UNITED STATES DISTRICT COURT

EASTERN DISTRICT OF LOUISIANA

	:	**MDL NO. 1657**
IN RE: VIOXX PRODUCTS LIABILITY LITIGATION	: :	**SECTION: L**
	: :	**JUDGE FALLON**
	:	**MAG. JUDGE KNOWLES**
.. ..	:	

THIS DOCUMENT RELATES TO:
***Arnold v. Merck & Co., Inc.*, No. 05-2627**
***Gomez v. Merck & Co., Inc.*, No. 05-1163**

ORDER & REASONS

Before the Court is Merck & Co., Inc.'s Motion for Summary Judgment (Rec. Doc. 5842) in two individual Vioxx cases on federal preemption grounds. The Court heard oral argument and took this motion under submission. Because the Court finds that the plaintiffs' claims are not expressly nor impliedly preempted by virtue of the federal regulation of prescription drugs, Merck's motion is now DENIED.[1]

---

[1] Although the instant motion focuses on the *Arnold* and *Gomez* cases, the following discussion of federal preemption also supplies the rationale for certain jury instructions and oral rulings delivered on the issue during each bellwether trial that has been conducted in this multidistrict litigation. *See Plunkett v. Merck & Co., Inc.*, No. 05-4046; *Barnett v. Merck & Co., Inc.*, No. 06-485; *Smith v. Merck & Co., Inc.*, No. 05-4379; *Mason v. Merck & Co., Inc.*, No. 06-810; *Dedrick v. Merck & Co., Inc.*, No. 05-2524. Accordingly, the Court expressly incorporates the following discussion into the record of these bellwether cases as well.

I. BACKGROUND

Vioxx, known generically as rofecoxib, belongs to a general class of pain relievers known as non-steroidal anti-inflammatory drugs ("NSAIDs"). NSAIDs work by inhibiting cyclooxygenase ("COX"), an enzyme that stimulates synthesis of prostaglandins, which are chemicals produced in the body that promote certain effects. Traditional NSAIDs, such as Advil (ibuprofen), Aleve (naproxen), and Voltaren (diclofenac), have been longstanding treatment options for patients needing relief from chronic or acute inflammation and pain associated with osteoarthritis, rheumatoid arthritis, and other musculoskeletal conditions. This relief, however, has historically come with significant adverse side effects. Specifically, traditional NSAIDs greatly increase the risk of gastrointestinal perforations, ulcers, and bleeds ("PUBs"). This risk is further increased when high doses are ingested, which is often necessary to remedy chronic or acute inflammation and pain.

In the early 1990s, scientists discovered that the COX enzyme had two forms—COX-1 and COX-2—each of which appeared to have several distinct functions. Scientists believed that COX-1 affected the synthesis or production of prostaglandins responsible for protection of the stomach lining, whereas COX-2 mediated the synthesis or production of prostaglandins responsible for pain and inflammation. This belief led scientists to hypothesize that "selective" NSAIDs designed to inhibit COX-2, but not COX-1, could offer the same pain relief as traditional NSAIDs with a reduced risk of fatal or debilitating PUBs. In addition, scientists believed that such drugs might also prove beneficial for the prevention or treatment of other conditions, such as Alzheimer's disease and certain cancers, where evidence suggests that inflammation may play a causative role. In light of these scientific developments,

pharmaceutical companies began developing such drugs, which became known as "COX-2 inhibitors" or "coxibs." Merck developed a COX-2 inhibitor and named it Vioxx.

On November 23, 1998, Merck submitted a new drug application for Vioxx to the Food and Drug Administration ("FDA") and requested an expedited review of its application. Six months later, on May 20, 1999, the FDA approved Vioxx as safe and effective for treatment of osteoarthritic pain, primary dysmenorrhea (menstrual pain), and acute pain based on the data and label supplied by Merck. From its initial approval, Vioxx gained widespread acceptance among physicians treating patients with arthritis and other conditions causing chronic or acute pain.

