UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
ORLANDO DIVISION

IN RE: SEROQUEL PRODUCTS LIABLITY LITIGATION

MDL DOCKET NO: 6:06-MDL-1769-ACC-DAB

This Document Relates to:

Barnes v. AstraZeneca Pharms. LP, 6:07-cv- 16752-ACC-DAB
Colman v. AstraZeneca Pharms. LP, 6:07-cv- 16751-ACC-DAB
Donaldson v. AstraZeneca Pharms. LP, 6:07-cv-16742-ACC-DAB
Duncan v. AstraZeneca Pharms. LP, 6:07-cv-16736-ACC-DAB
Gordon v. AstraZeneca Pharms. LP, 6:07-cv-16738-ACC-DAB
Jackson v. AstraZeneca Pharms. LP, 6:07-cv-00522-ACC-DAB
Jensen v. AstraZeneca Pharms. LP, 6:07-cv-16743-ACC-DAB
Makinson v. AstraZeneca Pharms. LP, 6:07-cv-16757-ACC-DAB
Sauvageau v. AstraZeneca Pharms. LP, 6:07-cv-16754-ACC-DAB
Thomas v. AstraZeneca Pharms. LP, 6:07-cv-16748-ACC-DAB
Wilson v. AstraZeneca Pharms. LP, 6:07-cv-16740-ACC-DAB

PLAINTIFFS' RESPONSE IN OPPOSITION TO ASTRAZENECA'S MOTION FOR PARTIAL JUDGMENT ON THE PLEADINGS ON THE BASIS OF FEDERAL PREEMPTION AND INCORPORATED MEMORANDUM OF LAW

Plaintiffs submit this Memorandum of Law in Opposition to AstraZeneca's Motion for Partial Judgment on the Pleadings on the Basis of Federal Preemption. As explained herein, Defendant's Motion is based on a premise that is unsupported by FDA regulations and is out of line with the reasoning of an overwhelming majority of courts that have considered the issue.

I. BACKGROUND

Seroquel, known generically as quetiapine fumarate, belongs to a class of neuroleptic drugs known as "atypical" antipsychotics.[1]

Throughout the course of its promotion of Seroquel, Defendant has misrepresented the link between Seroquel and serious side effects. In so doing, Defendant has both failed to provide prescribers with critical safety information and distorted and compromised the limited warnings contained in Seroquel's labeling.

Defendant's deviations from Seroquel's labeling in its marketing are well documented. The FDA reprimanded Defendant for making false statements in its promotion of Seroquel immediately after launch. In a May 1999 letter from the FDA to Anthony Rogers, Director of Marketed Products Group (the "May 1999 DDMAC Letter"), the agency referenced its November 24, 1998 Warning Letter requesting information about statements that the FDA found to be false and misleading.[2]

Among the statements contained in Defendant's promotion of Seroquel found to be false and misleading were:

- Defendant's claims that Seroquel is effective in a broader range of mental conditions than those for which it was approved, including bipolar disorder and schizoaffective disorder;
- Defendant's claims as to how Seroquel "works" (the mechanism of action of antipsychotic drugs is unknown); and

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[1] Defendant obtained approval from the FDA to market Seroquel tablets for treatment of adults with schizophrenia in September 1997. On January 12, 2004 the FDA approved Seroquel tablets for treatment of adults with acute mania associated with Bipolar I Disorder and combination therapy with lithium or divalproex for acute manic episodes associated with bipolar I disorder. On October 20, 2006, Seroquel tablets were approved for treatment of adults with major depressive episodes associated with bipolar disorder.

[2] May 1999 DDMAC letter attached hereto as Exhibit "A."

- Defendant's claims that Seroquel had been proven safer and more effective than first generation antipsychotics.

The FDA's 1999 letter did not deter Defendant. In 2006, the FDA caught Defendant deceptively downplaying the association between Seroquel and diabetes.[3] According to the FDA, Defendant's marketing of Seroquel "raises significant public health and safety concerns through its minimization of the risks associated with Seroquel." Among Defendant's false and misleading statements regarding Seroquel's safety were the following:

- **Failing to warn doctors of the increased risk of treatment-emergent hyperglycemia-related adverse events in patients treated with Seroquel in its promotions, thus undermining the FDA-approved labeling**;
- **Misrepresenting the incidence of diabetes in post-marketing adverse event reports**; and
- **Failing to include relevant risk information about Seroquel**.

The 2006 DDMAC letter is critical to the Court's consideration of the instant motion. According to FDA, Defendant's marketing characterizes Seroquel in a manner that "**undermine[s]**" the approved warning related to diabetes. (Ex. B at 4.) Defendant's deceptive deviations from its approved labeling resulted, again according to FDA, in its **failure to warn** doctors that treating their patients with Seroquel could result in an increased risk of new onset diabetes. All Plaintiffs whose claims Defendant seeks to dismiss took Seroquel and contracted diabetes **before** the FDA issued this letter.[4]

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[3] 2006 DDMAC letter attached hereto as Exhibit "B."

