EXHIBIT B

Briefs and Other Related Documents

Desiano v. Warner-Lambert & Co.C.A.2 (N.Y.),2006.Only the Westlaw citation is currently available.

United States Court of Appeals,Second Circuit.

Caesar DESIANO et al., Plaintiffs-Appellants,

v.

WARNER-LAMBERT & CO., et al, Defendants-Appellees.

Docket Nos. 05-1705-cv(L), 05-1743-cv(CON), 05-1745-cv(CON).

Argued: Nov. 8, 2005.

Decided: Oct. 5, 2006.

Background: Michigan residents alleging injuries caused by Rezulin, a drug marketed and sold by drug companies for the treatment of Type-2 diabetes, brought suit in state court asserting various common law claims including, inter alia, breach of implied and express warranties, negligence, negligent misrepresentation, negligence per se, fraud, defective design, defective manufacturing, and loss of consortium. Drug companies removed. The United States District Court for the Southern District of New York, Lewis A. Kaplan, J., granted drug companies' motion for judgment on the pleadings, and appeal was taken.

Holdings: The Court of Appeals, Calabresi, Circuit Judge, held that:

(1) Second Circuit Court of Appeals, a transferee court, was not bound by Sixth Circuit's ruling in decision involving the laws of Michigan, a state within its circuit, with respect to questions of federal law, and

(2) federal law did not preempt traditional common law claims brought by Michigan residents.

Vacated and remanded.

[1] **Courts 106 ⇐96(5)**

106 Courts

106II Establishment, Organization, and Procedure

106II(G) Rules of Decision

106k88 Previous Decisions as Controlling or as Precedents

106k96 Decisions of United States Courts as Authority in Other United States Courts

106k96(5) k. Decisions in Other Circuits. Most Cited Cases

Federal Courts 170B ⇐157

170B Federal Courts

170BII Venue

170BII(B) Change of Venue

170BII(B)5 Multi-District Litigation; Transfer for Pre-Trial Proceedings

170Bk157 k. Effect of Transfer and Subsequent Proceedings. Most Cited Cases

Second Circuit Court of Appeals, a transferee court, was not bound by Sixth Circuit's ruling in decision involving the laws of Michigan, a state within its circuit, with respect to questions of federal law, in action brought by Michigan residents alleging injuries caused by Rezulin, a drug marketed and sold by drug companies for the treatment of Type-2 diabetes.

Second Circuit Court of Appeals, a transferee court, was not bound by Sixth Circuit's ruling in decision involving the laws of Michigan, a state within its circuit, with respect to questions of federal law, in action brought by Michigan residents alleging injuries caused by Rezulin, a drug marketed and sold by drug companies for the treatment of Type-2 diabetes.

[2] **Products Liability 313A ⇐46.2**

313A Products Liability

313AI Scope in General

313AI(B) Particular Products, Application to

313Ak46 Health Care and Medical Products

313Ak46.2 k. Drugs in General. Most Cited Cases

States 360 ⇐18.65

360 States

360I Political Status and Relations

360I(B) Federal Supremacy; Preemption

360k18.65 k. Product Safety; Food and Drug Laws. Most Cited Cases
Federal law did not preempt provision of Michigan law excepting manufacturer of drug approved by Food and Drug Administration (FDA) from immunity from products liability claims where company misrepresented or withheld material information that would have altered FDA's decision to approve the drug, and thus did not preempt traditional common law claims brought by Michigan residents alleging injuries caused by diabetes drug, Rezulin; suits depended primarily on traditional and preexisting tort sources, not at all on a "fraud-on-the-FDA" cause of action created by state law, and only incidentally on evidence of such fraud. M.C.L.A. § 2946(5).

Federal law did not preempt provision of Michigan law excepting manufacturer of drug approved by Food and Drug Administration (FDA) from immunity from products liability claims where company misrepresented or withheld material information that would have altered FDA's decision to approve the drug, and thus did not preempt traditional common law claims brought by Michigan residents alleging injuries caused by diabetes drug, Rezulin; suits depended primarily on traditional and preexisting tort sources, not at all on a "fraud-on-the-FDA" cause of action created by state law, and only incidentally on evidence of such fraud. M.C.L.A. § 2946(5).

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Before: FEINBERG, CALABRESI, and B.D. PARKER, Circuit Judges.
CALABRESI, Circuit Judge:
***1** It has long fallen within the province of states to safeguard the health and safety of their citizens. *See Medtronic v. Lohr*, 518 U.S. 470, 475, 116 S.Ct. 2240, 135 L.Ed.2d 700 (1996). Consonant with the "historic primacy of state regulation" of these matters, *see Medtronic*, 518 U.S. at 485, 116 S.Ct. 2240, the power of states to govern in this field is considerable and undisputed. *See Metropolitan Life Ins. Co. v. Massachusetts*, 471 U.S. 724, 756, 105 S.Ct. 2380, 85 L.Ed.2d 728 (1985) ("The 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.' ") (quoting *Slaughter-House Cases*, 83 U.S. 36, 16 Wall. 36, 62, 21 L.Ed. 394 (1873); *Thorpe v. Rutland & Burlington R. Co.*, 27 Vt. 140, 149 (1854)). Historically, common law liability has formed the bedrock of state regulation, and common law tort claims have been described as "a critical component of the States' traditional ability to protect the health and safety of their citizens." *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 544, 112 S.Ct. 2608, 120 L.Ed.2d 407 (1992) (Blackmun, J., concurring in part and dissenting in part). In recent years, some states, in exercising their traditional authority with respect to the pharmaceutical industry, have narrowed common law liability in order to insulate drug companies from burdensome litigation. *See generally* David G. Owen, *Special Defenses in Modern Products Liability Law*, 70 Mo. L.Rev. 1, 22-23 (2005). The case before us concerns a supposed conflict between federal law and the products liability regime of one such state.

In 1995, the State of Michigan enacted legislation immunizing drugmakers from products liability claims so long as the Food and Drug Administration ("FDA") approved the pharmaceutical product at issue. *See* Mich. Comp. Laws § 600.2946(5) (hereinafter "M.C.L. § 2946(5)"). Michigan's immunity scheme contains an exception that preserves liability if the pharmaceutical company withheld or misrepresented information that would have altered the FDA's decision to approve the drug. In 2001, in a case dealing with different legal rules and a different jurisdiction, the Supreme Court held that state "fraud-on-the-FDA" claims were impliedly preempted by federal law. *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 348, 121 S.Ct. 1012, 148 L.Ed.2d 854 (2001). The question presented by this appeal is whether, under the rationale of *Buckman*, federal law also preempts traditional common law claims that survive a state's legislative narrowing of

common law liability through a fraud exception to that statutory limitation. For the reasons below, we conclude that federal law does not preempt these state claims. We therefore vacate the District Court's grant of judgment on the pleadings and remand the case for further proceedings consistent with this opinion.

BACKGROUND

A. Michigan's Immunity Statute

Prior to its amendment in 1995, Michigan's products liability statute provided that "evidence showing compliance with governmental or industry standards was admissible in a products liability action in determining if the standard of care had been met." *Taylor v. Smithkline Beecham Corp.*, 468 Mich. 1, 658 N.W.2d 127, 130 (2003). In describing the pre-amendment law, the Supreme Court of Michigan emphasized the limits on the probative value of this sort of evidence of compliance:

***2** We note that our Legislature has recently enacted a statute which provides that industrial and governmental standards are admissible in products liability actions [citing earlier version of M.C.L. § 600.2946]. The statute does not provide that such standards are conclusive. [We affirm the position] that compliance with governmental and industrial standards is admissible as evidence but is not conclusive as to whether the defendant was negligent or the product was defective.

Owens v. Allis-Chalmers Corp., 414 Mich. 413, 326 N.W.2d 372, 375-76 (1982).

In 1995, Michigan's legislature amended the law in order to confer immunity upon drugmakers in product liability suits where the FDA had approved the drug in question. *See Taylor*, 658 N.W.2d at 130 ("The 1995 amendment of the statute ... provided that compliance with federal governmental standards (established by the FDA) is conclusive on the issue of due care for drugs."). The relevant provision states:

In a product liability action against a manufacturer or seller, a product that is a drug is not defective or unreasonably dangerous, and the manufacturer or seller is not liable, if the drug was approved for safety and efficacy by the United States food and drug administration, and the drug and its labeling were in compliance with the United States food and drug administration's approval at the time the drug left the control of the manufacturer or seller.

M.C.L. § 2946(5). In addition to several qualifications not relevant to the case before us,[FN1] the immunity provision contains an important exception:This subsection does not apply if the defendant at any time before the event that allegedly caused the injury does any of the following:

(a) Intentionally withholds from or misrepresents to the United States food and drug administration information concerning the drug that is required to be submitted under the federal food, drug, and cosmetic act and the drug would not have been approved, or the United States food and drug administration would have withdrawn approval for the drug if the information were accurately submitted.

M.C.L. § 2946(5)(a) (internal citations omitted). Hence, under these provisions, so long as a drug company did not withhold or misrepresent information that would have affected the FDA's approval of a putatively harmful drug, the company can successfully defend itself against products liability litigation by establishing that its product received the FDA's approval and complied with the FDA's labeling and substantive requirements.

B. Procedural History

Appellants in this case are all Michigan residents alleging injuries caused by Rezulin, a drug marketed and sold by Appellees for the treatment of Type-2 diabetes. The FDA originally approved Rezulin in 1997. After adverse liver-related effects were documented in patients taking Rezulin, Appellees agreed to a series of label changes, which were authorized by the FDA on four occasions between November 1997 and June 1999. In March 2000, apparently at the FDA's request, *see Desiano v. Warner-Lambert Co.*, 326 F.3d 339, 344 (2d Cir.2003), Appellees withdrew Rezulin from the United States market.

***3** The instant litigation began in state courts in Michigan and California. Appellants asserted various

common law claims including, *inter alia,* breach of implied and express warranties, negligence, negligent misrepresentation, negligence *per se,* fraud, defective design, defective manufacturing, and loss of consortium. The drug companies removed the actions to federal court, and all of the claims were subsequently consolidated and transferred by the Judicial Panel on Multidistrict Litigation to Judge Lewis A. Kaplan in the Southern District of New York.

In the District Court, Appellees moved for judgment on the pleadings on the ground that liability was foreclosed under Michigan state law. To support their motion, Appellees emphasized *Buckman* and the Sixth Circuit's decision in *Garcia v. Wyeth-Ayerst Labs.*, 385 F.3d 961 (6th Cir.2004), which held (on the basis of *Buckman*) that the "fraud" exception in Michigan's statute was impliedly preempted by two federal laws-the Food, Drug and Cosmetic Act ("FDCA"), 21 U.S.C. § 301, *et seq.*, and the Medical Device Act ("MDA"), 21 U.S.C. §§ 360e(b)(1)(A)-(B)-and therefore had to be severed from the rest of the Michigan law.