Vioxx was subjected to a number of studies and tests both before and after its initial approval. In March of 2000, Merck received the preliminary results of the Vioxx GI Outcomes Research ("VIGOR") study. VIGOR was an 8,000-patient trial designed to assess the relative incidence of gastrointestinal PUBs in rheumatoid arthritis patients treated with Vioxx as compared to those treated with the drug naproxen. While VIGOR demonstrated that patients taking Vioxx suffered fewer serious gastrointestinal PUBs than patients taking naproxen, it also showed that patients on Vioxx suffered a statistically significant increase of serious cardiovascular thrombotic events compared to patients taking naproxen.[2]

In light of the new data obtained in the VIGOR study, Merck submitted a proposed label

---

[2] The VIGOR data was published in the New England Journal of Medicine. *See* Claire Bombardier, et al., *Comparison of Upper Gastrointestinal Toxicity of Rofecoxib and Naproxen in Patients with Rheumatoid Arthritis*, 343 New Eng. J. Med. 1520 (Nov. 23, 2000). Approximately five years later, the Journal published an "Expression of Concern" detailing certain inaccuracies in the underlying data and raising concerns about the conclusions of the original paper. *See* Gregory D. Curfman, et al., *Expression of Concern*, 353 New Eng. J. Med. 2813 (Dec. 29, 2005). The Journal subsequently published several responses from the original authors. *See* Correspondence, *Response to Expression of Concern Regarding VIGOR Study*, 354 New Eng. J. Med. 1196 (Mar. 16, 2006).

change for Vioxx to the FDA in June of 2000. After approximately *eighteen* months of "negotiation" with Merck over the content and organization of a new Vioxx label, the FDA approved a revised label on April 11, 2002. The new label incorporated the VIGOR data and noted that such data "should be taken into consideration and caution should be exercised when Vioxx is used in patients with a medical history of ischemic heart disease." (Def.'s Mot. for Summ. J. Ex. 23.)

On September 23, 2004, an external safety board monitoring the results of a separate long-term study, known as APPROVe, which was designed to assess whether Vioxx could help prevent the recurrence of precancerous colon polyps, informed Merck that the interim data from this study also showed a significantly increased rate of cardiovascular events in the Vioxx arm as compared to the placebo arm of the study. One week later, on September 30, 2004, Merck voluntarily withdrew Vioxx from the market.

Thereafter, thousands of individual lawsuits and numerous class actions were filed against Merck in state and federal courts throughout the country alleging various products liability, tort, failure-to-warn, fraud, and warranty claims. It is estimated that 105 million prescriptions were written for Vioxx in the United States between May 20, 1999 and September 30, 2004. Based on this estimate, it is thought that approximately 20 million patients have taken Vioxx in the United States. On February 16, 2005, the Judicial Panel on Multidistrict Litigation conferred multidistrict litigation status on Vioxx lawsuits filed in federal court and transferred all such cases to this Court to coordinate discovery and to consolidate pretrial matters pursuant to 28

U.S.C. § 1407. *See In re Vioxx Prods. Liab. Litig.*, 360 F. Supp. 2d 1352 (J.P.M.L. 2005).[3]

II. PRESENT MOTION

On July 18, 2006, Merck filed the instant motion for summary judgment in the following two individual Vioxx cases:

- *Arnold v. Merck & Co., Inc.*, No. 05-2627: Lene Arnold alleges that she used Vioxx between July 2003 and October 2004, and that she suffered a heart attack on December 28, 2003 as a result of taking the drug. She filed suit on June 27, 2005 directly in this Court pursuant to Pretrial Order No. 11, asserting strict liability, negligence, warranty, and fraud claims against Merck.
- *Gomez v. Merck & Co., Inc.*, No. 05-1163: Joe G. Gomez allegedly used Vioxx from November 21, 2002 until January 7, 2003, the day on which he suffered a fatal heart attack. His surviving spouse and children filed suit on January 7, 2005 in the United States District Court for the Western District of Texas, asserting strict liability, negligence, warranty, and fraud claims against Merck. Their case was subsequently transferred to this Court pursuant to 28 U.S.C. § 1407.

Merck argues that the plaintiffs' failure-to-warn claims in these cases are preempted, that is, precluded as a matter of law, because the Vioxx label was approved by the FDA. Specifically, Merck contends that a finding of implied preemption is appropriate because the federal regulatory scheme devised for regulating prescription drugs cannot function properly if juries applying state law are allowed to "force" drug manufacturers to add information to prescription

[3] For a more detailed procedural background, see *In re Vioxx Prods. Liab. Litig.*, 478 F. Supp. 2d 897 (E.D. La. 2007) and *In re Vioxx Prods. Liab. Litig.*, 239 F.R.D. 450 (E.D. La. 2006).

drug labels beyond language that the FDA has approved. In support of its argument, Merck principally relies upon recent FDA statements to this effect accompanying new labeling regulations. *See Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products*, 71 Fed. Reg. 3922 (Jan. 24, 2006) (hereinafter "2006 Final Rule"). In the preamble to the 2006 Final Rule, the FDA asserts that its requirements are "both a minimum 'floor' and a maximum 'ceiling' for the content and format" of prescription drug labels and that state-law failure-to-warn claims are, therefore, preempted. *Id.* at 3933-36. The FDA explains its reasoning as follows:

> Given the comprehensiveness of FDA regulation of drug safety, effectiveness, and labeling under the act, additional requirements for the disclosure of risk information are not necessarily more protective of patients. Instead, they can erode and disrupt the careful and truthful representation of benefits and risks that prescribers need to make appropriate judgments about drug use. Exaggeration of risk could discourage appropriate use of a beneficial drug.
>
> . . . .
>
> State law actions also 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.