[4] Defendant attempts to confuse the issue of the timing of Plaintiffs' taking Seroquel relative to the issuance of FDA warnings regarding the drug. (Motion at 4.) By arguing that all the initial *Jackson v. AstraZeneca Pharms., L.P.* Plaintiffs began taking Seroquel after the September 2003 labeling modifications referenced in Defendant's Motion, Defendant ignores the subsequent reprimand it received in November 2006 for undermining the same label warnings and misinforming prescribers regarding Seroquel's safety, described above (*see* Ex. B at 1-5), not to mention representations made by the Defendant's salespeople regarding the drugs purported safety, all of which should be considered in determining the adequacy of warnings regarding Seroquel's side effects. *See, e.g., In re Zyprexa Prods. Liab. Litig.*, 489 F.Supp.2d 230, 240-41, 250-53

II. STANDARD OF REVIEW

The legal standards for review of motions pursuant to Rules 12(c) and 12(b)(6) are indistinguishable. *DeMuria v. Hawkes*, 328 F.3d 704, 706 n.1 (2d Cir. 2003).[5] A court should dismiss a suit under Rule 12(c) only if "it appears beyond doubt that the plaintiff can prove *no set of facts* in support of his claim which would entitle him to relief." *Conley v. Gibson*, 355 U.S. 41, 45-46 (1957) (emphasis added). "A court's task in ruling on a 12[(c)] motion is merely to assess the legal feasibility of the complaint, not to assay the weight of the evidence which might be offered in support thereof." *Official Comm. Of the Unsecured Creditors of Color Tile, Inc. v. Coopers & Lybrand, L.L.P.*, 322 F.3d 147, 158 (2d Cir. 2003).[6] The Court "must accept all facts in the complaint as true and view them in the light most favorable to the plaintiffs." *Moore v. Liberty Nat'l Life Ins. Co.*, 267 F.3d 1209, 1213 (11th Cir. 2001). Because a judgment on the pleadings is a decision on the merits, courts are reluctant to grant such motions unless it is *clear* that the merits of the claim can be summarily decided.[7]

(E.D.N.Y. 2007).

[5] The principal distinction of a Rule 12(c) motion is that it can be asserted after "the pleadings are closed." Fed. R. Civ. P. 12(c). Because Defendant has already answered the suits it seeks to dismiss, it is unable to assert a Rule 12(b)(6) motion.

[6] Should the Court, pursuant to Rule 12(c), convert Defendant's motion to a Rule 56 motion for summary judgment, Plaintiffs respectfully request notice of such conversion and the opportunity to file a motion and supporting affidavit pursuant to Rule 56(f) to complete additional discovery prior to filing their Rule 56 response.

[7] *See Ortega v. Christian*, 85 F.3d 1521, 1524-25 (11th Cir. 1996); *Abbott Labs. v. Nutramax Prods., Inc.*, 844 F. Supp. 443, 445 (N.D. Ill. 1994); 5 Charles Alan Wright & Arthur R. Miller, *Federal Practice & Procedure* § 1369.

III. ARGUMENT

Defendant argues that plaintiffs' post-label change claims are preempted because a state jury verdict based on such claims would require warnings different than those sanctioned by the FDA. Defendant further contends that a state requirement of additional or enhanced warnings that would render Seroquel 'misbranded', under FDA regulations, is *de facto* state regulation that impermissibly conflicts with decisions made by the FDA in the lawful exercise of its Congressionally delegated authority. Defendant is incorrect.

A. Defendant Makes No Showing of Congressional Intent to Preempt State Law Claims.

The preemption analysis begins with a simple truth: in our federalist system, Congress does not "cavalierly pre-empt state-law causes of action." *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996). In fields traditionally occupied by the States, such as health and safety regulation, there is a strong presumption against federal preemption.[8]

To overcome this presumption, the party urging preemption must show that either (1) Congress or an agency with delegated authority has expressly stated that preemption is intended ("express preemption"), *see Medtronic*, 518 U.S. at 484-85; *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 516 (1992); or (2) Congress intended to occupy the field ("field preemption"), *see Travelers*, 514 U.S. at 654; or (3) state causes of action conflict with Congressionally delegated federal objectives to such a large degree that harmony between the two becomes impossible ("conflict preemption"). *Hillsborough County*, 471 U.S. at 715. Defendant argues that implied conflict preemption applies here.