The District Court agreed with Appellees, concluding that the immunity exception should be severed because under the reasoning of *Buckman,* it was preempted by federal law.[FN2] The court gave two reasons for its decision. First, the District Court believed that, although it was not "absolutely bound" by *Garcia,* the Sixth Circuit's reasoning was owed "quite substantial deference" under *Factors Etc., Inc. v. Pro Arts, Inc.*, 652 F.2d 278 (2d Cir.1981), a decision by a panel of this circuit which stated that conclusive deference should be given to a federal court of appeals' interpretation of the law of a state within its circuit. Second, "apart from *Factors*," the District Court reasoned that "[i]f plaintiffs covered by the Michigan statute were able to litigate claims of fraud on the FDA in individual personal injury suits, whether in state courts or in federal courts, the potential would exist for the FDA's personnel to be drawn into those controversies on a case-by-case basis over and over again." Concluding that this would generate "a wholly impractical situation," the court held "that the exception in the Michigan statute is preempted, except where the plaintiff relies on a finding by the FDA, or in an action brought by the FDA, of material fraud in the new drug approval process absent which approval would not have been granted." Hence, the court granted the drugmakers' motion for judgment on the pleadings and dismissed all of Appellants' complaints.

Appellants filed a timely appeal.

DISCUSSION

We review *de novo* a district court's dismissal of a suit pursuant to a motion for judgment on the pleadings. *See King v. Am. Airlines, Inc.*, 284 F.3d 352, 356 (2d Cir.2002); *Burnette v. Carothers*, 192 F.3d 52, 56 (2d Cir.1999). "In deciding a Rule 12(c) motion, we apply the same standard as that applicable to a motion under Rule 12(b)(6), accepting the allegations contained in the complaint as true and drawing all reasonable inferences in favor of the nonmoving party." *Burnette*, 192 F.3d at 56.

*4 This appeal raises two separate and significant questions. First, under the rule in *Factors,* must we follow our sister circuit's holding in *Garcia* because the Sixth Circuit's decision involved the laws of Michigan, a state within its circuit? Second, even if we are not required to defer conclusively to *Garcia,* should we nonetheless conclude, applying the logic of *Buckman,* that Appellants' common law claims-preserved by Michigan's exception-conflict with, and are therefore preempted by, federal law?

I.

[1] The District Court interpreted *Factors* to mean that, although it was not "absolutely bound" by the Sixth Circuit's ruling, *Garcia* was owed "substantial deference." Appellees advocate an interpretation of *Factors* that insists upon more than deference. They contend that, under *Factors,* we are not free to reach a conclusion contrary to *Garcia* unless a different result is compelled by prior or subsequent pronouncements of the Supreme Court of Michigan. For their part, Appellants do not identify any contrary Michigan law to refute the *Garcia* court's decision that federal law preempts Michigan's immunity exception.[FN3] As a result, Appellees maintain that *Garcia* binds us to dismiss Appellants' suit. Appellees may be correct in their reading of *Factors,*

when it applies. But like the District Court they misgauge the relevance of *Factors* to the case before us.

Factors involved a contract dispute governed exclusively by Tennessee state law. In that context, we held that a federal court exercising diversity jurisdiction should give "conclusive deference" to "a ruling by a court of appeals deciding the law of a state within its circuit." *Factors*, 652 F.2d at 279. We elaborated that conclusive deference was owed except in very narrow circumstances:

We need not and do not conclude that the state law holding of the pertinent court of appeals is automatically binding upon the federal courts of all the other circuits. The ultimate source for state law adjudication in diversity cases is the law as established by the constitution, statutes, or authoritative court decisions of the state. A federal court in another circuit would be obliged to disregard a state law holding by the pertinent court of appeals if persuaded that the holding had been superseded by a later pronouncement from state legislative or judicial sources, or that prior state court decisions had been inadvertently overlooked by the pertinent court of appeals.

Factors, 652 F.2d at 283 (internal citation omitted). Because neither of these circumstances applied to the sister circuit's decision-*i.e.*, the court of appeals' decision had not been weakened by subsequent developments in state law, nor was the decision contrary to prior state precedent-the *Factors* court mandated deference:Where, as here, the pertinent court of appeals has essayed its own prediction of the course of state law on a question of first impression within that state, the federal courts of other circuits should defer to that holding, perhaps always, and at least in all situations except the rare instance when it can be said with conviction that the pertinent court of appeals has disregarded clear signals emanating from the state's highest court pointing toward a different rule.

***5** *Factors*, 652 F.2d at 283.

But *Factors* instructed us to defer conclusively to another circuit's judgment only when that court of appeals' decision addressed questions of *state* law from a state within that circuit. It asserted no obligation to defer to a foreign circuit's views on *federal* law. As to issues of federal law, we are permitted-indeed, required-to reach our own conclusions. *See Pan Am. World Airways, Inc. v. C.A.B.*, 517 F.2d 734, 741 (2d Cir.1975) ("[W]e are not bound by the decision or the rationale of [another circuit] court."); *see also Colby v. J.C. Penney Co., Inc.*, 811 F.2d 1119, 1123 (7th Cir.1987) ("We have an intermediate obligation to our sister federal courts of appeals. Bearing in mind the interest in maintaining a reasonable uniformity of federal law and in sparing the Supreme Court the burden of taking cases merely to resolve conflicts between circuits, we give most respectful consideration to the decisions of the other courts of appeals and follow them whenever we can. Our district judges should, of course, do likewise with regard to such decisions.... But neither this court nor the district courts of this circuit give the decisions of other courts of appeals automatic deference; we recognize that, within reason, the parties to cases before us are entitled to our independent judgment." (internal citation omitted)).

This obligation does not change in the context of transferred cases. In *Menowitz v. Brown*, 991 F.2d 36 (2d Cir.1993) (per curiam), we considered securities fraud claims that had been consolidated and transferred to the Southern District of New York only to be dismissed as untimely under our circuit's limitations guidelines. One set of claims, however, had originally been filed in the Southern District of Florida and would have been timely under the statute of limitations applicable under the Eleventh Circuit's rule (which would have borrowed Florida's "blue sky" limitations period). Thus, the question presented was "whether Second Circuit doctrine directs application of the Eleventh Circuit limitations rule to such a transferred action." *Menowitz*, 991 F.2d at 40. We stated that "[r]esolution of this question turns on whether the choice of the applicable limitations period is properly understood as a matter of state or of federal law." *Id.* Were it an issue of state law, we indicated that "a transferee court applies the substantive state law, including choice-of-law rules, of the jurisdiction in which the action was filed." *Id.* But since we concluded that the proper statute of limitations applicable to a federal claim was a matter of federal law, we disregarded the Eleventh Circuit's approach

to the federal issue and opted instead to follow our own. In so doing, we emphasized that, even in the transfer context, a court of appeals must develop its own circuit law on federal questions; it cannot mechanically adopt the reasoning and conclusions of its sister circuits:

***6** We have previously held that a transferee federal court should apply its interpretations of federal law, not the constructions of federal law of the transferor circuit.... [F]ederal courts comprise a single system applying a single body of law, and no litigant has a right to have the interpretation of one federal court rather than that of another determine his case....

[U]ntil the Supreme Court speaks, the federal circuit courts are under duties to arrive at their own determinations of the merits of federal questions presented to them; ... [I]f a federal court simply accepts the interpretation of another circuit without [independently] addressing the merits, it is not doing its job.

Id. (internal citations and quotation marks omitted).

The problem, therefore, with the District Court's decision and with the position taken by Appellees is that both fail to appreciate that this appeal-unlike the Tennessee contract dispute in *Factors*-is not governed primarily, and certainly not exclusively, by state law. Rather, the question of whether federal law impliedly preempts part of Michigan's statutory scheme depends on significant issues of federal law including, *inter alia,* the meaning of Supreme Court precedents, *e.g.,* *Buckman,* and the scope of federal statutes, *e.g.,* FDCA. As a result, in resolving this appeal, we operate under twin mandates with respect to the Sixth Circuit's opinion in *Garcia.* On the one hand, under *Factors,* we are bound to follow *Garcia's* conclusions as to questions of Michigan state law. On the other hand, under *Menowitz,* we are obligated to answer independently questions of federal law, applying only the usual intercircuit regard for the Sixth Circuit's analysis of these federal issues.

Accordingly, the central question presented by this appeal-*i.e.,* whether federal law preempts Michigan's immunity exception-is controlled by the decision in *Garcia* only to the extent that the Sixth Circuit's conclusion rested solely on findings as to state law. *Garcia* did begin with an explanation of state law:

[M.C.L. § 2946(5)] presents a somewhat different legal regime from the one invalidated in *Buckman.* The Michigan legislature has provided a general immunity for drug manufacturers with a specific exception for circumstances involving, *inter alia,* fraud on the FDA rather than a specific cause of action for fraud on the FDA.

Garcia, 385 F.3d at 965-66 (internal footnote omitted). Under *Factors,* therefore, we must accept the Sixth Circuit's conclusion that M.C.L. § 2946(5) *does not* create a new cause of action for misleading the FDA. And that holding guides our review of the federal issues before us.[FN4]

After issuing this interpretation of M.C.L. § 2946(5), the Sixth Circuit turned to issues of federal law. And, on the basis of *its* understanding of the Supreme Court's decision in *Buckman,* the Sixth Circuit concluded that the difference it had just identified-between those preexisting common law claims that survived M.C.L. § 2946(5) and those arising under a specific cause of action for fraud-on-the-FDA, like those invalidated in *Buckman*-was "immaterial." *See Garcia,* 385 F.3d at 966 ("As the [Michigan] district court properly found, '*Buckman* teaches that state tort remedies requiring proof of fraud committed against the FDA are foreclosed since federal law preempts such claims.' ").

***7** Nothing in *Factors* requires that we adopt the Sixth Circuit's reading of *Buckman.* On the contrary, because *Garcia's* conclusions as to preemption depended on its analysis of federal (and not state) law, we must decide for ourselves whether Michigan's surviving common law cause of action is implicitly preempted by federal law under the rationale of *Buckman.* It is to this question that we, therefore, now turn.

II.

