benjamin's death in February 1997. Plaintiffs maintain that shortly after Paxil's 1992 approval for use in the treatment of adult depression, SB/GSK became aware, via Study 329, that pediatric patients taking Paxil were at an increased risk of suicide. According to plaintiffs, SB/GSK began receiving reports from clinical investigators of adolescents experiencing suicidality on Paxil as early as late 1994 and that by the Fall of 1996, a "substantial number of the adolescents taking Paxil had experienced an adverse event

involving suicidality and/or hostility." (Opp'n at 9:8-9; ADF ¶s 34-37.)

Plaintiffs' counsel conceded at oral argument that to the extent these arguments sound in a claim of fraud allegedly perpetrated on the FDA by SB/GSK, such claim would be preempted by the Supreme Court's decision in Buckman. In Buckman, the Court held that patients' "state-law-fraud-on-the-agency" claims against a manufacturer's representative were impliedly preempted because the state claim of fraud would "inevitably conflict with the FDA's responsibility to police fraud consistently with the Administration's judgment and objectives." Buckman Co. v. Plaintiffs' Legal Comm., 531 U.S. 341, 350 (2001). The court found that as a practical matter, complying with the FDA's detailed regulatory regime in the shadow of 50 States' tort regimes would dramatically increase the burdens facing potential applicants--burdens that were not contemplated by Congress in enacting the FDCA. Id.[15] Recognizing Buckman's parameters, plaintiffs' counsel clarified plaintiffs' position at oral argument.[16] Significantly, counsel stated clearly that plaintiffs are not pressing a Buckman-theory. He conceded that there may well be a direct conflict of law in this case between

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[15] The Court explained further that fraud-on-the-FDA claims would also cause applicants to fear that their disclosures to the FDA, although deemed appropriate by the Administration, will later be judged insufficient in state court. Applicants would then have an incentive to submit a deluge of information that the Administration neither wants nor needs, resulting in additional burdens on the FDA's evaluation of the application. Id. at 351.

[16] Plaintiffs did not clearly make this concession in their briefs; nor did they clearly articulate their theory for why a direct conflict of law is not present in this case.

what the FDA required, at the time, and what plaintiffs' state tort claims seek to impose. However, plaintiffs contend nonetheless that there is no "impossibility preemption" in this case because their theory rests not on what *the FDA* required of SB/GSK with respect to the labeling and warnings for Paxil but what *SB/GSK* was obligated to do by virtue of the federal statutes and regulations at issue. In particular, the CBE regulation, 21 C.F.R. § 314.70(c)(6)(iii)(A), permitting a manufacturer to unilaterally make changes, without prior FDA approval, to "add or strengthen a contraindication, warning, precaution or adverse reaction." Under this and the corollary laws, plaintiffs contend SB/GSK was obligated to include the very warning plaintiffs seek based on the evidence it had in its possession as early as 1989. According to plaintiffs, federal and state law consistently required the warning plaintiffs urge, and thus, there is no conflict of law warranting a finding of preemption.

Therefore, the critical inquiry is whether reasonable evidence existed to support the warning plaintiffs urge under the federal standards. Both parties agree that SB/GSK was only obligated to warn of the claimed risk if there was reasonable evidence of an association of a serious hazard with the drug. 21 C.F.R. § 201.57(c)(6)(I). The parties, however, dispute whether such evidence existed at the relevant time.

B. No Reasonable Evidence Supported Contrary Label or Warning Pre-February 1997

Plaintiffs' proffered evidence is not sufficient to demonstrate that prior to February 1997 there was reasonable evidence of an association between Paxil and an increased risk of

suicidality in pediatric patients. With respect to the 1989 and 1991 data submitted by SB to the FDA, said data related to adults only. Plaintiffs have not shown through their experts' testimony or otherwise, that this data, even assuming plaintiffs' analysis is correct, demonstrates that SB was aware or should have been aware of an increased risk of suicidality in *pediatric* patients. At best, this initial data represents an increased risk in adult patients;[17] however, plaintiffs proffer no evidence that this data is translatable to the pediatric population. (See generally Decls. of Drs. Grimson and Glenmullen, filed Nov. 14, 2007 [Docket #s 149 and 150], attaching expert reports, filed under seal.) Indeed, plaintiffs' expert, Dr. Joseph Glenmullen, testified at deposition that: "I can't represent to you what they [SB/GSK] did and did not know as of February, '97 from the pediatric data." (Glenmullen Dep., filed Oct. 10, 2007, at 174:2-174:4 [Docket #122].)