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[8] *Id.*, 518 U.S. at 485; *N.Y. State Conference of Blue Cross & Blue Shield Plans v. Travelers Ins., Co.*, 514 U.S. 645, 654-55 (1995); *Hillsborough County v. Automated Med. Labs. Inc.*, 471 U.S. 707, 715 (1985).

Notwithstanding Defendant's repeated contention that the FDA's position on preemption should control, "an agency cannot supply, on Congress's behalf, the clear legislative statement of intent required to overcome the presumption against preemption." *Desiano v. Warner-Lambert & Co.*, 467 F.3d 85, 97 n.9 (2d Cir. 2006); *see also Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 449 (2005) ("The long history of tort litigation against manufacturers of poisonous substances adds force to the basic presumption against pre-emption. If Congress had intended to deprive injured parties of a long available form of compensation, it surely would have expressed that intent more clearly."); *Medtronic*, 518 U.S. at 487 ("It is, to say the least, difficult to believe that Congress would, without comment, remove all means of judicial recourse for those injured by illegal conduct.").[9]

Thus, it has long been presumed that state laws—particularly those such as the provision of tort remedies to compensate for personal injuries—are not to be preempted by a federal statute unless it is the clear and manifest purpose of Congress to do so. *See Medtronic*, 518 U.S. at 480; *Geier v. Am. Honda Motor Co., Inc.*, 529 U.S. 861, 894 (2000) (Souter, J., dissenting). Evidence of legislative intent must be derived from the text of an act of Congress. *See Hughes Aircraft Co. v. Jacobson*, 525 U.S. 432, 438 (1999). An executive agency's creation of its own authority to preempt state law would amount to usurpation of Congress's constitution-based ability to delegate such authority, or to withhold it. In the

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[9] Defendant's contrary contention, based on *Geier v. Am. Honda Motor Co.*, is unavailing because that case is distinguishable in several important respects. 529 U.S. 861 (2000). First, *Geier* is not a drug case, nor does it purport to decide the preemptive scope and force of FDA regulations. Instead, *Geier* decided whether state law superseded federal passive restraint regulations for automobiles issued by the federal Department of Transportation ("DOT"). *Id.* at 865-66. Second, *Geier* was a *design defect* case, and no "failure to warn" claims were at issue. *Id.* at 864. Third, the preemptive force of DOT regulations at issue in *Geier* was buttressed by nearly 30 years of DOT's consistent research and efforts to employ passive restraints and airbags on automobiles, as opposed to the FDA's nascent, and conflicting, regulations and opinions regarding prescription drug warnings, as illustrated below. *See id.* at 875-83.

words of Justice Scalia, "[a]gencies may play the sorcerer's apprentice but not the sorcerer himself." *Alexander v. Sandoval*, 532 U.S. 275, 291 (2001).

Defendant makes no showing of clear and manifest congressional intent to preempt state law claims such as those brought by Plaintiffs, as it must. Nevertheless, in assessing the soundness of Defendant's position, it is appropriate that the Court begin its analysis with an examination of the Congressionally delegated federal objectives at issue.

i. FDA Regulation of Prescription Drug Labeling Provides A Minimum Warnings "Floor," But Does Not Absolve Manufacturers of State Liability.

As explained below, the FDA labeling review process is intended to provide patients with certain basic information available at the time a drug is approved. It is the responsibility of *manufacturers*, through post-marketing surveillance, to propose appropriate adjustments to drug labeling. According to federal regulations, an FDA approved label is not intended to be a final assessment of a drug's risks or benefits or a "ceiling" on a manufacturer's duty to provide new or strengthened warnings. Rather, FDA regulations direct that the addition of necessary warnings is an essential corollary to the its limited post-marketing surveillance capabilities.

FDA regulations require that approved drug labeling include, among other things, warnings and precautions, contraindications, dosage information, adverse reactions and interactions with other prescription drugs. 21 C.F.R. §201.56. Once a label has been approved, the FDA permits two types of labeling changes.[10]

[10] Major changes require the prior approval of the FDA. *Id.* at §§314.70(b), 601.12(f)(1). However, manufacturers are permitted to unilaterally change warning labels in a "minor" way without prior approval, as long as the agency is notified of the change. Such changes are specifically defined to include strengthening language regarding warnings, contraindications, precautions and adverse events. *Id.* at §314.70(c)(6)(iii)(A).