[2] In *Buckman,* the Supreme Court considered whether federal law-specifically, the FDCA and the MDA-preempted state "fraud-on-the-FDA" claims. The plaintiffs in *Buckman* contended that a medical device manufacturer had obtained FDA approval for

its product only after making fraudulent misrepresentations to the federal agency. Claiming that the FDA would not have approved the device but for these misrepresentations, the plaintiffs sought damages under California state law. The Court began by stating what is undoubtedly true that "[p]olicing fraud against federal agencies is hardly a field which the States have traditionally occupied." *Buckman*, 531 U.S. at 347, 121 S.Ct. 1012 (internal citation and quotation marks omitted). As a result, the presumption against federal preemption of a state law cause of action did not apply to fraud-on-the-FDA claims. *Id.*

In the absence of any presumption against preemption, the Court found that fraud-on-the-FDA claims conflicted with, and were therefore impliedly preempted by, federal law. "The conflict stems from the fact that the federal statutory scheme amply empowers the FDA to punish and deter fraud against the Administration, and that this authority is used by the Administration to achieve a somewhat delicate balance of statutory objectives." *Id.* at 348, 121 S.Ct. 1012. In other words, *policing fraud on the FDA* through a tort action could interfere with how the FDA might wish to police that kind of fraud itself.

The *Buckman* Court went on to express its concern that the potential conflict between federal law and the competing regulatory regimes of 50 states would unduly burden drug companies seeking to obtain FDA approval for their products. The Supreme Court worried that these companies, fearful of state liability, would file "a deluge of information" that the FDA does not require, thereby burdening the federal agency as well. *Id.* at 351, 121 S.Ct. 1012. But the Court ended by emphasizing that the plaintiffs' claims before it were not rooted in traditional state law, and were instead derivative of federal law:

> In sum, were plaintiffs to maintain their fraud-on-the-agency claims here, they would not be relying on traditional state tort law which had predated the federal enactments in questions. On the contrary, the existence of ... federal enactments is a critical element in their case.

Id. At 353. For these reasons, the Court invalidated the plaintiffs' fraud-on-the-FDA claims as impliedly preempted by federal law.

Echoing the conclusion of the Sixth Circuit, Appellees argue that, notwithstanding *Garcia's* statement that M.C.L. § 2946(5) did not create "a specific cause of action for fraud on the FDA," *Garcia*, 385 F.3d at 966, there is no meaningful difference between the fraud-on-the-FDA claims struck down in *Buckman* and Appellants' claims under Michigan tort law. We disagree. There are three differences between the nature of the claim which M.C.L. § 2946(5) exempts from abolition and the claim in *Buckman*. Given the bases of *Buckman's* holding, each of these is crucial.

A. *Presumption Against Preemption*

***8** First, the presumption against federal preemption of state law obtains in the case before us. In *Medtronic*, the Supreme Court explained that "because the States are independent sovereigns in our federal system, we have long presumed that Congress does not cavalierly pre-empt state-law causes of action." *Medtronic*, 518 U.S. at 485, 116 S.Ct. 2240. In *Buckman*, the Court held that this presumption did not apply *because "[p]olicing fraud against federal agencies is hardly a field which the States have traditionally occupied."* *Buckman*, 531 U.S. at 347, 121 S.Ct. 1012 (internal citation and quotation marks omitted) (emphasis added).

In the case before us, instead, the cause of action (which survives the changes made by M.C.L. § 2946(5)) cannot reasonably be characterized as a state's attempt to police fraud against the FDA. And, significantly, *Garcia* did not so characterize it. Rather, as *Garcia* recognized, M.C.L. § 2946(5) did not invent new causes of action premised on fraud against the FDA. The object of the legislative scheme was rather to regulate and restrict when victims could continue to recover under preexisting state products liability law.[FN5]

The Michigan legislature's desire to rein in state-based tort liability falls squarely within its prerogative to "regulat[e] matters of health and safety," which is a sphere in which the presumption against preemption applies, indeed, stands at its strongest. *See Buckman*, 531 U.S. at 348, 121 S.Ct. 1012 (citing *Medtronic*, 518 U.S. at 485, 116 S.Ct. 2240 as gov-

erning "situations implicating 'federalism concerns and the historic primacy of state regulation of matters of health and safety,' " and contrasting these to the case before it). As a result, while there may be reasons to override that presumption, the existence of the presumption in the instant case requires an altogether different analysis from that made in *Buckman*.[FN6]

B. Traditional Common Law Liability

Second, Appellants here are not pressing "fraud-on-the-FDA" claims, as the plaintiffs in *Buckman* were understood by the Supreme Court to be doing. They are, rather, asserting claims that sound in traditional state tort law. In *Buckman*, the Supreme Court mentioned two characteristics of preempted "fraud-on-the-FDA" claims that distinguish them from claims sounding in preexisting common law.

The *Buckman* Court suggested that the source and "vintage" of the *duty* the drug maker is accused of breaching in "fraud-on-the-FDA" claims is different from the source and "vintage" of the duty that obtains in traditional tort claims. On this basis, the *Buckman* Court distinguished the plaintiff's unpreempted claims in *Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238, 104 S.Ct. 615, 78 L.Ed.2d 443 (1984), from those before it and wrote: "Silkwood's claim was not based on any sort of fraud-on-the-agency theory, but on traditional state tort law principles of the duty of care owed by the producer of plutonium fuel pins to an employee working in its plant." *Buckman*, 531 U.S. at 352, 121 S.Ct. 1012.

***9** Significantly, all of the claims advanced by Appellants in this case are premised on traditional duties between a product manufacturer and Michigan consumers. None of them derives from, or is based on, a newly-concocted duty between a manufacturer and a federal agency. As a result, were we to conclude that Appellants' claims were preempted, we would be holding that Congress, without any explicit expression of intent, should nonetheless be taken to have modified (and, in effect, gutted) traditional state law duties between pharmaceutical companies and their consumers. We see no reason, nor can we identify any precedent, to justify such a result.[FN7]

The second difference between common law actions and "fraud-on-the-FDA" claims, suggested in *Buckman*, is that in FDA-fraud cases, proof of fraud against the FDA is *alone sufficient* to impose liability. In *Buckman*, there were no freestanding allegations of wrongdoing apart from the defendant's purported failure to comply with FDA disclosure requirements. And *Buckman* explicitly distinguished *Medtronic* on this ground. *Medtronic*, the *Buckman* Court said, involved a "common-law negligence action against the manufacturer of an allegedly defective" product:

> [T]he *Medtronic* claims arose from the manufacturer's alleged failure to use reasonable care in the production of the product, not *solely* from the violation of FDCA requirements. In the present case, however, the fraud claims exist *solely* by virtue of the FDCA disclosure requirements. Thus, although *Medtronic* can be read to allow certain state-law causes of actions that parallel federal safety requirements, it does not and cannot stand for the proposition that *any* violation of the FDCA will support a state-law claim.

Buckman, 531 U.S. at 352-53, 121 S.Ct. 1012 (emphasis added) (internal citation omitted).

As in *Medtronic*, the plaintiffs' claims in the case before us "parallel federal safety requirements" but are not premised principally (let alone exclusively) on a drug maker's failure to comply with federal disclosure requirements. On the contrary, the plaintiffs' complaints allege a wide range of putative violations of common law duties long-recognized by Michigan's tort regime. These pre-existing common law claims survive under M.C.L. § 2946(5) because there is also evidence of fraud in FDA disclosures. But, unlike the claims in *Buckman*, they are anything but based *solely* on the wrong of defrauding the FDA. Given *Buckman's* explanation of *Medtronic*, *Buckman* cannot be read as precluding such preexisting common law liability based on other wrongs, even when such liability survives only because there was *also* evidence of fraud against the FDA.

Significantly, this reading of *Buckman* reflects the position the pharmaceutical industry articulated at oral argument in *Buckman*. Thus, the industry's present-

ation to the Supreme Court began by stressing the unusual and narrow claim before the *Buckman* Court:

***10** The plaintiffs in this case are people who underwent back surgery in which particular medical devices were used. They brought this suit under State law to recover for injuries allegedly caused by thereby these devices, but this is a very unusual form of State law product liability action. The plaintiffs don't claim that these devices were in any way defective. There's no claim here of manufacturing defect. There's no claim here of design defect. The plaintiffs also don't claim that the surgeons who used these devices did anything wrong. There's no claim here of medical malpractice.

Instead, the plaintiffs' sole claim in this case is the following. They assert that the Federal Food & Drug Administration was deceived into giving regulatory clearance to these devices, that, absent this deception, these devices would never have been on the market, and that, if the devices had never have been on the market, they wouldn't have been used in their surgeries and they wouldn't have suffered any injuries.

Oral Argument Transcript, *Buckman*, 531 U.S. 341, 346-347, 121 Ct. 1012 (2000) (No. 98-1768).[FN8]

C. Immunity as Affirmative Defense

Third, and once more unlike *Buckman*, the Michigan Supreme Court has indicated that proof of fraud against the FDA is not even an *element* of a products liability claim like the one here brought. The existence of properly-obtained FDA approval becomes germane *only* if a defendant company chooses to assert an affirmative defense made available by the Michigan legislature in M.C.L. § 2946(5). *See Taylor*, 658 N.W.2d at 131. Thus, in *Taylor's* discussion of M.C.L. § 2946(5), Michigan's highest court offered this characterization of the statute: "[A] manufacturer or seller of a drug that has been approved by the FDA has an absolute *defense* to a products liability claim if the drug and its labeling were in compliance with the FDA's approval at the time the drug left the control of the manufacturer or seller." *Id.* (emphasis added). And, throughout its opinion, the *Taylor* court spoke of the *defendant's* references to the *FDA's* findings, suggesting again that it is the defendant that must invoke the FDA's decision to approve its drug if it wishes to insulate itself from liability, *Taylor*, 658 N.W.2d at 134. We take this to mean that the Michigan law in question does no more than create a defense that drug makers may invoke, if they so decide, and that it is not up to the plaintiff to prove fraud as an element of his or her claim.

Finding preemption of traditional common law claims where fraud is not even a required element-but may be submitted to neutralize a drugmaker's use of an affirmative defense available under state law-would result in preemption of a scope that would go far beyond anything that has been applied in the past. Until and unless Congress states explicitly that it intends invalidation of state common law claims merely because issues of fraud may arise in the trial of such claims, we decline to read general statutes like the FDCA and the MDA as having that effect. *See Medtronic*, 518 U.S. at 485, 116 S.Ct. 2240 ("[P]articularly in [circumstances] in which Congress has 'legislated ... in a field which the States have traditionally occupied,' we 'start with 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.' " (internal citations omitted) (emphasis added)).

* * *

***11** The *Buckman* Court did, however, mention practical concerns with allowing "fraud-on-the-FDA" suits to go unpreempted. Specifically, it said that permitting such suits would result in a deluge of information that could swamp FDA administrators. The *Garcia* court, in applying *Buckman* to a suit like the one before us, made reference to these same concerns. But these worries, if deemed controlling, would prove too much. They would result in preemption of a scope that no one is contemplating, let alone advocating.