The Plaintiffs' Steering Committee ("PSC") opposes Merck's motion, contending that the FDA's current view on preemption is unpersuasive, inconsistent with its prior views, and thus

not entitled to deference.[4] Indeed, the PSC notes that state-law claims have coexisted with federal regulation of prescription drugs for decades and urges the Court to ensure that no claims in this multidistrict litigation are vanquished by what they view as administrative fiat, regardless of when any given plaintiff may have ingested Vioxx.[5]

III. LAW & ANALYSIS

Summary judgment is appropriate in these cases if "there is no genuine issue as to any material fact and . . . the defendant is entitled to a judgment as a matter of law." Fed. R. Civ. P. 56(c). "The moving party bears the burden of demonstrating that there exists no genuine issue of

---

[4] The PSC went so far during argument as to equate the FDA's recent preemption statements with ancient attempts by various oligarchies and aristocracies to elevate property rights over the human rights of individuals. While, ultimately, the Court will rely on more contemporary sources, the PSC's voyage through the history of law in civilization as it relates to this ongoing struggle was nonetheless interesting.

[5] Alternatively, the PSC asks the Court to deny Merck's motion as premature. Attached to the PSC's opposition brief is a Rule 56(f) affidavit from Plaintiffs' Liaison Counsel Russ M. Herman. "The purpose of Rule 56(f) is to provide non-movants with a much needed tool to keep open the doors of discovery in order to adequately combat a summary judgment motion." *Wichita Falls Office Assocs. v. Banc One Corp.*, 978 F.2d 915, 919 (5th Cir. 1993). Mr. Herman submits that further discovery is necessary to completely explore issues regarding the timing and contents of Merck's submissions of its new drug application and supplemental applications for Vioxx, the negotiations between Merck and the FDA regarding Vioxx labeling, and Merck's employees' use of FDA labeling regulations.

In the absence of the Court's wholesale rejection of Merck's preemption argument, it should be noted that numerous factual disputes would also otherwise preclude summary judgment in these cases. First, the PSC's Rule 56(f) request appears to be well-founded and the Court would seriously consider allowing such discovery to proceed. Second, factual disputes abound in this litigation regarding what Merck knew about the safety of Vioxx and when the company acquired such knowledge. Merck would have the Court find as a matter of law that the VIGOR study was the first and only indication (prior to APPROVe) of an increased cardiovascular risk, and that the FDA's approval of a revised Vioxx label that incorporated the VIGOR data preempts the claims of those plaintiffs who began taking the drug after April 11, 2002. But the extent of Merck's knowledge beyond this date, and thus whether or not the company had a renewed duty to warn in light of "newly discovered risks," are genuine questions of fact that are disputed.

material fact." *In re Methyl Tertiary Butyl Ether ("MTBE") Prods. Liab. Litig.*, 475 F. Supp. 2d 286, 291 (S.D.N.Y. 2006). In determining whether a genuine issue of material fact exists, the Court must "review the facts drawing all inferences most favorable to the party opposing the motion." *Gen. Universal Sys., Inc. v. Lee*, 379 F.3d 131, 137 (5th Cir. 2004). But because "only those disputes over facts that might affect the outcome of the lawsuit under the governing substantive law will preclude summary judgment," questions that are "unnecessary" to the resolution of a particular issue "will not be counted." *Phillips Oil Co. v. OKC Corp.*, 812 F.2d 265, 272 (5th Cir. 1987).