As to plaintiffs' reliance on Study 329, which did involve clinical trials of adolescents taking Paxil, GSK could not have known whether the study revealed a reasonable association of any risk for pediatric patients until after Benjamin's death in February 1997. It is undisputed that the results of Study 329 were not available for evaluation until after *October* 1997 when GSK broke the blind on the acute phase of the study. (UF ¶

[17] However, the court notes that the FDA's current position with respect to an increased risk of suicidality in adults, over the age of 24, is to the contrary. While presently a warning regarding an increased risk of suicidality is required by the FDA with respect to pediatric patients, no such warning is similarly required regarding some adults. (See UF ¶s 70-91.)

43.)[18] Any clinical investigator reports that GSK may have received prior to this time were not actionable as they did not represent the final results of the study, and as explained by GSK's counsel at oral argument, GSK would have been penalized for breaking the blind on the study early. Thus, Study 329 is not evidence which raises a triable issue of fact that GSK was aware or should have been aware of an increased risk of suicidality in pediatric patients *prior* to Benjamin's death in February 1997.[19]

In sum, plaintiffs' contention that because a statutory procedure existed to petition the FDA for a label change, GSK could have included a suicide warning regarding pediatric patients in Paxil's labeling in February 1997 is unavailing.

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[18] Indeed, plaintiffs' expert, Dr. Glenmullen, analyzed the data from Study 329, as reflected in GSK's "Final Clinical Report on Study 329," which was completed on November 24, 1998, over a year after Benjamin's death. Thus, Dr. Glenmullen's ultimate finding that GSK obscured, like with the 1989 and 1991 data on adults, a "statistically significant risk of Paxil-induced suicidality in children" by inappropriately coding treatment-emergent suicidality as emotional lability, hostility, worsening depression, and euphoria, is not relevant to the instant motion. (Ex. 2 to Glenmullen Decl. at 73.) Plaintiffs correctly chose not to rely expressly on this opinion in their briefing. Instead, plaintiffs only point to certain investigator reports made during the study (which occurred from April 24, 1994 to May 7, 1997) and which pre-dated Benjamin's death. (See ADF ¶s 34-37.) However, these reports, even assuming the truth thereof, cannot raise a triable issue of fact since Study 329 was not finalized until 1998.

[19] In fact, by early 2004, the FDA had reviewed three Paxil studies regarding suicidality and children and adolescents and concluded that the studies were inconsistent with one another because "a signal emerges from 1 study (329), but without even a weak signal from the other 2 studies in the program." (Arning Decl. at Ex. 25 at 16.) Not until October 2004, after the FDA completed its review of the *aggregate* data from antidepressants generally did the agency conclude that there may be an increased risk of suicidality in pediatric patients. At this point, the FDA directed all manufacturers of antidepressants to add a "black box" warning of an association between pediatric patients and suicidality.

Plaintiffs' argument fails to acknowledge the significance of the fact that GSK was under this obligation by statute *only if* there was reasonable evidence to support such a warning. 21 C.F.R. § 201.57(c)(6)(I). As set forth above, plaintiffs have failed to raise a triable issue of fact that such evidence existed. As Tucker and Bextra make clear, to prevail on this argument, plaintiffs must overcome the fact that "reasonable evidence" of an association between Paxil and an increased risk of suicide in pediatric patients was lacking prior to February 1997 to support such a warning. That later clinical studies ultimately led to a clear signal of pediatric suicidality, and that these studies arguably reflected the initial data in 1989 and 1991 of similar associations among adults, simply does not provide "reasonable evidence" of the association of pediatric suicidality in February 1997.

Absent reasonable evidence of a risk, GSK had no basis to petition FDA and simply did not have the option under federal law to include or secure a lawful warning for that risk in the drug's labeling. Had it done so, GSK would have misbranded the drug in violation of the FDCA and subjected itself to a possible federal enforcement action against it or the withdrawal of its NDA by the FDA. Stated otherwise, the obligation under state law on GSK that plaintiffs advance is flatly contrary to GSK's obligations under federal law. As such, plaintiffs' claims must be found preempted.