In terms of deluging the FDA, there is little difference between (a) causes of action, like the instant one, where proof of fraud against the FDA is not the basis of the cause of action but is necessary to negate a limitation on state liability, and (b) causes of action where proof of fraud against the FDA is permitted but not conclusive (as it was under the precursor to

the Michigan law at issue here, *see supra,* and as it presumably is in most states in the country). So long as a court or jury is *allowed to consider* evidence of fraud against the FDA in an ordinary common law tort suit, and so long as juries are likely to react to such evidence, there will be substantial inducements on the pharmaceutical industry to provide the federal agency with just the kind of information that troubled the *Buckman* and *Garcia* Courts. Requiring such evidence when a plaintiff seeks to counter a statutory defense from liability would not significantly alter that incentive. Only when proof of fraud is by itself *sufficient* to impose liability-and indeed is the sole basis of liability (as it was in *Buckman*)-does the incentive to flood the FDA appreciably escalate.

In other words, the incentive to supply additional data to the FDA under the Michigan law before us is no greater than the incentive that exists whenever evidence of what a company submitted, or failed to submit, to the FDA is admissible and probative of liability. It follows that under *Garcia's* reading of *Buckman,* unless a state barred the submission of evidence of fraud against the FDA in run of the mill tort cases, the policy concerns that *Buckman* expressed in a very narrow context would seemingly justify invalidating any product liability suit brought against a drug-maker. We do not believe *Buckman* meant to go anywhere near so far.[FN9]

III.

Because of its important role in state regulation of matters of health and safety, common law liability cannot be easily displaced in our federal system. *Buckman* underscored this fact, finding implied preemption of a newly-fashioned state cause of action only where (1) no presumption against federal preemption obtained, and (2) the cause of action, by assigning liability *solely* on the basis of fraud against the FDA, imposed significant and distinctive burdens on the FDA and the entities it regulates. The appeal before us presents a very different set of circumstances, one in which there is a clear presumption against preemption of long-standing common law claims. In the presence of this presumption, because Michigan law does not in fact implicate the concerns that animated the Supreme Court's decision in *Buckman,* and because Appellants' lawsuits depend primarily on traditional and preexisting tort sources, not at all on a "fraud-on-the-FDA" cause of action created by state law, and only incidentally on evidence of such fraud, we conclude that the Michigan immunity exception is not prohibited through preemption. It follows that common law liability is not foreclosed by federal law, and Appellants' claims should not have been dismissed.

***12** For the foregoing reasons, we VACATE the District Court's grant of judgment on the pleadings, and we REMAND the case to the District Court for further proceedings.

FN1. Michigan's law also states that the immunity "subsection does not apply to a drug that is sold in the United States after the effective date of an order of the United States food and drug administration to remove the drug from the market or to withdraw its approval." M.C.L. § 2946(5). And the immunity "does not apply if the defendant at any time before the event that allegedly caused the injury ... [m]akes an illegal payment to an official or employee of the United States food and drug administration for the purpose of securing or maintaining approval of the drug." M.C.L. § 2946(5)(b).

FN2. Before addressing the preemption issue, Judge Kaplan considered the choice-of-law question for those claims originally filed in California state court and concluded that there was "no serious argument for the application of California substantive law." In fact, the attorney representing those Michigan residents who filed suit in California conceded that he was the only tie his clients had to California. Moreover, Judge Kaplan observed that California's choice-of-law provisions required that the case be governed by the law of Michigan, where the plaintiffs reside and where the alleged injuries took place. None of the parties have challenged this finding on appeal.

FN3. Appellants' arguments against preemp-

tion rely mainly on federal precedent. The only Michigan case they focus on, *Maki v. East Tawas*, 385 Mich. 151, 188 N.W.2d 593 (1971), bears solely on severability, not preemption.

FN4. It should be noted that *Factors*, a case involving Tennessee state law, was decided in 1981. At that time, the Tennessee Supreme Court did not accept certified questions. *See Holt by Holt v. Hypro, a Div. of Lear Siegler, Inc.*, 746 F.2d 353, 354 (6th Cir.1984) ("We[, the Sixth Circuit,] are somewhat puzzled by the [Tennessee] statute as it applies to minors injured by products over ten years old, and we sought to certify the question to the Tennessee Supreme Court. That Court has now advised us that they do not have the judicial power to accept certified questions. We are left to divine the meaning of the Tennessee Legislature on our own."). In fact, it was not until 1989 that Tennessee adopted a certification rule. *See* Tennessee Supreme Court Rule 23 ("The Supreme Court may, at its discretion, answer questions of law certified to it by the Supreme Court of the United States, a Court of Appeals of the United States, a District Court of the United States in Tennessee, or a United States Bankruptcy Court in Tennessee.") (made effective February 17, 1989). It may well be, therefore, that *Factors* would not foreclose us from certifying a question of state law to the relevant state court, even where the pertinent federal court of appeals has provided its interpretation.
We need not, and hence do not, however, decide in this case the significance of *Factors* when certification is available and appropriate. Certification to Michigan is available. *See* Michigan Court Rule 7.305(B)(1) ("When a federal court, state appellate court, or tribal court considers a question that Michigan law may resolve and that is not controlled by Michigan Supreme Court precedent, the court may on its own initiative or that of an interested party certify the question to the Michigan Supreme Court."). But *Garcia's* holding that the state law at issue in this case does not *create* a new cause of action is so clearly correct, both on its face, and in view of the relationship of the current statute to the previous Michigan law (which allowed defendants to introduce evidence of compliance with government standards, *Taylor*, 658 N.W.2d at 130), that certification would not be appropriate. 12

FN5. We also have found no evidence that the goal of preventing or punishing fraud against the FDA in any way motivated Michigan legislators to enact the statutory framework in question. M.C.L. § 2946(5) grew out of Michigan Senate Bill 344; the "Bill Analysis," produced by the state Senate Fiscal Agency, suggests that the main impetus driving the legislation was a desire to limit the liability of drug makers under state tort law. *See generally* S. Fiscal Agency, SFA B. Analysis, Revised Enrolled Analysis, S.B. 344, H.B. 4508, at * 1 (Jan. 11, 1996) ("According to many, over the past several decades there has been an explosion of product liability litigation, resulting in unfair and excessive judgments against manufacturers and sellers.... In Congress and state legislatures, a number of proposals have been advanced to reduce manufacturers' and sellers' exposure to liability.").

FN6. This fact also substantially diminishes the persuasive effect of the federal law analysis made in *Garcia*, since the Sixth Circuit's holding in *Garcia* was based on the assumption that no presumption against preemption applied.

FN7. This may be seen as another way of saying that, unlike the situation in *Buckman*, the presumption against preemption is at its strongest in the instant case.

FN8. Similarly, a second lawyer for the industry indicated that traditional tort remed-

ies were *not* implicated by *Buckman.* When asked about what remedies an injured plaintiff would have under his theory of the case, the attorney responded: "The *fraud* claim is preempted, but if there is negligent design, negligent manufacturing, failure to warn, common law malpractice, all of those claims are available...." *Id.* at 21 (emphasis added). In the case before us, Appellants have asserted precisely "negligent design, negligent manufacturing, [etc.] ..." and claim only that the Michigan exclusion from liability does not apply to their traditional tort law claims because there was *also* fraud on the FDA.

FN9. Since we heard oral argument in this case, the FDA issued a final rule governing the content and format of drug product labeling. *See* 71 Fed.Reg. 3922 (Jan. 24, 2006). In the amended regulation, the FDA announced its view that FDA labeling requirements preempt state law claims that impose additional or different requirements: "[The] FDA believes 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." *Id.* at 3934. In so doing, the FDA apparently confined its view that state claims undermine federal law to circumstances "when [state laws] purport to compel a firm to include in labeling or advertising a statement that [the] FDA has considered and found scientifically unsubstantiated." *Id.* at 3935.

Although any statement by a federal agency carries persuasive weight, the FDA's recent pronouncement does not ultimately affect our analysis in this case. First, the FDA's statement seemingly concerns only preemption of state laws that impose additional *labeling* requirements. Appellants' claims rest on far broader allegations, *e.g.,* defective design and manufacturing.

Second, even to the extent that the FDA's statement might bear peripherally on the claims asserted in this case, it is not clear what, if any, deference would be owed to the FDA's view. Assertions of implied preemption arguably originate in statutory ambiguity as to which an agency's interpretations may be accorded deference. *See generally Chevron U.S.A. Inc. v. Natural Res. Def. Council,* 467 U.S. 837, 104 S.Ct. 2778, 81 L.Ed.2d 694 (1984). And-at least in a field of regulation in which no presumption against preemption applies-we recently indicated that we will give *Chevron* deference to an agency's regulation even though its interpretation has the resultant effect of preempting state law. *See Wachovia Bank, N.A. v. Burke,* 414 F.3d 305, 314-15 (2d Cir.2005).

But, whatever deference would be owed to an agency's view in contexts where a presumption against federal preemption does apply, an agency cannot supply, on Congress's behalf, the clear legislative statement of intent required to overcome the presumption against preemption. *Cf. Alexander v. Sandoval,* 532 U.S. 275, 291, 121 S.Ct. 1511, 149 L.Ed.2d 517 (2001) ("Agencies may play the sorcerer's apprentice but not the sorcerer himself."). Because we find that a presumption against preemption applies in the instant case, we are bound also to conclude that, absent a clear statement from Congress, the common law claims preserved by Michigan's immunity exception cannot be preempted by federal law. Accordingly, an FDA statement to the contrary-even if the one it issued could be treated as such-could not alter our conclusion that Congress did not intend to preempt Appellants' traditional and preexisting common law claims.

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Briefs and Other Related Documents (Back to top)

- 05-1743 (Docket) (Apr. 6, 2005)
- 05-1745 (Docket) (Apr. 6, 2005)
- 05-1705 (Docket) (Apr. 1, 2005)

END OF DOCUMENT

Conclusions of Law

1. The defendant violated the general terms of his probation as set forth above. Specifically, the defendant violated Standard Condition # 3 by not following the instructions of his probation officer and Standard Condition # 5 by failing to find full time employment or make a reasonable effort to do so.

2. The defendant's violations are Grade C violations.

An appropriate Order follows.

ORDER

AND NOW, this 24th day of May, 2006, upon consideration of the Petition for Revocation of Probation, the Government's Proposed Findings of Fact and Conclusions of Law, and after a hearing, it is hereby **ORDERED** as follows:

1. Defendant's probation is **REVOKED.**

2. Defendant is committed to community confinement for a term of ninety (90) days. Defendant shall surrender when notified by the Probation Office that a facility is available for him.

3. No further period of probation is imposed.

Joseph C. COLACICCO, Plaintiff,

v.

APOTEX, INC., et al., Defendants.

Civil Action No. 05–5500.

United States District Court,
E.D. Pennsylvania.

May 25, 2006.

Background: Consumer's husband brought products liability suit against brand-name and generic drug manufacturers based on common law tort principles, alleging that inadequate labeling of prescription drug led to the suicide of consumer. Manufacturers filed motions to dismiss.