A. Federal Regulation of Prescription Drugs

To put this matter in the proper context, it is helpful to briefly review the development and scope of federal regulation of prescription drugs. Prior to 1902, the States provided the primary and possibly the exclusive source of regulatory control over the labeling of foods and drugs. During the past century, however, the federal government has entered the area and imposed increasingly stringent requirements on those who would manufacture or distribute foods and drugs in interstate commerce. Federal regulation of the market in this respect can be traced back to the False Branding or Marking Act of 1902, Pub. L. No. 57-223, 32 Stat. 632 (codified at 21 U.S.C. §§ 16-17), which continues to prohibit the introduction of "any dairy or food products which shall be falsely labeled or branded as to the State or Territory in which they are made, produced, or grown." With the Pure Food and Drug Act of 1906, Pub. L. No. 59-384, 34 Stat. 768 (repealed 1938), Congress supplemented this prohibition by precluding the manufacture and shipment of both foods and drugs that were either adulterated or misbranded. Then, in 1938, Congress significantly expanded its reach into this arena with the comprehensive Federal Food,

Drug, and Cosmetic Act ("FDCA"), Pub. L. No. 75-717, 52 Stat. 1040 (codified as amended at 21 U.S.C. §§ 301-392). In general, the FDCA prohibits "[t]he introduction or delivery for introduction into interstate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded." 21 U.S.C. § 331.

Of particular relevance to this litigation, the FDCA also mandates that "[n]o person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of [a new drug application] is effective with respect to such drug." 21 U.S.C. § 355(a). Among other things, the new drug application ("NDA") sent to the FDA must include the following:

> (A) full reports of investigations which have been made to show whether or not such drug is safe for use and whether such drug is effective in use; (B) a full list of the articles used as components of such drug; (C) a full statement of the composition of such drug; (D) a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such drug; (E) such samples of such drug and of the articles used as components thereof as the Secretary may require; [and] (F) specimens of the labeling proposed to be used for such drug.

21 U.S.C. § 355(b)(1). The FDA "will approve an application after it determines that the drug meets the statutory standards for safety and effectiveness, manufacturing and controls, and labeling." 21 C.F.R. § 314.105(c). Thus, in making this determination, the FDA must rely heavily, if not exclusively, on the data provided by the manufacturer, the very entity that seeks approval of the drug and its label. Although FDA scientists review this data, they do not conduct independent tests or trials with the drug.

The FDA has promulgated detailed regulations governing the content and format of prescription drug labels. *See* 21 C.F.R. § 201.56. Pursuant to these labeling requirements, the FDA "will approve an application . . . on the basis of draft labeling if the only deficiencies in the application concern editorial or similar minor deficiencies in the draft labeling. Such approval

will be conditioned upon the applicant incorporating the specified labeling changes exactly as directed, and upon the applicant submitting to FDA a copy of the final printed labeling prior to marketing." 21 C.F.R. § 314.105(b). But the FDA will reject an NDA if it finds that "based on a fair evaluation of all material facts, [the proposed] labeling is false or misleading in any particular." 21 U.S.C. § 355(d)(7).

The FDCA regulations also set forth detailed guidelines that drug manufacturers must follow when seeking to make changes to an approved NDA. *See* 21 C.F.R. § 314.70. In general, prior to making any "major changes," a supplemental NDA must be submitted and approved by the FDA. *See* 21 C.F.R. § 314.70(b). Certain "moderate changes" may also require FDA approval, although merely submitting notice of such changes may suffice depending on the circumstances. *See* 21 C.F.R. § 314.70(c). Prior FDA approval is not required, however, where the manufacturer seeks to "add or strengthen a contraindication, warning, precaution, or adverse reaction" to the labeling. 21 C.F.R. § 314.70(c)(6)(iii)(A). "Thus, it is apparent that prior FDA approval need not be obtained, nor will a product be deemed mislabeled, if the manufacturer voluntarily or even unilaterally strengthens the approved warnings, precautions or potential adverse reactions upon the label." *McNellis v. Pfizer, Inc.*, No. 05-1286, 2005 WL 3752269, at *5 (D. N.J. Dec. 29, 2005). Although the FDA's regulations "do grant it the power to later disapprove a label strengthened pursuant to [21 C.F.R.] § 314.70 . . . the power to disapprove does not retroactively make the manufacturer's strengthened label a violation of any law. Rather, if the FDA exercises its power to disapprove, the manufacturer simply stops distributing the new label." *Witczak v. Pfizer, Inc.*, 377 F. Supp. 2d 726, 729 (D. Minn. 2005).