When new information regarding the risks associated with a drug is available to the manufacturer, the drug's labeling must be changed, regardless of whether a causal link between the drug and a newly-discovered risk has been definitively proved. *Id.* at 201.57(c)(6)(i).[11]

Because it assigns the duty to monitor post-marketing drug safety to manufacturers, FDA has repeatedly emphasized that the foregoing regulations do not bar tort liability for conduct subject to FDA regulation. In a 2000 Proposal of its amendments related to drug labeling, the FDA explicitly stated that it "ha[d] determined that this proposed rule does not contain policies that have federalism implications or that preempt State law." 65 Fed. Reg. 81082, 81103 (Dec. 22, 2000). This statement followed the FDA's 1998 Final Rule relating to the provision of labeling directly to patients for certain prescription drugs.[12]

The open-ended nature of manufacturers' responsibilities under the foregoing regulations, and the FDA's consistent interpretation of its limited role in the federalist system, has led courts to the logical conclusion that FDA regulations represent only

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[11] "The labeling must be revised to include a warning about a clinically significant hazard as soon as there is reasonable evidence of a causal association with a drug; a causal relationship need not have been definitively established."

[12] The 1998 Final Rule noted the following:

> Tort liability can not be a major consideration for FDA which must be guided by the basic principles and requirements of the act in its regulatory activities. Nevertheless, FDA does not believe this rule would adversely affect civil tort liability...
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> FDA does not believe that the evolution of state tort law will cause the developments of standards that would be at odds with the agency's regulations.

63 Fed. Reg. 66378, 66383-84 (Dec. 1, 1998).

minimum safety standards, or a "floor" of permissible conduct, and do not absolve prescription drug manufacturers of state tort liability.[13]

ii. The FDA's 2006 Preamble to the Final Rule Is Entitled to No Deference.

Defendant identifies no evidence of Congressional intent in support of its position. Rather, Defendant's Motion relies heavily on FDA's own advisory pronouncements regarding the preemptive effect of its regulations. (Motion at 19.) As Defendant acknowledges, the Court need not defer to the FDA's opinions on the preemption issue. (Motion at 21.) The FDA's position on preemption is, at most, persuasive authority, which numerous courts have disregarded or rejected outright, as shown below.

On January 24, 2006, the FDA issued a Final Rule governing the "Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products." 71 Fed. Reg. 3922 (January 24, 2006) (hereinafter "preamble"). The preamble and Final Rule became effective on June 30, 2006. The preamble is a nonbinding advisory opinion and **does not** carry the force of law. 21 C.F.R. §10.85(d)(1).

The preamble directly contradicts the FDA's repeated position on the potential conflict between state-law based warnings claims and FDA regulation.[14] The preamble seeks

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[13] *Hill v. Searle Labs.*, 884 F.2d 1064, 1068 (8th Cir. 1989) ("FDA approval is not a shield to liability"); *Wells v. Ortho Pharm. Corp.*, 788 F.2d 741, 745-46 (11th Cir. 1986); *Ferebee v. Chevron Chem. Co.*, 736 F.2d 1529, 1543 (D.C.Cir. 1984) ("federal legislation has traditionally occupied a limited role as a *floor* of safe conduct . . . .") (emphasis in original); *Salmon v. Parke Davis & Co.*, 520 F.2d 1359, 1362 (4th Cir. 1975); *Caraker v. Sandoz Pharm. Corp.*, 172 F.Supp.2d 1018, 1033 (S.D. Ill. 2001) ("The FDA's drug labeling decisions impose only 'minimum' standards that are open to supplementation by state law through a jury's verdict enforcing a manufacturer's common law duty to warn.") (citations omitted); *Motus v. Pfizer, Inc.*, 127 F.Supp.2d 1085, 1092 (C.D. Cal. 2000); *Kociemba v. G.D. Searle & Co.*, 680 F.Supp. 1293, 1299 (D.Minn. 1988) ("FDA regulation of prescription drugs establishes minimum standards, both as to design and warning.") (citations omitted); *Edwards v. Basel Pharm.*, 933 P.2d 298, 302 (Okla. 1997); *Savina v. Sterling Drug, Inc.*, 795 P.2d 915, 931 (Kan. 1990).

to preempt state law causes of action based upon a theory of inadequate warning if the label at issue has been approved by the FDA. *Id.* This statement precisely captures the type of claim sought to be dismissed in Defendant's Motion.

Courts almost universally rejected this assertion prior to the issuance of the preamble. According to the preamble, these rulings are based on the misconception that "FDA labeling requirements represent a minimum safety standard." *Id.* at 3934. The preamble attempts to establish the FDA's regulation under the Food Drug & Cosmetics Act as both a floor and a ceiling on manufacturers' duties with respect to warnings.

Moreover, while an administrative agency's interpretation of the statutory scheme it administers is entitled to deference, such deference is appropriate only if "it appears that Congress delegated authority to the agency generally to make rules carrying the force of law, and that the agency interpretation claiming deference was promulgated in the exercise of that authority." *United States v. Mead Corp.*, 533 U.S. 218, 226-27 (2001); *Chevron USA, Inc. v. Nat'l Res. Def. Council, Inc.*, 467 U.S. 837, 842-43 (1984).