Holdings: The District Court, Baylson, J., held that:

(1) Food, Drug and Cosmetic Act (FDCA) impliedly preempted state law failure-to-warn claims;

(2) there was no duty of care owed by a brand-name prescription drug manufacturer to a plaintiff allegedly injured by a generic equivalent drug manufactured by another company;

(3) learned intermediary doctrine did not bar inadequate warning claims; and

(4) *Hahn v. Richter* barred claims not sounding in negligence.

Motions granted.

1. States ⇨18.5

Conflict preemption exists where either (1) the state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress or (2) it is impossible for a party to comply with both state and federal law. U.S.C.A. Const. Art. 6, cl. 2.

2. Administrative Law and Procedure ⇐413, 797

An agency's interpretation of the statute and regulations it administers is entitled to deference; however, in deciding whether to afford it, courts should review the consistency with which the agency has applied the particular interpretation.

3. States ⇐18.11

Preemptive intent of legislation may properly be communicated in amicus briefs, as well as in regulations, preambles, interpretive statements and responses to comments. U.S.C.A. Const. Art. 6, cl. 2.

4. Products Liability ⇐46.2
States ⇐18.65

Prescription labeling provisions of Food, Drug and Cosmetic Act (FDCA) impliedly preempted state law failure-to-warn claims against prescription drug manufacturers; Act's preemption preamble merely clarified existing law and had no prohibited retroactive effect, and preemption preamble was only one of several pieces of evidence which reflected the Food and Drug Administration's (FDA) position that such claims were preempted. U.S.C.A. Const. Art. 6, cl. 2; Federal Food, Drug, and Cosmetic Act, § 301(a, b, k), 21 U.S.C.A. § 331(a, b, k); 21 C.F.R. § 314.150.

5. Administrative Law and Procedure ⇐394

If a rule merely clarifies or explains existing law or regulations, it will be deemed interpretive, and thus exempted from Administrative Procedure Act's (APA) notice and comment requirement. 5 U.S.C.A. § 553(b)(A).

6. Administrative Law and Procedure ⇐394, 417

General statements of policy are excluded from the Administrative Procedure Act's (APA) notice and comment requirements, and lack the force of law. 5 U.S.C.A. § 553(b)(A).

7. Products Liability ⇐46.2

Under Pennsylvania law, there was no duty of care owed by a brand-name prescription drug manufacturer to a plaintiff allegedly injured by a generic equivalent drug manufactured by another company.

8. Products Liability ⇐46.2

Under Pennsylvania law, generic drug manufacturer owed a duty of care to consumer who ingested its drug.

9. Products Liability ⇐46.2

Under Pennsylvania's "learned intermediary" doctrine, a prescription drug manufacturer meets its duty to warn by providing an adequate warning to a "learned intermediary" (usually a physician) as opposed to the public or individual patient-consumers.

10. Products Liability ⇐46.2

Pennsylvania's learned intermediary doctrine did not bar inadequate warning claims against drug manufacturers where complaint alleged that manufacturers failed to provide adequate warnings to patient's treating and/or prescribing physician.

11. Antitrust and Trade Regulation ⇐282
Damages ⇐57.29
Products Liability ⇐46.2
Sales ⇐427

Since claims were all based on prescription drug manufacturers' inadequate warnings, Pennsylvania state law claims against manufacturers for breach of implied warranty, fraud by intentional misrepresentation, intentional infliction of emotional distress, strict products liability, and claim for violation of New York consumer protection law were barred by

Hahn v. Richter, which provided that failure to exercise reasonable care was the only cause of action that could be permitted for claims based on failure-to-warn. N.Y.McKinney's General Business Law § 349.

12. Sales ⇐274

Claim for breach of implied warranty is not available under Pennsylvania law in cases involving prescription drugs.

13. Fraud ⇐3

Elements of fraud by intentional misrepresentation under Pennsylvania law are: (1) a representation; (2) which is material to the transaction at hand; (3) made falsely, with knowledge of its falsity or recklessness as to whether it is true or false; (4) with the intent of misleading another into relying on it; (5) justifiable reliance on the misrepresentation; and, (6) the resulting injury was proximately caused by the reliance.

14. Fraud ⇐16

Under Pennsylvania law, tort of intentional non-disclosure has the same elements as fraud by intentional misrepresentation, except that in the case of an omission, the party intentionally conceals something rather than making an affirmative misrepresentation.

15. Antitrust and Trade Regulation ⇐134

A prima facie case for recovery under New York consumer protection law for "deceptive acts or practices" requires a showing that defendant is engaging in an act or practice that is deceptive or misleading in a material way and that plaintiff has been injured by reason thereof; the allegedly deceptive acts, representations or omissions must be misleading to a reasonable consumer and defendant's acts must be directed at consumers. N.Y.McKinney's General Business Law § 349.

16. Antitrust and Trade Regulation ⇐163

To assert a cause of action under New York law for false advertising, a plaintiff must demonstrate that the advertisement: (1) had an impact on consumers at large; (2) was deceptive or misleading in a material way; and (3) resulted in injury. N.Y.McKinney's General Business Law § 350.

17. Antitrust and Trade Regulation ⇐235

Learned intermediary doctrine precluded failure-to-warn claim against prescription drug manufacturer under New York's consumer protection statute. N.Y.McKinney's General Business Law § 349.

18. Damages ⇐57.27

Where extreme and outrageous conduct that intentionally or recklessly causes severe emotional distress to another is directed at a third person, the actor can only be subject to liability under Pennsylvania law for causing emotional distress to a member of such person's immediate family who is present at the time.

19. Damages ⇐57.29

Prescription drug manufacturers, whose drug labels allegedly failed to warn of increased risk of suicide, could not be held liable to consumer's husband under Pennsylvania law for intentional or negligent infliction of emotion distress where husband did not contemporaneously observe wife's suicide.

20. Negligence ⇐202

Under Pennsylvania law, the elements of negligence are: (1) a duty recognized by law, requiring the actor to conform to a certain standard of conduct for protection of others against unreasonable risks; (2) failure to conform to the standard re-

quired; (3) a causal connection between the conduct and resulting injury; and (4) actual loss or damage resulting to interests of another.

21. Negligence ⇐238, 259

Pennsylvania's doctrine of negligence per se liability does not create an independent basis of tort liability but rather establishes, by reference to a statutory scheme, a standard of care appropriate to the underlying tort.

22. Fraud ⇐13(3)

Under Pennsylvania law, elements of negligent misrepresentation are: (1) a misrepresentation of a material fact; (2) made under circumstances in which the party ought to have known its falsity; (3) with an intent to induce another to act on it, and; (4) which results in injury to a party acting in justifiable reliance on the misrepresentation.

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MEMORANDUM

BAYLSON, District Judge.

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I. Introduction

Presently before this Court are two Motions to Dismiss, pursuant to F.R. Civ. P. 12(b)(6), filed separately by Defendants Apotex, Inc. and Apotex Corp. ("Apotex") and Defendant GlaxoSmithKline ("GSK").

The threshold issue presented by these motions is preemption—whether regulations of a federal agency, promulgated pursuant to a federal statute, and implementing that statute, require the Court to dismiss this pharmaceutical products liability suit based on common law tort principles alleging that inadequate labeling of a prescription drug led to the suicide of Plaintiff's wife.

The answer is "yes"—when Congress passed the Federal Food, Drug and Cosmetic Act ("FDCA"), 21 U.S.C. § 355(a), the law which gives the Food and Drug Administration ("FDA") control over the regulation of the prescription drug industry, it vested the FDA with authority to regulate the specifics of drug labeling, making important judgments of what is required for safety of the consuming public, what new drugs may appear in the marketplace, and what warnings their instructions and labels must carry. The analysis that follows will reveal many conflicting court decisions on this topic. Fundamentally, a series of Supreme Court decisions point this Court in the direction of deference, and require dismissal of this case. Accordingly, both Defendants' motions to dismiss will be granted.

II. Background

A. Procedural Background

Plaintiff Joseph Colacicco ("Plaintiff") filed his original complaint on October 21, 2005, alleging the suicide death of his wife, Lois, resulted from the Defendant drug manufacturers' failure to warn of the increased risk of suicidal behavior linked to the anti-depressant Paxil and/or its generic equivalent. On November 22, 2005, Defendant GSK filed its Motion to Dismiss (Doc. No. 5) ("Def. GSK Mem."). Plaintiff filed a Response (Doc. No. 9) on December 20, 2005, and GSK filed a Reply brief (Doc. No. 11) on December 27, 2005. Defendant Apotex filed a Motion to Dismiss (Doc. No. 10) on December 26, 2005 ("Def. Apotex Mem."), to which Plaintiff responded on

February 7, 2006 (Doc. No. 19). By letter dated March 2, 2006, this Court asked counsel to answer questions that arose from its review of the briefs to date. All parties responded on March 13, 2006.(See Doc. No. 26 by Plaintiff, Doc. No. 27 by Defendant GSK, and Doc. No. 28, by Apotex) ("Supp. Mem."). Oral argument was held on March 17, 2006, at which Plaintiff's counsel withdrew Count I (breach of express warranty). On March 22, 2006, we again asked counsel by letter to answer additional questions that had surfaced, to which counsel responded on March 27, 2006 (See Doc. No. 33 by Apotex, Doc. No. 34 by GSK, and Doc. No. 38 by Plaintiff) ("2nd Supp. Mem."). Plaintiff filed an Amended Complaint on March 24, 2006 (Doc. No. 32), which asserted in Count III (fraud and violation of consumer protection law against GSK only) what had in the original complaint been plead as two counts against both Defendants–Count III (fraud) and Count X (violation of consumer protection law).[1] Both Defendants GSK and Apotex filed a Response to the Amended Complaint and Supplemental Brief in Support of their Motions to Dismiss, on March 31, 2006 (Doc. Nos. 39 and 40, respectively), and Plaintiff filed a memorandum in opposition to the renewed motions to dismiss on April 6, 2006 (Doc. No. 41). ("3rd Supp. Mem."). Then, due to the novel preemption issues presented in this case, the Court requested that the FDA file an *amicus* brief, which it did on May 10, 2006 (Doc. No. 45). *See* Brief for United States as *Amicus Curiae* Supporting Defendants, *Colacicco v. Apotex,* Civ. No. 05–5500, Doc. No. 45 (E.D.Pa. May 10, 2006) ("Colacicco Amicus"). Finally, the parties each submitted a response to the *amicus* brief on May 17, 2006 (Docs. No. 48, 49, 50) ("4th Supp. Mem.").

B. Allegations in the Complaint

According to the Complaint, Plaintiff's wife, Lois Ann Colacicco, complained to her oncologist on October 6, 2003 of mild fatigue and depression. She was prescribed Paxil,[2] an anti-depressant drug manufactured by Defendant GSK. Soon thereafter, she began taking the generic version of the drug, paroxetine hydrochloride, which is a bio-equivalent of Paxil and manufactured by Defendant Apotex.[3] On October 28, 2003, after twenty-two days of ingesting the drug, Lois Colacicco committed suicide in her home.