While the scope of the FDA's duty is vast, it is increasingly argued that the agency's

staffing, laboratory facilities, and research capacity is sorely lacking; calls for changes in the FDA's structure and procedures have only increased in the wake of Merck's voluntary withdrawal of Vioxx from the market. *See, e.g., FDA, Merck and Vioxx: Putting Patient Safety First?: Hearing Before the S. Comm. on Finance*, 108th Cong. (2004); Institute of Medicine, *The Future of Drug Safety: Promoting and Protecting the Health of the Public* (2006); Jerry Avorn, *FDA Standards–Good Enough for Government Work?*, 353 New Eng. J. Med. 969 (Sept. 8, 2005). Particular attention has been focused on the FDA's need to "negotiate" proposed labeling changes with the entities it regulates, rather than possessing authority to mandate changes it considers necessary. Indeed, Congress is currently considering modifications to the FDA's drug approval and oversight functions. *See Food and Drug Administration Revitalization Act*, S.1082, 110th Cong. (2007) (as passed by the Senate on May 9, 2007); *Enhancing Drug Safety and Innovation Act of 2007*, H.R. 1561, 110th Cong. (2007) (as introduced in the House on March 19, 2007).

B. Federal Preemption in General

With this brief discussion of the development and scope of federal regulation of prescription drugs, the Court now turns to the issue of preemption. The concept of federal preemption emanates from the Supremacy Clause of the United States Constitution. *See* U.S. Const. art. VI, cl. 2 ("This Constitution, and the laws of the United States which shall be made in pursuance thereof; and all treaties made, or which shall be made, under the authority of the United States, shall be the supreme law of the land; and the judges in every state shall be bound thereby, anything in the Constitution or laws of any State to the contrary notwithstanding."). The United States Supreme Court has noted that "state law is pre-empted under the Supremacy

Clause in three circumstances," which in some instances may overlap. *English v. Gen. Elec. Co.*, 496 U.S. 72, 78-79 & n.5 (1990) (internal citation omitted).

"First, Congress can define explicitly the extent to which its enactments pre-empt state law." *Id.* at 78. This is known as express preemption. For example, in the Medical Device Amendments of 1976, Congress provided that "no State . . . may establish or continue in effect with respect to a device intended for human use any requirement (1) which is different from, or in addition to, any requirement applicable under this Act to the device, and (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this Act." Pub. L. No. 94-295, § 2, 90 Stat. 539, 574 (codified at 21 U.S.C. § 360k).[6] But the FDCA does not contain an express statement that Congress intended to displace state-law claims in the prescription drug context. Indeed, when Congress amended the FDCA in 1962, it stated that "[n]othing in the amendments . . . shall be construed as invalidating any provision of State law which would be valid in the absence of such amendments unless there is a direct and positive conflict between such amendments and such provision of State law." Drug Amendments of 1962, Pub. L. No. 87-781, § 202, 76 Stat. 780, 793. The Supreme Court has noted that "[t]he case for federal pre-emption is particularly weak where Congress has indicated its awareness of the operation of state law in a field of interest, and has nonetheless decided to stand by both concepts and to tolerate whatever tension there [is] between them." *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 166-67 (1989) (internal

[6] The Supreme Court has addressed the scope of the Medical Device Amendments' express preemption clause on several occasions and recently agreed to revisit the issue once again. *See Riegel v. Medtronic, Inc.*, 451 F.3d 104 (2d Cir. 2006), *cert. granted*, 75 U.S.L.W. 3065 (U.S. June 25, 2007) (No. 06-179). However, this line of cases does not govern the instant dispute regarding preemption of state-law claims against prescription drug manufacturers.

quotation omitted).

"Second, in the absence of explicit statutory language, state law is pre-empted where it regulates conduct in a field that Congress intended the Federal Government to occupy exclusively." *English*, 496 U.S. at 79. This is known as implied field preemption. "The question whether the regulation of an entire field has been reserved by the Federal Government is, essentially, a question of ascertaining the intent underlying the federal scheme." *Hillsborough County v. Automated Med. Labs., Inc.*, 471 U.S. 707, 714 (1985). Merck concedes that Congress did not intend to completely occupy the field of prescription drug regulation with the FDCA, and, thus, this form of implied preemption is not implicated in the instant cases.

Third, "state law is pre-empted to the extent that it actually conflicts with federal law," *English*, 496 U.S. at 79, that is, where it is either "impossible for a private party to comply with both state and federal requirements, or where state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress," *Sprietsma v. Mercury Marine*, 537 U.S. 51, 64 (2002) (internal citations omitted). This is known as implied conflict preemption, and its later variety is the version of preemption relied upon by Merck in the present matter.