A final, alternative argument, plaintiffs contend that, at least in part, there is no conflict in this case, because their claims are not limited to Paxil's warning labeling, but extend to

"promotion, advertising and 'Dear Doctor' letters." (Pls.' Opp'n at 23.) This argument is illogical. All promotional material must be consistent with a drug's labeling. See 21 C.F.R. § 202.1. If the warning is prohibited in the labeling (the prescribing information), the warning is not permitted in promotional material. The FDA has comprehensive statutory authority over all aspects of safety, efficacy, labeling, marketing, advertising, and promotion of prescription drugs. The FDCA and the FDA's regulations define "labeling" to include all hard-copy promotional material "upon" or "accompanying" the drug, which includes the package insert for the drug, and everything from booklets to calendars, if the material is textually related to the drug. 21 U.S.C. § 321(m); 21 C.F.R. § 202.1(l)(2). FDA's regulation of prescription drug labeling would be meaningless if GSK were free to undermine and contradict FDA-mandated warnings through other publication means.[20] See Dowhal v. SmithKline Beecham Cons. Healthcare, 32 Cal. 4th 910, 929 (2004) ("Warnings through point-of-sale posters or public advertising could have the same effect of frustrating the purpose of federal policy.")

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[20] The court finds that Perry v. Novartis Pharma. Corp., 456 F. Supp. 2d 678 (E.D. Pa. 2006), the sole case relied upon by plaintiffs in support of this argument, is wrongly decided as contrary to the FDA statutes and regulations described above. In Perry, the court denied the defendant's motion to dismiss, finding that even if it were inclined to find that the defendant could not have modified the FDA-approved labeling for Elidel to include a warning about pediatric cancers, the court would still deny the motion to dismiss because the plaintiffs were not specific about the types of warnings they asserted defendant should have provided; the court found that regardless of the label warning, a plaintiff may have a viable, non-preempted claim relating to another type of warning; for example, if the plaintiff claimed that a manufacturer was negligent in not sending an appropriate letter to prescribing physicians. Id. at 686.

CONCLUSION

The court's preemption holding herein is a narrow one. The court does not hold that FDA drug approvals in general preempt state law failure-to-warn claims. Rather, it finds on the specific facts of this case, the precise state law failure-to-warn claims plaintiffs assert are preempted because they are in direct, actual conflict with federal law. Prior to February 1997, it is undisputed that the FDA had considered the issue of an increased risk of suicidality and SSRIs, including Paxil, and found that no casual relationship existed to merit a specific suicidality warning for adults or pediatric patients. It was not until 2004, seven years after Benjamin's death that the FDA required such a warning for pediatric patients; to date, no such warning is required for adults over the age of 24. Importantly, GSK had no obligation to include a warning for pediatric patients prior to February 1997 because there was no reasonable evidence of an association between the drug and suicidality in children and adolescents.

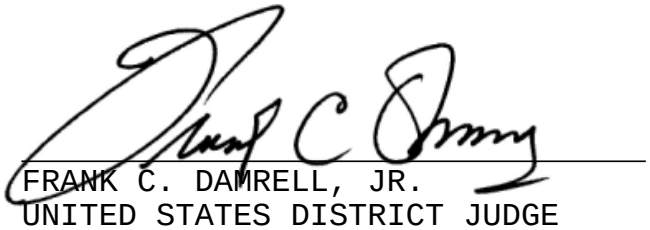
The court acknowledges that there is an understandable sense of frustration when clinical studies reveal critical conclusions after the fact as in this case, after the tragic suicide of Benjamin Bratt. However, the failure of those studies to timely signal adverse effects on pediatric patients does not overcome conflict preemption here.

Thus, for the foregoing reasons, GSK's motion for summary judgment on preemption grounds is GRANTED. Plaintiffs' complaint against GSK is dismissed in its entirety. The Clerk of the Court

is directed to close this file.[21]

IT IS SO ORDERED.

DATED: January 30, 2008



FRANK C. DAMRELL, JR.
UNITED STATES DISTRICT JUDGE

[21] The April 25, 2008 hearing on GSK's other pending motions (Docket #s 91, 111, 116) is hereby VACATED and the motions are DENIED as moot.