Paxil is one of a class of drugs known as Selective Serotonin Reuptake Inhibitors ("SSRIs"), which are prescribed for the treatment of depression and anxiety. Plaintiff alleges that despite ample peer-reviewed scientific literature published from the mid–1990s onward linking SSRIs to an increased risk of suicidality, at the time of Plaintiff's decedent's death the FDA—approved label did not warn of an association between Paxil (manufactured by GSK) and/or its generic equivalent (manufactured by Apotex) and suicidality.[4]

1. As Plaintiff's counsel withdrew Count I (breach of express warranty) on the record at the March 17, 2006 oral argument, the Court understands the Amended Complaint to omit that count as well.

2. The medical records do not indicate whether Lois' physician prescribed Paxil or its generic version; however, it is undisputed that she actually took the generic version.

3. The FDA approved Apotex's application to produce the generic form of Paxil on June 30, 2003.

4. The FDA recently retreated from its long-standing position that no linkage existed associating suicidality in adults with SSRI antidepressants, including Paxil. On June 30, 2005, the FDA issued a public health advisory warning of the potential for antidepressant medications to cause suicidal thoughts and behavior in adults. FDA Public Health Advi-

Plaintiff filed suit against both Defendants GSK and Apotex, asserting the liability of either or both based on a failure-to-warn theory. Plaintiff contends the warnings, which were disseminated to doctors and the public by GSK, were inadequate to inform adult users of the risk of suicide associated with the drug. He asserts the labeling was prepared solely by Defendant GSK and copied verbatim by Defendant Apotex, which was required as part of the process to obtain approval from the federal FDA to manufacture the generic version of the drug. Alternately, Plaintiff asserts Defendant Apotex manufactured the drug which caused Lois Colacicco's death, and failed to warn adult users of the risk of suicide posed by the drug.

III. Jurisdiction and Legal Standard

A. Jurisdiction

This Court has diversity jurisdiction over this complaint pursuant to 28 U.S.C. § 1332 because the matter in controversy exceeds $75,000 and is between citizens of different states. Plaintiff is a resident of New York. Defendant GSK is a citizen of Pennsylvania. Defendant Apotex is citizen of Florida and Canada.

Venue is appropriate in this district, pursuant to 28 U.S.C. § 1391 because a substantial part of the events or omissions giving rise to Plaintiff's claims occurred in Pennsylvania or were intended to have consequences in Pennsylvania.

B. Legal Standard

When deciding a motion to dismiss pursuant to F.R. Civ. P. 12(b)(6), the court may grant the motion only if, accepting all well-pleaded allegations in the complaint as true, and viewing them in the light most favorable to plaintiff, the plaintiff is not entitled to relief. *Doug Grant, Inc. v. Greate Bay Casino Corp.*, 232 F.3d 173, 183 (3d Cir.2000). Accordingly, a federal court may dismiss a complaint for failure to state a claim only if it is clear that no relief could be granted under any set of facts that could be proved consistent with the allegations. *Doe v. Delie*, 257 F.3d 309, 313 (3d Cir.2001).

C. Applicable State Law

As a federal court sitting in diversity, *Erie R.R. Co. v. Tompkins*, 304 U.S. 64, 58 S.Ct. 817, 82 L.Ed. 1188 (1938), requires that we apply the substantive law of the forum state. *Id.* at 78–80, 58 S.Ct. 817. Pursuant to a joint stipulation of all parties, Pennsylvania is the appropriate forum state, and thus the law of Pennsylvania will be applied to Counts I–II, and IV–IX, as well as the fraud portion of Count III of Plaintiff's Complaint. *See* Exhibit A, Joint Stip. of the Parties at p. 2 ¶ 1.[5] Count III

sory, *Suicidality in Adults Being Treated with Antidepressant Medications*, June 30, 2005, *available at* http://www.fda.gov/cder/drug/advisory/SSRI200507.htm. The FDA is currently engaged in a comprehensive scientific review of existing studies to determine whether there is an increased risk of suicidal behavior in adults treated with antidepressant drugs. *Colacicco Amicus* at 11. On May 11, 2006, citing the results of a clinical study of nearly 15,000 patients treated with both Paxil and placebos, GlaxoSmithKline warned doctors via a letter that Paxil may raise teen suicide risk. *See* Associated Press, *FDA Warns of Suicide Risk for Paxil*, May 12, 2006, *available at* http://hosted.ap.org/dynamic/stories/P/PAXIL_SUICIDE_RISK?_SITE=COBOU & SECTION=HOME & TEMPLATE=DEFAULT.

5. Given that Plaintiff's decedent's prescription was prescribed and filled in New York, and she ingested it there, this Court asked counsel by letter dated March 2, 2006 to identify any possible conflict of law issues. The stipulation, which arose as a response to this letter, states that with regard to Counts I through IX, "the law of New York and the law of Pennsylvania are not in conflict, and thus, the laws of Pennsylvania should be applied there-

also asserts a violation of the New York Consumer Protection law, to which New York law applies.

IV. Contentions of the Parties

A. Defendants

Both Defendants GSK and Apotex contend Plaintiff's entire complaint must be dismissed, because (1) it is impliedly preempted by federal law, (2) Defendants do not owe the Plaintiff a duty of care, (3) the learned intermediary doctrine applies, and (4) *Hahn v. Richter,* 543 Pa. 558, 673 A.2d 888, 891 (1996), precludes all Plaintiff's claims except those against the seller that sound in negligence.

Speaking to the threshold issue of preemption, Defendants urge that allowing Plaintiff's case to proceed would thwart the purpose of, and thus actually conflict with, the FDCA, and also that this Court must afford deference to the FDA's position that its regulations preempt state tort claims. Regarding a duty of care, GSK decrees that as an innovator drug manufacturer, it does not owe a legal duty to a consumer of the generic equivalent of its drug. Apotex asserts that pursuant to the statute governing FDA approval of generic drugs, it was not responsible for the form or content of the paroxetine hydrochloride labeling, and therefore it too did not owe a duty of care to Plaintiff. Third, Defendants urge that the learned intermediary doctrine applies to bar Plaintiff's complaint because adequacy is a question of law and the FDA's grant of original approval presumptively shows that the warnings were adequate. Finally, Defendants argue that *Hahn,* which held that "where the adequacy of warnings associated with prescription drugs is at issue, . . . the manufacturer's negligence is the only recognized basis of liability," precludes all Plaintiff's claims except those that sound in negligence. 673 A.2d at 891.

Defendants also advance several arguments for dismissal with regards to Plaintiff's individual causes of action. First, Defendant Apotex contends that a claim for breach of implied warranty (Count II) is not available in cases involving prescription drugs under Pennsylvania law. Next, Defendant GSK argues that Count III (fraud and violation of New York consumer protection statute), which is advanced only against it, fails because: (1) the fraud portion lacks the required particularity under F.R. Civ. P. 9(b), and (2) the consumer protection portion is alleged under the wrong statutory section, does not plead reliance, and is inconsistent with the learned intermediary doctrine. Third, both Defendants assert that Plaintiff's infliction of emotional distress counts (Counts V and VI) fail because the alleged wrongful conduct visited upon his wife did not occur in Plaintiff's presence. Next, Apotex urges Plaintiff's negligence claim (Count VII) must be dismissed because Plaintiff cannot show the existence of a duty and the negligence *per se* claim (Count VIII) is impliedly preempted. Last, as to the negligent misrepresentation claim (Count IX), Apotex urges that since it made no statements regarding the efficacy and safety of paroxetine hydrochloride to the FDA, Plaintiff cannot show the required element that Apotex knew or should have known that any such representations were false.

B. Plaintiff

Plaintiff argues that preemption is inappropriate for several reasons, including that: (1) the FDCA merely establishes minimum standards and permits manufacturers to unilaterally strengthen warning labels, and (2) deference is unsuitable be-

to." Exhibit A, Joint Stip. of the Parties at p. 2.

cause the FDA's policy has been inconsistent, and would violate the principle forbidding retroactive application of new rules. Next, Plaintiff urges that pursuant to Pennsylvania's nuanced duty of care analysis, the Court should find that Defendant GSK owed him a duty of care. As to Apotex, Plaintiff asserts that Apotex, like all product manufacturers, cannot escape the duty it owes to its consumers. Further, Plaintiff contends that the learned intermediary doctrine requires an analysis of the adequacy of the warnings, which is a question of fact that cannot be determined at the 12(b)(6) stage. Finally, regarding *Hahn,* Plaintiff asserts that a broad reading is improper; *Hahn* is better understood to have a narrower holding.

As to the individual counts, Plaintiff argues his implied warranty claim is viable, attempting to distinguish the case cited by Apotex. He also cites to numerous specific allegations in his complaint supporting the fraud claim, and argues GSK's prolific, deceptive, "direct-to-consumer" advertising sufficiently supports his consumer protection claim. Next, Plaintiff contends that as to the infliction of emotion distress counts, it is sufficient that he observed the *result* of the alleged intentionally outrageous or negligent conduct. Advancing the same arguments as it did earlier, Plaintiff asserts he has shown a duty of care sufficient to underlie the negligence count, and that preemption is inapplicable to the negligence *per se* claim. Finally, Plaintiff maintains that at the 12(b)(6) stage, the Court must accept his averments that material submitted to the FDA and the labeling itself was intentionally false and misleading.

V. Federal Regulatory Process: Process to Obtain Approval from the FDA to Market and Sell Prescription Drugs

Analysis of the parties' arguments requires some understanding of the process for approval to market and sell generic drugs. The FDCA mandates that drugs are "safe and effective." 21 U.S.C. § 355(a). Therefore, pharmaceutical manufacturers must obtain regulatory approval for prescription drugs prior to marketing them. *Id.* For drugs that have not been marketed before, the process for approval requires submission of a new drug application ("NDA"). 21 U.S.C. § 355(a)-(i). The NDA must contain proof of the efficacy and safety of the drug, based on extensive laboratory testing. 21 U.S.C. § 355(b). Further, the FDCA requires refusal of any NDA that includes labeling that "is false or misleading in any particular." 21 U.S.C. § 355(d) (grounds for refusing new drug application). The obligation against misbranding drugs continues thereafter. 21 U.S.C. § 331(a), (b), (k). Under the FDCA, a drug is unlawfully misbranded when its labeling is false or misleading, or does not provide adequate directions for use or adequate warnings against any use dangerous to health. *Colacicco Amicus* at 4; 21 U.S.C. § 352.