At its core, "[p]re-emption fundamentally is a question of congressional intent." *English*, 496 U.S. at 78. When Congress expressly preempts state law via statute, it does so through the normal legislative process and its intentions are generally clear. When Congress does not speak on preemption, as it has not with respect to state-law claims against prescription drug manufacturers, its intent to preempt must be implied for preemption to be applicable. The Court is mindful that a finding of implied preemption (whether by an agency or by the courts) is likely

never preceded by the same level of vigorous debate that accompanies an express preemption statement by Congress. Indeed, as discussed below, such a finding may not be preceded by any debate at all. For this reason and others,[7] courts should be cautious in applying the doctrine of implied preemption.

C. Federal Preemption in this Multidistrict Litigation

The *Arnold* and *Gomez* plaintiffs, indeed all plaintiffs in this multidistrict litigation, assert various state-law claims against Merck related to its activities vis-à-vis Vioxx. "[B]ecause the States are independent sovereigns in our federal system," the Supreme Court has "long presumed that Congress does not cavalierly pre-empt state-law causes of action." *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996). Moreover, "[i]n fields traditionally occupied by the states, such as health and safety regulation, there is a strong presumption against federal preemption." *In re Zyprexa Prods. Liab. Litig.*, ___ F. Supp. 2d ___, 2007 WL 1678078, at *35 (E.D.N.Y. June 11, 2007). Indeed, the Supreme Court has "worked on the 'assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress.'" *N.Y. State Conference of Blue Cross & Blue Shield Plans v. Travelers Ins. Co.*, 514 U.S. 645, 654-55 (1995) (quoting *Rice v. Santa Fe Elevator Corp.*, 331

[7] For example, a recent study by the *Harvard Law Review* concludes that the presumption against preemption is justified in part by the lack of Congressional responses to preemption decisions, and argues for a pragmatic approach to preemption issues. *See* Note, *New Evidence on the Presumption Against Preemption: An Empirical Study of Congressional Responses to Supreme Court Preemption Decisions*, 120 Harv. L. Rev. 1604, 1623-24 (2007) ("In many preemption cases, finding state law preempted leaves plaintiffs with no make-whole remedy, creates inequitable results, or produces a dangerous regulatory gap. . . . Why choose the presumption against preemption as the pragmatic default rule instead of the opposite presumption? Because the presumption against preemption allows each state to satisfy the preferences of its own citizens, while a presumption in favor of preemption would impose a uniform national policy even when national preferences are unclear.").

U.S. 218, 230 (1947)).

As noted, Congress has never spoken on preemption with respect to prescription drugs; thus, state-law failure-to-warn claims against drug manufacturers are not expressly preempted. Moreover, in the absence of "clear and manifest" direction from Congress, the courts have also generally refused to broaden the doctrine of implied preemption in this context. Indeed, prior to the FDA's recent statements in the preamble to the 2006 Final Rule, courts routinely found that state law failure-to-warn claims were not impliedly preempted. *See, e.g., In re Zyprexa Prods. Liab. Litig.*, ___ F. Supp. 2d ___, 2007 WL 1678078, at *37 (E.D.N.Y. June 11, 2007) (collecting authorities). For example, in *Osburn v. Anchor Laboratories, Inc.*, the United States Court of Appeals for the Fifth Circuit addressed this issue:

> [T]he regulations required [the defendant] to submit a proposed label of its own choosing, which the FDA would then approve or reject. Of special significance is the fact that the FDA regulations specifically permitted [the defendant] to add additional warnings to a previously approved label as soon as it became aware of the necessity to do so–without any need to first obtain FDA approval of the supplemental warnings. . . . We therefore conclude that federal law neither made it practically (nor legally) impossible, nor would it have posed an obstacle to accomplishing the objectives of the FDCA, for [the defendant] to give warnings that would have satisfied its duty under Texas law. Since [the defendant] has not convinced us that the FDA regulations actually conflict with its duty to warn under Texas law, or that Congress intended to exclusively occupy the field presented by [the plaintiffs'] claims, we reject [the defendant's] preemption challenge.

825 F.2d 908, 912-13 (5th Cir. 1987) (internal citations omitted); *see also Hurley v. Lederle Labs. Div. of Am. Cyanamid Co.*, 863 F.2d 1173, 1176-78 & n.2 (5th Cir. 1988) (collecting authorites); *Abbot v. Am. Cyanamid Co.*, 844 F.2d 1108, 1111-14 (4th Cir. 1988); *Caraker v. Sandoz Pharm. Corp.*, 172 F. Supp. 2d 1018, 1029-44 & n.11 (S.D. Ill. 2001); *Feldman v. Lederle Labs.*, 479 A.2d 374, 389-91 (N.J. 1984).