If an agency interpretation lacks the "power to control"—because it was not promulgated in the exercise of Congressionally-delegated authority under *Chevron*—it serves

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[14] According to the preamble:

State law actions . . . threaten FDA's statutorily prescribed role as the expert Federal agency responsible for evaluating and regulating drugs. State actions are not characterized by centralized expert evaluation of drug regulatory issues. Instead, they encourage, and in fact require, lay judges and juries to second-guess the assessment of benefits versus risks of a specific drug to the general public-the central role of FDA—sometimes on behalf of a single individual or group of individuals. That individualized reevaluation of the benefits and risks of a product can result in relief—including the threat of significant damage awards or penalties—that creates pressure on manufacturers to attempt to add warnings that FDA has neither approved nor found to be scientifically required. This could encourage manufacturers to propose "defensive labeling" to avoid State liability, which, if implemented, could result in scientifically unsubstantiated warnings and underutilization of beneficial treatments.

Id. at 3935.

as guidance for litigants, but will only be respected to the extent that it has the "power to persuade."[15]

Factors taken into account in assessing an agency interpretation's power to persuade are "the thoroughness evident in its consideration, the validity of its reasoning, its consistency with earlier and later pronouncements, and all those factors which give it power to persuade, if lacking power to control." *Skidmore*, 323 U.S. at 140. Further, when an agency's own regulations conflict with its interpretation, the deference due decreases significantly. *Id.*

The FDA's inability to supply the legislative intent required to overcome the presumption against preemption in this case removes the preamble from the class of interpretations entitled to *Chevron* deference. *Medtronic*, 518 U.S. at 487; *Desiano*, 467 F.3d at 97, n.9.

Thus, the preamble is entitled to deference only to the extent that it has the power to persuade. The inconsistency of the preamble with FDA's prior interpretation of its regulations is dispositive of the preamble's persuasiveness. As noted above, prior to the 2006 preamble, FDA consistently interpreted the very regulations it now asserts preempt state law as "not containing policies that have federalism implications or that preempt State law." 65 Fed. Reg. 81082 (Dec. 22, 2000). This statement appears in FDA's 2000 notice of proposed rulemaking, **out of which grew the 2006 Final Rule**.

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[15] *Mead*, 533 U.S. at 228; *Skidmore v. Swift & Co., Inc.*, 323 U.S. 134, 140 (1944). An agency's position on ambiguities in its own regulations is entitled only to *Skidmore* deference. *Christensen v. Harris County*, 529 U.S. 576, 587 (2000) ("[A]n interpretation contained in [the FDA's legal briefs, for example, as cited by Defendant], not one arrived at after . . . a formal adjudication or notice-and-comment rulemaking[,] . . . do[es] not warrant *Chevron*-style deference.").

Further, in direct response to comments on its 1998 proposed Final Rule urging it to provide for federal preemption of State civil tort claims, the FDA affirmed that its Final Rule, and the regulations it interpreted, would not "adversely affect civil tort liability." 63 Fed. Reg. 66378, 66383-84 (Dec. 1, 1998).

The preamble asserts that it "represents the government's long-standing views on preemption." 71 Fed. Reg. at 3934. This statement is inexplicable in light of the fact that Congress has never spoken on preemption with respect to prescription drugs and that the preamble does not represent FDA's own "long-standing views on preemption."

This lack of harmony between FDA's traditional interpretation of the preemptive effect of its regulations and the preamble has led all courts that have decided the issue, save three (relied upon by Defendant),[16] to conclude that the preamble has no power to persuade.[17]

Under the final *Skidmore* factor, any deference due to the FDA's views in the preamble decreases further because the interpretation conflicts with existing FDA regulations. Specifically, as stated above, manufacturers have a duty to unilaterally strengthen existing warnings in labeling when new information regarding the risks associated

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[16] *Sykes v. Glaxo-SmithKline*, 484 F.Supp.2d 289, 306-17 (E.D.Pa. 2007); *Colacicco v. Apotex, Inc.*, 432 F.Supp.2d 514, 523-38 (E.D. Pa. 2006) (acknowledging that FDA's prior interpretations are "difficult to reconcile" with the preamble); *In re Bextra & Celebrex Mktg. Sales Practices & Prod. Liab. Litig.*, MDL 1699, 2006 WL 2374742, at *5-12 (N.D. Cal. Aug. 16, 2006).