Before 1984, generic drug manufacturers were required to submit their own NDA. *Foster v. American Home Products,* 29 F.3d 165 (4th Cir.1994) (applying Maryland law); *Tri-Bio Labs., Inc. v. United States,* 836 F.2d 135, 138–39 (3d Cir.1987). Because investigations conducted by the innovator companies were considered trade secrets, generic manufacturers were required to perform their own safety and effectiveness studies. This resulted in additional expenses being passed to consumers, and delay in bringing generic drugs to the market. *Id.*

The Drug Price Competition and Patent Term Restoration Act of 1984, also known as the Hatch–Waxman Amendments ("H–W Amendments") to the FDCA, Pub.L.

No. 98–417, 98 Stat. 1585 (codified at 21 U.S.C. § 355(j), 35 U.S.C. §§ 156, 271, 281), relaxed the procedure for obtaining approval from the FDA to market and sell a generic drug, allowing the generic maker to submit an abbreviated NDA ("ANDA"). *Id.*[6] The ANDA applicant need only certify that the generic manufacturer will produce a bio-equivalent of the brand name drug and that the labeling and warnings of the generic drug are identical to that of the approved innovator drug. 21 U.S.C. § 355(j)(2)(A).

After approval, a manufacturer may "add or strengthen a contraindication, warning, precaution, or adverse reaction" or "delete false, misleading, or unsupported indications for use or claims for effectiveness." 21 C.F.R. § 314.70(c)(6)(iii)(A), (D). However, in its *amicus* brief submitted to the Court in connection with this case, the FDA explained that "a generic drug manufacturer is not permitted to add a warning or caution to the label without prior approval from the FDA." *Colacicco Amicus* at 17. This is to assure that any changes to the label would not be "false or misleading," and thus misbrand the drug.

VI. Preemption Issues

In their briefs and at oral argument, both Defendants contended that Plaintiff's claims are preempted by the federal FDCA, urging that: (1) Plaintiff's claims are impliedly preempted under general preemption principles, and (2) the Supreme Court's holding in *Buckman Co. v. Plaintiffs' Legal Committee,* 531 U.S. 341, 121 S.Ct. 1012, 148 L.Ed.2d 854 (2000) requires that we find preemption. Further, in response to this Court's request that the FDA file a brief on the novel preemption issues presented in this case, the government submitted an *amicus* brief to the Court on May 10, 2006 which also takes the position that Plaintiff's state law claims are barred by implied preemption.

A. Implied Preemption

Pursuant to the Supremacy Clause, any state law conflicting with the exercise of enumerated federal power is preempted. U.S. Const. art. VI, cl. 2. The United States Supreme Court has long recognized that federal preemption of state law can occur in three types of situations: (1) where Congress explicitly preempts state law ("express preemption"), (2) where preemption is implied because Congress has occupied the entire field ("field preemption"), and (3) where preemption is implied because there is an actual conflict between federal and state law ("conflict preemption"). *Schneidewind v. ANR Pipeline Co.,* 485 U.S. 293, 299–300, 108 S.Ct. 1145, 99 L.Ed.2d 316 (1988); *Pokorny v. Ford Motor Co.,* 902 F.2d 1116, 1121–22 (3d Cir.1990).

[1] Defendants concede that express and field preemption are not implicated, Def. Apotex's Mem. at 9, pursuing only the "conflict" preemption argument. Such a conflict exists where either (1) the state law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress" or (2) it is "impossible for a ... party to comply with both state and federal law." *Geier v. Am. Honda Motor Co., Inc.,* 529 U.S. 861, 899, 120 S.Ct. 1913, 146 L.Ed.2d 914 (2000); *Pokorny,* 902 F.2d at 1120; *C.E.R. 1988, Inc. v. Aetna Cas. & Sur. Co.,* 386 F.3d 263, 268 (3d Cir.2004).

6. The purpose of the H–W Amendments is "to balance the interests of the generic drug manufacturers, who sought to avoid unnecessary testing, against the research investments of the innovator manufacturers, at the same time mindful of the public need for safe commercial drugs." *Tri–Bio Labs.,* 836 F.2d at 139.

Geier is the most recent in a consistent, long line of cases that articulate the Supreme Court's principles on implied preemption. In that case, an injured motorist and her parents brought a defective design claim against an automobile manufacturer based on a lack of an automobile airbag in their 1987 Honda Accord. *Geier,* 529 U.S. at 865, 120 S.Ct. 1913. After concluding that the National Traffic and Motor Vehicle Safety Act of 1966 did not expressly preempt petitioners' claims, the Court held that the claims nonetheless actually conflicted with the objectives of Federal Motor Vehicle Safety Standard 208 ("Standard 208") which gave automobile manufacturers a range of choices among different passive restraint devices which were to be gradually introduced over time. The Court reasoned that plaintiff's claims depended upon the manufacturer having a duty to install an airbag in all 1987 vehicles, which presented an obstacle to the variety and mix of devices that Standard 208 sought. *Id.* at 881, 120 S.Ct. 1913. Therefore, because the Supremacy Clause "forbids conflicts that make it impossible for private parties to comply with both state and federal law," the Court concluded that plaintiff's claims were impliedly preempted. *Id.* at 873, 875, 886, 120 S.Ct. 1913.

Despite the generality of the definition of conflict preemption, the Supreme Court has urged caution in its application: "[B]ecause the States are independent sovereigns in our federal system, we have long presumed that Congress does not cavalierly preempt state-law causes of action." *C.E.R.1988,* 386 F.3d at 269–70 (quoting *Medtronic Inc. v. Lohr,* 518 U.S. 470, 485, 116 S.Ct. 2240, 135 L.Ed.2d 700 (1996) (case involving express preemption)). Thus, conflict preemption will be found only if the need for it is clear. *Pokorny,* 902 F.2d at 1122. In fact, "consideration under the Supremacy Clause starts with the basic assumption that Congress did not intend to displace state law." *Bldg. & Constr. Trades Council of Metro. Dist. v. Assoc. Builders & Contractors of Mass. /R.I., Inc.,* 507 U.S. 218, 224, 113 S.Ct. 1190, 122 L.Ed.2d 565 (1993).

In contending that Plaintiff's claims are impliedly preempted by federal law, Defendants principally assert that assigning state tort liability would thwart the purpose of—and thus actually conflict with—the Hatch–Waxman Amendments.[7] Further, Defendants argue that under clearly established caselaw, this Court must afford deference to the FDA's position that its regulations preempt state tort claims for inadequate warnings, which it has articulated in several *amicus* briefs and in the preamble to new drug labeling regulations issued in 2006. *See* Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed.Reg. 3922–97 (Jan. 24, 2006) (effective date June 30, 2006) (to be codified at 21 C.F.R. pts. 201, 314, 601) (hereinafter, "Preemption Preamble" to the "Final Rule") (Def. Apotex Mem. at 9–15; Def. GSK Mem. at 9; Apotex Supp. Mem. at 18–24; GSK Supp. at 10–18; Apotex 2nd Supp. Mem. at 2–10; GSK 2nd Supp. Mem. 1–5).

In its *amicus* brief to this Court, the FDA goes even further, asserting that because prior to October 2003, the agency had repeatedly determined that there was inadequate evidence of an association between adult use of SSRIs and suicidality, Plaintiffs' state law failure-to-warn claims are preempted because such a warning statement would actually have been "false and misleading," and thus contrary to fed-

7. See *supra* Part V for an in depth discussion of the Hatch–Waxman Amendments.

eral law. *Colacicco Amicus,* at 1. We address these arguments in turn.

1. Deference to the FDA's Position that Plaintiff's Claims are Preempted

The Defendants and the FDA point to several pieces of evidence which reflect the FDA's position that Plaintiff's inadequate warning claims are preempted: (1) the May 10, 2006 *amicus* brief filed in this case representing that the FDA would consider such a warning false and misleading (as well as two prior *amicus* briefs filed in other cases by the FDA in 2005 and 2002, respectively, indicating the same), (2) the 2006 Preemption Preamble, an official agency statement purporting to establish preemption of conflicting state law claims.

[2] The FDA's view is critical to this Court's analysis because Supreme Court precedent dictates that an agency's interpretation of the statute and regulations it administers is entitled to deference. *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.,* 467 U.S. 837, 844, 104 S.Ct. 2778, 81 L.Ed.2d 694 (1984) (holding that it has been "long recognized that considerable weight should be accorded to an executive department's construction of a statutory scheme it is entrusted to administer"). *See also Thomas Jefferson Univ. Hosp. v. Shalala,* 512 U.S. 504, 512, 114 S.Ct. 2381, 129 L.Ed.2d 405 (1994); *NVE Inc. v. Dept. of Health & Human Servs.,* 436 F.3d 182, 186 (3d Cir.2006); *C.E.R. 1988,* 386 F.3d at 271 n. 11. However, deference is not absolute; in deciding whether to afford it, courts should review *inter alia* the consistency with which the agency has applied the particular interpretation. *NLRB v. N.J. Bell Tel. Co.,* 936 F.2d 144, 147 (3d Cir.1991) (citing *West v. Bowen,* 879 F.2d 1122, 1134 (3d Cir.1989)).

In the context of preemption specifically, the Supreme Court held in 1985 that in the absence of clearly expressed Congressional intent or subsequent developments that reveal a change in that position, the FDA's position on the preemptive scope of its regulatory authority "is dispositive." *Hillsborough County v. Automated Med. Labs. Inc.,* 471 U.S. 707, 714, 105 S.Ct. 2371, 85 L.Ed.2d 714 (1985).

[3] Further, the Court has made clear that such preemptive intent may properly be communicated in *amicus* briefs, *Geier,* 529 U.S. at 883, 120 S.Ct. 1913, as well as in "regulations, preambles, interpretive statements and responses to comments." *Hillsborough County,* 471 U.S. at 718, 105 S.Ct. 2371. In recent years, each time the Supreme Court has confronted the question of whether the FDCA preempts state law, it has deferred to the FDA's preemption position.[8] *See Geier,* 529 U.S. at 883, 120 S.Ct. 1913 (noting that the Court "place[s] some weight upon [the federal agency's interpretation of the regulation's] objectives and its conclusion ... that a tort suit ... would stand as an obstacle to the accomplishment and execution of those objectives"); *Medtronic,* 518 U.S. at 496, 116 S.Ct. 2240 (holding that state law claims involving FDCA section 510(k) medical devices, which are subjected to a relatively cursory approval process, were not preempted because the FDA had taken the position that its regulations only preempted claims involving section 360e(c) devises, which go through a rigorous pre-market approval process); *Buckman,* 531 U.S. at 353, 121 S.Ct. 1012 (in which the Court's holding that the FDCA, as amended by

8. For a history of how the Supreme Court has responded to the FDA's position on preemption, *see* Eric G. Lasker, *How Will FDA's New Label Rule Impact Drug Litigation?,* 9 No. 10 Andrews Drug Recall Litig. Rep. 9, at 2 (Mar. 13, 2006).

the Medical Devices Amendment ("MDA"), impliedly preempted patients' state law "fraud-on-the-agency" claims mirrored the position taken by the FDA in its *amicus* brief submitted to the court [9]).