The issue presented in this litigation is whether the preamble to the 2006 Final Rule

mandates a change. Recently, some courts have deferred to the FDA's current view that its requirements are "both a minimum 'floor' and a maximum 'ceiling' for the content and format" of prescription drug labels, 71 Fed. Reg. at 3935, and have recognized an implied Congressional intent to preempt certain state-law claims. *See, e.g., Sykes v. Glaxo-SmithKline*, 484 F. Supp. 2d 289, 306-17 (E.D. Pa. 2007); *In re Bextra & Celebrex Mktg. Sales Practices & Prod. Liab. Litig.*, MDL 1699, 2006 WL 2374742, at *5-12 (N.D. Cal. Aug. 16, 2006); *Colacicco v. Apotex, Inc.*, 432 F. Supp. 2d 514, 523-38 (E.D. Pa. 2006). But the majority of courts continue to find that state-law claims against prescription drug manufacturers are not preempted, affording little to no deference to the FDA's recent statements. *See, e.g., In re Zyprexa Prods. Liab. Litig.*, ___ F. Supp. 2d ___, 2007 WL 1678078 (E.D.N.Y. June 11, 2007); *Weiss v. Fujisawa Pharm. Co.*, 464 F. Supp. 2d 666 (E.D. Ky. 2006); *Perry v. Novartis Pharma. Corp.*, 456 F. Supp. 2d 678 (E.D. Pa. 2006); *McNellis v. Pfizer, Inc.*, No. 05-1286, 2005 WL 3752269 (D. N.J. Dec. 29, 2005); *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 (Vt. Oct. 27, 2006), *petition for cert. filed*, 75 U.S.L.W. 3500 (U.S. Mar. 12, 2007) (No. 06-1249).

In the instant cases, Merck argues that the Court must defer to the FDA's recent statements on preemption because those statements are interpretations of either the FDCA or the FDA's own prescription drug regulations. Generally, when Congress has not directly spoken on an issue, an administrative agency's interpretation of the *statute* it administers is entitled to substantial deference. *See Chevron U.S.A., Inc. v. Natural Res. Def. Counsel, Inc.*, 467 U.S. 837, 843 (1984). But this deference is only appropriate when "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). Moreover, an agency's statements clarifying ambiguities in its own *regulations* are also entitled to a level of deference. *See Auer v. Robbins*, 519 U.S. 452, 461 (1997).

The Court finds that the FDA's current position on preemption is neither entitled to the deference suggested in *Chevron*, nor to the deference espoused in *Auer*. The FDA's current views on preemption were not promulgated pursuant to its rulemaking authority, nor do they seek to clarify any ambiguity in the FDA regulations. Rather, the FDA added these views at the end of the rulemaking process in a preamble to the 2006 Final Rule, that is, "through the back door." *In re Zyprexa Prods. Liab. Litig.*, ___ F. Supp. 2d ___, 2007 WL 1678078, at *39 (E.D.N.Y. June 11, 2007); *see also* Catherine M. Sharkey, *Preemption by Preamble: Federal Agencies and the Federalization of Tort Law*, 56 Depaul L. Rev. 227 (2007) (discussing the "backdoor federalization" of products liability law). Moreover, the FDA's preemption statements in the preamble actually *conflict* with statements made in the original notice of proposed rulemaking out of which the 2006 Final Rule grew. *See* 65 Fed. Reg. 81082, 81103 (Dec. 22, 2000) ("[T]his proposed rule does not preempt State law. . . . [T]his proposed rule does not contain policies that have federalism implications or that preempt State law."). At best, the preamble merely offers an opinion on the viability of the plaintiffs' state-law claims given the existence of the federal regulatory scheme as a whole; it does not purport to interpret any specific statutory or regulatory provision, nor is it a regulation itself.

> The weight of such [an opinion] in a particular case will depend upon 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 v. Swift & Co., 323 U.S. 134, 140 (1944).