[17] *In re Zyprexa Prods. Liab. Litig.*, 489 F.Supp.2d 230, 275-78 (E.D.N.Y 2007); *Perry v. Novartis Pharm. Corp.*, 456 F.Supp.2d 678 (E.D. Pa. 2006); *Weiss v. Fujisawa Pharm. Co.*, 464 F.Supp.2d 666 (W.D.Ky. 2006) (concluding that courts are not bound by FDA position in preamble); *Jackson v. Pfizer, Inc.*, 432 F.Supp.2d 964, 968 n.3 (D.Neb. 2006); *In re Vioxx Prods. Liab. Litig.*, __ F.Supp.2d __, MDL No. 1657, C.A. No 05-2627, 2007 WL 1952964, at *10 (E.D. La. July 3, 2007); *McNellis ex re. DeAngelis v. Pfizer, Inc.*, 2006 WL 2819046, at *13 (D.N.J. Sept. 29, 2006); *In re Vioxx Litig.*, Nos. ATL-L-3553-05-MT & ATL-L-1296-05-MT, slip op. (N.J. Sup. Ct. June 8, 2007); *Levine v. Wyeth*, ___ A.2d___, 2006 WL 3041078, at ¶34 (Vt. Oct. 27, 2006), *petition for cert. filed*, 75 U.S.L.W. 3500 (Mar. 12, 2007) (No. 06-1249).

with a drug is available to the manufacturer, regardless of whether a causal link between the drug and a newly-discovered risk has been definitively proved.[18]

Were the preamble correct, FDA regulations placing an affirmative duty upon drug manufacturers to revise a drug's label to include a warning "as soon as there is reasonable evidence of an association of serious hazard with a drug . . ." would be nullified. The "ceiling" on manufacturers' liability, afforded in the preamble, would remove any incentive for the dissemination of such information. Such an interpretation would also mean that a manufacturer could not disseminate vital, urgent information related to its drug until the FDA was afforded an opportunity to perform its regulatory tasks.

Further, the preamble attempts to conflate a manufacturer's practical application of its duty under 201.57(c)(6)(i) with a risk of misbranding by adding information that may ultimately prove unfounded. However, this **potential** intersection of duties is addressed by 21 C.F.R. §314.70(c)(7), which allows the agency to disapprove of supplemental labeling and order the manufacturer to cease its distribution. This power to interrupt the distribution of inaccurate labeling can be easily reconciled with a manufacturer's duty to quickly provide the greatest possible warning to patients. While it is possible that a manufacturer could add a warning that FDA later determines to be false or misleading because its warnings are proved inaccurate, such circumstances are not only purely theoretical,[19] they do not actually represent any conflict because of §314(c)(7).

Finally, the preamble is not convincing because the FDA itself is not convinced. The preamble's preemption argument concludes with the statement: "the FDA believes that at

[18] 21 C.F.R. §201.57(c)(6)(i).
[19] *See* the 2006 DDMAC Letter. (Ex. B.)

least the following [six] claims would be preempted by its regulation of prescription drug labeling[.]" 71 Fed. Reg. at 3936. In other words, the preamble asserts that **all** failure to warn claims are preempted but later clumsily offers that perhaps "all" does not mean "all."

Because its interpretations in the preamble are equivocal, contradictory and represent a marked change from its longstanding views, the FDA's position is not entitled to deference.

B. Notwithstanding the FDA's Position, There is no Conflict Between State Jury Verdicts and FDA Regulation.

No real conflict exists here. State law warnings claims not only exist harmoniously with, but also complement, FDA regulations. "Throughout our history the several States have exercised their police powers to protect the health and safety of their citizens." *Medtronic*, 518 U.S. at 474. "Because these are 'primarily, and historically, ...matter[s] of local concern,...States traditionally have had great latitude under their police powers to legislate as to the protection of the lives, limbs, health, comfort, and quiet of all persons." *Id.* (citing *Hillsborough*, 471 U.S. at 719; *Metropolitan Life Ins. Co. v. Massachusetts*, 471 U.S. 724, 756 (1985)).

Further, an essential tenet of federalism is that federal regulation and state tort law serve distinct purposes. *Ferebee*, 736 F.2d at 175. The fact that a federal regulatory agency has determined that a label is adequate for federal regulatory purposes does not compel a jury to find that the label is also adequate for purposes of state tort law. *Id.* Compliance with federal standards does not eliminate a defendant's susceptibility to the will of state juries. *Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238, 264 (1984).

According to the Eleventh Circuit, this principle is directly applicable to the instant motion. *Wells*. 788 F.2d at 746 (citing *Ferebee*, 736 F.2d at 1535). "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." *Id.*[20]

"FDA labeling regulations and state law adequacy of warning claims have existed harmoniously from the time the FDCA was first enacted." *In re Zyprexa*, 489 F.Supp.2d at 276. It is clear that states may not, by positive statutory enactment, require a "drug manufacturer to include a warning within the labeling for its product that the FDA had previously rejected as scientifically unsubstantiated." *Id.* Such a requirement could expose a manufacturer to liability for misbranding under 21 U.S.C. §352.