[4] The Third Circuit has not rendered an opinion as to the level of deference that should be afforded to the FDA's position on whether the FDCA impliedly preempts state failure-to-warn claims. However, the Third Circuit considered whether to defer to the FDA's position on express preemption in the 2004 case *Horn v. Thoratec Corp.*, 376 F.3d 163, 171 (3d Cir.2004). *Horn* held that the plaintiff's state law claims against a heart valve manufacturer were preempted by the express preemption provision of the MDA. *Id.* at 180. In coming to this conclusion, the court stated that the Supreme Court's decision in *Medtronic* required it to afford deference to the FDA's position that the claims were preempted. *Id.* at 179. Moreover, it held that this was the case even though this stance was a change from the FDA's prior position. *Id.* (noting "we cannot agree [with Plaintiff] that the FDA's position is entitled to no deference or 'near indifference' simply because it represents a departure from its prior position."). The court noted that the Supreme Court in *Chevron* held that a "revised interpretation by an agency is [still] entitled to deference because an initial agency interpretation is not instantly carved in stone," *Id.* (citing *Chevron*, 467 U.S. at 863–64, 104 S.Ct. 2778), and that an agency may change its position "so long as it can justify its change with reasoned analysis." *Id.* (citing *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 42, 103 S.Ct. 2856, 77 L.Ed.2d 443 (1983)). *Horn* held that it was "fully persuaded" that the FDA adequately justified its change in position on preemption. *Id.* Importantly, while the facts of *Horn* involved the express preemption provision of the MDA, to which there is no corollary part in the prescription labeling provisions of the FDCA, the *Horn* court broadly announced a policy of affording deference to the FDA's position on preemption, and did not narrow the holding only to cases involving express preemption.

a. The Government's Amicus Briefs

In the *amicus* brief submitted to this Court, the FDA re-affirmed its view that Plaintiff's claims are preempted. *Colacicco Amicus* at 1, 13, 15. Explaining this position, the FDA noted that the FDCA prohibits the misbranding of drugs. 21 U.S.C. § 331(a), (b), (k). As explained above, under the FDCA, a drug is unlawfully misbranded when its labeling is false or misleading, or does not provide adequate directions for use or adequate warnings against any use dangerous to health. *Colacicco Amicus* at 4. Therefore, to the extent that before and up to October 2003,[10] the date of Plaintiff's decedent's

9. *See* Brief for United States as *Amicus Curiae*, *Buckman Co. v. Plaintiffs' Legal Comm.*, Civ. No. 98–1768, 531 U.S. 341, 121 S.Ct. 1012, 148 L.Ed.2d 854 (2001) (available at 2001 WL 167647).

10. The brief, accompanied by a lengthy appendix, outlines how on no less than six occasions between July 1991 and October 2003, the FDA rejected proposals seeking changes in drug labeling regarding suicide for SSRIs. In briefs responding to the *Colacicco Amicus*, Defendants argued that the Court may consider this information without converting the 12(b)(6) into a motion for summary judgment. (Def. Apotex 4th Supp. Mem at 3–8; Def. GSK 4th Supp. Mem at 5–8). Although the information about the FDA rejecting proposals seeking changes in drug labeling is evidence outside the record, a court may properly take judicial notice of public records and consider them in a 12(b)(6) motion. *Pension Benefit Guaranty Corp. v. White Consol. Indus. Inc.*, 998 F.2d 1192, 1197 (3d Cir.1993). However, *how* the FDA came to its conclusion

death, the FDA specifically and repeatedly rejected claims that adult use of SSRI's was associated with increased suicidality because there was no reasonable evidence to support the linkage, the FDA contends that any such warning would have been false or misleading, and contrary to the public interest. For this reason, the FDA asserts that Plaintiff Colacicco's failure-to-warn claims are preempted by federal law. *Id.* at 17.

Moreover, the FDA explained that public policy requires that warnings be scientifically substantiated. Dissemination of unsupported warnings, the FDA urged, would deprive patients of efficacious treatment, thereby chilling the drug's otherwise beneficial use. *Id.* at 13. The FDA also flatly rejected the often-cited proposition by many courts refusing to apply preemption in prescription drug cases that 21 C.F.R. § 314.70(c) permits drug makers to unilaterally strengthen a warning label without FDA approval. *Id.* at 6, 17. Instead, it decreed that despite what numerous lower courts [11] around the nation have stated, a "*drug manufacturer is not permitted to add a warning or caution to the label without prior approval from the FDA.*" *Id.* at 17 (emphasis added).

This position is consistent with the view taken in two prior *amicus* briefs prepared by the FDA in other failure-to-warn cases. *See* Brief for United States as *Amicus Curiae* Supporting Defendant, *Kallas v. Pfizer, Inc.*, Civ. No. 2:04–cv–0998, 34, 37–38 (D.Utah Sept. 15, 2005) (FDA amicus brief arguing that plaintiff's failure-to-warn claims were preempted because the FDA lacked reasonable evidence of an association between SSRIs and suicidality in children in November 2002; thus, the proposed warning would have misbranded Zoloft, the SSRI at issue) ("*Kallas Amicus*"); Brief for United States as *Amicus Curiae* Supporting Defendant, *Motus v. Pfizer, Inc.*, Civ. Nos. 02–cv–55372, 02–cv–55498, (9th Cir. Sept.10, 2002), 2002 WL 32303084, at *16 (amicus brief submitted by FDA contending plaintiff's failure-to-warn case was preempted because, before plaintiff's decedent's death in 1998, the FDA had considered, and rejected, claims that SSRIs were linked to suicidal behavior in adults, and any warning label would have been "false or misleading" and would therefore have misbranded Zoloft, the SSRI at issue) ("*Motus Amicus*").[12] *See also* Lori J. Parker, *Proof of Injury Resulting from Antidepressant Medication*, 87 Am.Jur. Proof of Facts 3d 119, § 3 (2006).

is far less relevant than the fact that the FDA *did* conclude Plaintiff's claims are preempted. It is the latter to which we give deference, and therefore these extra-record factual allegations are not determinative to our conclusion.

11. *See, e.g., McNellis v. Pfizer, Inc.*, Civ. No. 05–1286, 14 (D.N.J. Dec. 29, 2005); *Witczak v. Pfizer*, 377 F.Supp.2d 726, 729 (D.Minn. 2005); *Zikis v. Pfizer, Inc.*, Civ. No. 04–8104, 6 (N.D.Ill. May 9, 2005); *Cartwright v. Pfizer*, 369 F.Supp.2d 876, 882 (E.D.Tex.2005). These case are discussed below at pages 32–34. However, neither the Supreme Court nor the Third Circuit has spoken on this issue.

12. Notably, while the FDA filed *amicus* briefs in both cases, neither *Kallas* nor *Motus* resulted in a judicial decision as to preemption. The *Kallas* case settled before the District of Utah rendered a decision. *Kallas v. Pfizer, Inc.*, Civ. No. 2:04–cv–0998 (D.Utah Oct. 24, 2005) (order granting stipulated motion to dismiss pursuant to settlement). In *Motus*, while the Ninth Circuit rendered a decision affirming summary judgment in favor of defendant, it did so based on lack of causation, declining to reach the issue of preemption. *Motus v. Pfizer, Inc.*, 358 F.3d 659, 660 (9th Cir.2004) (because plaintiff failed to establish a sufficient causal link between her husband's suicide and the drug manufacturer's conduct, "we need not reach the preemption issues raised by [defendant]").

According to the FDA, therefore, it is clear that any insert in October 2003 associating use of paroxetine hydrochloride with suicidality would have constituted misbranding, because it was contrary to the scientific evidence, and thus "false and misleading." Pursuant to the principles announced in the Supreme Court's decisions in *Chevron*, *Medtronic*, *Geier* and their progeny, as well as the Third Circuit's broad holding in *Horn*, it is therefore appropriate to afford deference to the FDA's position based on the *Colacicco Amicus* alone.

However, in his response to the *Colacicco Amicus*, Plaintiff argues that we ought not pay the *amicus* any deference because (1) the FDA glosses over the importance of 21 C.F.R. § 314.70, which it argues allows manufacturers to strengthen labels without prior FDA approval—and which almost every court that has heretofore rejected preemption has cited, and (2) the FDA has no authority to simply declare that a drug is misbranded, and, at any rate, such opinion is merely hypothetical, as at no time prior to Plaintiff's decedent's death did either Defendant request a stronger warning. (Pl.'s 4th Supp. Mem. at 3 n. 3, 5, 8–10).

We disagree. As to the Plaintiff's first objection, Plaintiff notes that the plain language of § 314.70 states that the holder of an approved application may make changes in the labeling to "add or strengthen a contraindication, warning, precaution, or adverse reaction," and may "*commence distribution of the drug product involved upon receipt by the agency* of a supplement for the change." 21 C.F.R. § 314.70(c)(6)(iii)(A). He thus contends the provision's plain language explicitly permits manufacturers to strengthen labels *without* prior FDA approval. (Pl.'s 4th Supp. Mem. at 3 n. 3). However, 21 C.F.R. § 314.150, cited by the FDA in its *amicus* brief and by Defendant Apotex, directly supports the FDA's position that generic drug makers *can not* unilaterally strengthen their drug. 21 C.F.R. § 314.150 states that the FDA will withdraw approval of a generic maker's ANDA if the label ceases to be identical to that of the name-brand drug. Interpreting § 314.150, the FDA explained, "[i]f an ANDA applicant believes new safety information should be added to a product's labeling, it should contact FDA, and FDA will determine whether the labeling for the generic and listed drugs should be revised. After approval of an ANDA, if an ANDA holder believes that new safety information should be added, it should provide adequate supporting information to FDA, and FDA will determine whether the labeling for the generic and listed drugs should be revised." 57 Fed.Reg. at 17961. Moreover, despite the plain language of § 314.70, and even if the FDA's position were not bolstered by 21 C.F.R. § 314.150, this Court believes that principles of deference do not allow us to question the FDA's interpretation of its own regulations—e.g. that generic drug manufacturers can not make changes without prior approval.

As to the second assertion, Plaintiff argues that the FDA must prosecute an enforcement action to establish a drug is misbranded, citing 21 U.S.C. §§ 331–37, 352. However, these sections merely discuss the requirements of an enforcement or injunctive action if one is brought; no where does the statute declare that the FDA must bring a prosecution to state an *opinion* as to whether a particular drug would have been misbranded if a certain warning had been attached. Further, it is not in dispute that the FDA's position is a hypothetical. In fact, it is in part *because* neither Defendant requested a stronger warning that the vacuum of information was created that necessitated this Court asking the FDA to render an opinion as to