A number of commentators have noted the tension that arises between the "presumption against preemption" and judicial deference doctrines when an agency attempts to preempt state law. *See, e.g.*, Richard C. Ausness, *"After You, My Dear Alphonse!": Should the Courts Defer to the FDA's New Interpretation of § 360k(a) of the Medical Device Amendments?*, 80 Tul. L. Rev. 727, 769-71 (2006); Nina A. Mendelson, Chevron *and Preemption*, 102 Mich. L. Rev. 737, 758-98 (2004). In the instant cases, however, the Court is guided by the Supreme Court's statement that "[w]e may assume (without deciding) that . . . the question of *whether* a statute is pre-emptive . . . must always be decided *de novo* by the courts." *Smiley v. Citibank*, 517 U.S. 735, 744 (1996); *see also Medtronic, Inc. v. Lohr*, 518 U.S. 470, 512 (1996) (O'Connor, J., concurring in part and dissenting in part) ("It is not certain that an agency regulation determining the pre-emptive effect of *any* federal statute is entitled to deference."). Because the preamble to the 2006 Final Rule does not carry the force of law and does not purport to interpret a specific statutory or regulatory provision, the Court concludes that the preamble is only entitled to *Skidmore* deference; thus, the Court will defer to the FDA's current views only to the extent that they have the "power to persuade." The weight to be given to the preamble depends on the thoroughness evident in its consideration, the validity of its reasoning, its consistency with earlier and later pronouncements, the timing, manner, and procedure used to construct it, and all such factors which make it persuasive. *See Skidmore*, 323 U.S. at 140.[8]

[8] To be sure, the Court is not "insist[ing] on a specific expression of agency intent to pre-empt, made after notice-and-comment rulemaking." *Geier v. Am. Honda Motor Co., Inc.*, 529 U.S. 861, 885 (2000). Rather, the Court merely notes that the lack of such a formal expression dictates the level of *deference* that is due in these cases. Perhaps the result would be different if the preamble to the 2006 Final Rule interpreted an ambiguous preemption clause enacted by

When analyzed with these factors in mind, the Court cannot defer to the FDA in the instant cases because the agency's statements on preemption in the preamble to the 2006 Final Rule lack the "power to persuade." Until January 24, 2006, the FDA itself had consistently recognized that state-law claims could coexist with federal regulation of prescription drugs: "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); *see also In re Zyprexa Prods. Liab. Litig.*, ___ F. Supp. 2d ___, 2007 WL 1678078, at *36-37 (E.D.N.Y. June 11, 2007) (collecting additional prior statements by the FDA on preemption). Indeed, the FDA's current position on preemption represents a significant departure from well-settled administrative and judicial views on the issue, and ultimately is both unpersuasive and untenable in this multidistrict litigation.

In the preamble to the 2006 Final Rule, the FDA announces that it is the "expert Federal agency responsible for evaluating and regulating drugs." 71 Fed. Reg. at 3935. While this is certainly true, historically, "the several States have [also] exercised their police powers to protect the health and safety of their citizens." *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 475 (1996). Because there are no federal remedies for individuals harmed by prescription drugs, a finding of implied preemption in these cases would abolish state-law remedies and would, in effect, render legally impotent those who sustain injuries from defective prescription drugs. *See Wack v. Lederle Labs.*, 666 F. Supp. 123, 128 (N.D. Ohio 1987); *see also* Robert L. Rabin, *Poking Holes*

Congress, *see, e.g., Medtronic, Inc. v. Lohr*, 518 U.S. 470, 505-08 (1996) (Breyer, J., concurring in part and concurring in the judgment), or an ambiguous regulation promulgated by the FDA, *see, e.g., Belt v. Emcare, Inc.*, 444 F.3d 403, 416 & n.35 (5th Cir. 2006). But it does neither. Thus, whether or not the plaintiffs' claims in this litigation ultimately are preempted "turns on the identification of 'actual conflict.'" *Geier*, 529 U.S. at 884.

in the Fabric of Tort: A Comment, 56 Depaul L. Rev. 293 (2007). To take such drastic action based solely on a preamble inserted at the eleventh hour and drafted by an agency without the express or implied authority to abolish such remedies is Draconian and unacceptable. "If Congress had intended to deprive injured parties of a long available form of compensation, it surely would have expressed that intent more clearly." *Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 449 (2005). Far from standing "as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress," state-law claims against prescription drug manufacturers "necessarily perform an important remedial role in compensating" injured individuals. *Sprietsma v. Mercury Marine*, 537 U.S. 51, 64 (2002) (internal citations omitted). Following longstanding and well-reasoned precedent, the Court concludes that there is no actual conflict between the plaintiffs' state-law claims against Merck and federal law. Therefore, preemption of state law is inappropriate.

IV. CONCLUSION

Because the FDA's current view on the question of immunity for prescription drug manufacturers is entirely unpersuasive and thus not entitled to deference, and because "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), the Court reaches the inevitable conclusion that the plaintiffs' claims against Merck in this multidistrict litigation are not preempted in any respect because they do not actually conflict with federal law. Thus, IT IS ORDERED that Merck's Motion for Summary Judgment is DENIED.

New Orleans, Louisiana, this 3rd day of July, 2007.

UNITED STATES DISTRICT JUDGE