However, jury verdicts do not impose mandatory labeling requirements on drug manufacturers. *Medtronic*, 518 U.S. at 495-97. Jury verdicts do nothing but impose civil judgment. *In re Zyprexa*, 489 F.Supp.2d at 277. In response to a jury verdict, a manufacturer can either seek to change its labeling or it can leave its label as is despite the verdict. *Id.*

Further, jury verdicts and adequacy of warning claims serve an important safety function parallel to FDA regulation. *Id.* "State law adequacy of warning claims may alert the FDA to potential inadequacies in product labeling." *Id.* The FDA's 2006 DDMAC Letter to Defendant may be a testament to this fact.

As the Supreme Court has noted, "labels will evolve over time, as manufacturers gain more information about their products' performance in diverse setting...[T]ort suits can serve as a catalyst in this process." *Bates*, 544 U.S. at 451 (rejecting preemption challenge to state-

[20] Emphasizing that "compliance with regulatory standards may be admissible on the issue of care but does not require a jury [or judge as factfinder] to find a defendant's conduct reasonable."

law claims that warnings on herbicide labeling were inadequate, despite presence of an express preemption clause).

The complementary, rather than conflicting, roles of FDA oversight and state warnings law is firmly supported by FDA regulations. Defendant argues that the potential finding that a warning is inadequate by a civil jury infringes on FDA authority. However, as noted above, 201.57(c)(6)(i) contemplates that an approved warning may, at any point in the post-marketing period, be inadequate. Section 201.57(c)(6)(i), if nothing else, is a testament to the FDA's understanding that its approved labeling may not convey all available, legitimate safety information. Because this is the essential theory of state warnings claims in general, and Plaintiffs' claims specifically, FDA regulation and the claims at issue do not conflict.

Finally, Defendant argues that Plaintiffs' claims must be dismissed because FDA has considered and rejected proposed strengthened warnings. This argument not only ignores the parallel, complementary roles of FDA regulation and state failure to warn laws, but is based on facts that do not exist. Defendant did not propose an inclusion of warnings related to increased risks of hyperglycemia and diabetes in Seroquel's labeling. Rather, the FDA **compelled** Defendant to include a strengthened diabetes warning in its 2003 labeling directive. The FDA has never considered and rejected a stronger warning than that mandated in 2003. Moreover, as recently as November 2006, the FDA acknowledged that the relationship between Seroquel and diabetes "is not completely understood," but also recognized that epidemiological studies merit warning Seroquel patients of the increased risk of treatment-onset "hyperglycemia-related adverse events." (Ex. B at 3.) Thus, as in *Perry*,

"it is more in keeping with the narrow scope of preemption to allow state law to require the addition of warnings so long as there has been no specific FDA determination" regarding a particular warning. 456 F.Supp.2d at 685.

C. Defendant's Cases Supporting Deference to the FDA Position on Preemption Are Inapposite.

Defendant argues that the Court should follow a "flurry" of decisions in which courts have found preemption (Motion at 14-19), while ignoring the veritable blizzard of cases reaching the opposite conclusion. Defendant's cases are distinguishable in important respects that the Court should not overlook.

Significantly, in *In re Bextra and Celebrex Marketing Sales Practices and Product Liability Litigation*, the California federal district court observed that the plaintiffs had ***abandoned*** their failure to warn claims premised on the FDA-required label, in their opposition to the defendant's Motion to Dismiss.[21] Nevertheless, the district judge in the unreported decision opined regarding the preemptive effect of the FDA preamble. Such opinion amounts to mere obitur dictum.[22] Moreover, with regard to Celebrex, one of the drugs at issue in the case, FDA had specifically determined that Celebrex posed no greater heart attack/stroke risk than other similar formularies, and had ultimately included a "black box" warning on the Celebrex label that warned of the increased risks associated with the

[21] No. M:05-1699 CRB, 2006 WL 2374742, at *4 (N.D. Cal. Aug. 16, 2006); No. CV-05-1699 CRB, 2006 WL 2472484, at *3.

[22] The district judge reasoned that his preemption decision was nevertheless warranted because "[i]n their briefing after oral argument, plaintiffs *appear[ed]* to have reversed course again, this time arguing that state laws *may* require . . . additional warnings" on drug labels and in promotional materials." Given the uncertainty of whether a preemption issue was even before the district court at the time it ruled, *In re Bextra* should be accorded little, if any, weight.

drug. There is no evidence here that any similar "specific determination" has been made by the FDA with respect to the diabetes risk associated with Seroquel, as shown above.

Defendant's reliance on *Colacicco v. Apotex, Inc.* is similarly misplaced. 432 F.Supp.2d 514 (E.D. Pa. 2006). *Colacicco* involved a preemption challenge to plaintiff's claims against the manufacturers of the anti-depressant, "Paxil." *Id.* at 519-21. The court emphasized that the FDA had "specifically and repeatedly rejected claims [over a period of 12 years] that adult use of SSRI's was associated with increased suicidality," *Id.* at 527, and had determined that "the evidence was not strong enough to justify *the suggestion of even the possibility of a causal linkage* in the labeling." *Perry*, 456 F.Supp.2d at 686 (analyzing *Colacicco*). For that reason, the FDA asserted in *amicus* briefing that a stronger warning suggesting a link to suicide would have been false or misleading, and, therefore, the plaintiff's failure-to-warn claims were preempted by federal law, a position to which the court deferred. *Colacicco*, 432 F.Supp.2d at 527, 538. Here, again as shown above, the FDA has made no similar specific conclusion with respect to Seroquel's link to diabetes.

Likewise, in *Sykes v. Glaxo-SmithKline*, 484 F.Supp.2d 289 (E.D. Pa. 2007), the court noted that "[w]hen the FDA approved the defendants' products it had determined that thimerosal was an appropriate preservative because it was 'sufficiently nontoxic.'" *Id.* at 313. Therefore, the plaintiffs' claim that the drug's manufacturer failed to warn of the toxicity of thimerosal was preempted. *Id.* Again, here, Defendant has not shown that any such specific determination has been made by the FDA.

Lastly, Defendant asks the Court to ignore the overwhelming weight of authority holding that state law "failure to warn" claims do not conflict with FDA regulations and are, therefore, not preempted.[23] The Court should refuse to do so.

D. At A Minimum, No Conflict Exists Because Defendant Failed to Comply With FDA Regulations.

Even if this Court concludes that Defendant is insulated from state tort liability to the extent it complied with federal standards—which is not the law, as shown above—such a set of facts, according to FDA, is not at issue. According to the FDA, Defendant has officially failed to comply with federal mandates regarding warnings. (Ex. B.) Therefore, although such a finding is not necessary under existing preemption principles, the Court could find that the adequate warning referenced by Plaintiffs' complaints is merely the warning mandated by the FDA, from which Defendant has consistently deviated in promoting Seroquel. Obviously, should a state jury find the lack of such a warning to be the cause of Plaintiffs' damages, no conflict between state and federal law would (or could) exist here in light of Defendant's failure to comply with the very FDA regulations Defendant argues preempt Plaintiffs' state law claims.

CONCLUSION

In the absence of a clear statement from Congress or any persuasive interpretation from FDA, this Court is left with the presumption that the claims at issue are not preempted.

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[23] *See, e.g., Wells*, 788 F.2d at 746; *In re Zyprexa*, 489 F.Supp.2d at 275-78; *Perry*, 456 F.Supp.2d at 687; *Weiss v. Fujisawa Pharm. Co.*, 464 F.Supp.2d at 676; *Jackson v. Pfizer, Inc.*, 432 F.Supp.2d at 968 n.3; *Peters v. Astrazeneca, LP*, 417 F.Supp.2d 1051, 1056 (W.D. Wis. 2006); *Motus v. Pfizer Inc.*, 127 F.Supp.2d 1085, 1091 (C.D. Cal. 2000); *In re Vioxx Prods. Liab. Litig.*, 2007 WL 1952964, at *10; *McNellis*, 2006 WL 2819046 at *13; *Sikis v. Pfizer Inc.*, No. 04 C 8104, 2005 WL 1126909, at *3 (N.D. Ill. May 9, 2005); *Eve v. Sandoz Pharm. Corp.*, No. IP 98-1429-C-Y/S, 2002 WL 181972, at *3 (S.D. Ind. Jan. 28, 2002); *In re Vioxx Litig.*, slip op.; *Levine*, 2006 WL 3041078, at ¶34.

Defendant's countervailing arguments and cited authority are unpersuasive and, therefore, Defendant's Motion for Judgment on the Pleadings should be denied.

Respectfully submitted

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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on this 10th day of August, 2007, I electronically filed the foregoing : PLAINTIFFS' RESPONSE IN OPPOSITION TO ASTRAZENECA'S MOTION FOR PARTIAL JUDGMENT ON THE PLEADINGS ON THE BASIS OF FEDERAL PREEMPTION AND INCORPORATED MEMORANDUM OF LAW with the Clerk of the Court by using the CM/ECF system which will send a Notice of Electronic Filing to the counsel listed on the attached Service List.. I further certify that I mailed the foregoing document and the Notice of Electronic Filing by First-Class U. S. Mail delivery to the non-CM/ECF Participants listed on the attached Service List.

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