**UNITED STATES DISTRICT COURT**
**DISTRICT OF MINNESOTA**

Kimberly Kay Witczak, Surviving Spouse and Trustee for the Next of Kin of Timothy Michael Witczak,

Plaintiff,

vs.

Pfizer, Inc.,

Defendant.

Civil File No. 04-CV-2819-JMR-FLN

# MEMORANDUM OF AMICUS CURIAE STATE OF MINNESOTA IN OPPOSITION TO DEFENDANT PFIZER, INC.'S MOTION FOR SUMMARY JUDGMENT (PREEMPTION)

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## INTRODUCTION

Amicus curiae State of Minnesota ("State") submits this Memorandum in opposition to the motion of Defendant Pfizer, Inc. ("Pfizer") for summary judgment on federal preemption grounds. The Court should deny Pfizer's motion because it is based upon a flawed analysis of the federal preemption doctrine that does not properly account for important federalism principles. Neither the federal Food, Drug and Cosmetic Act ("FDCA"), 21 U.S.C. §§ 301-399 (2002), nor certain statements or litigation amicus curiae briefs of the FDA, preempt the type of state common law product liability tort claims against a prescription drug manufacturer that are asserted in the Plaintiff's Complaint against Pfizer.[1]

## STATE'S INTERESTS IN THIS MOTION

The State has several interests in the federal preemption issue raised by Pfizer's summary judgment motion. First, the State wants to ensure that the Court is made aware of the important federalism principles underlying the strong presumption against federal preemption. States have a compelling interest in the potential erosion of their sovereignty by the unwarranted application of federal preemption. The State seeks to prevent the inappropriate recognition of a federal preemption defense in cases such as this one that can only contribute to such an erosion of states' rights in yet other areas of traditional state concern. In addition, the State has a strong general interest in protecting the legal rights of its citizens, like the Plaintiff here, and to ensure that the Plaintiff and the State's other citizens are not precluded, on the grounds of an alleged and legally

[1] The State has generally limited this amicus brief to a discussion of the legal framework for analyzing alleged federal preemption defenses and the legal arguments in opposition to Pfizer's federal preemption claim based on the FDCA and certain FDA statements. The Plaintiff has already presented the Court with more detailed factual information regarding Zoloft and the FDA's historical consideration of the labeling and warnings for this drug and other similar antidepressant drugs.

improper federal preemption defense, from being able to seek redress for their injuries caused by the tortious conduct of others.

On a more specific level, the State has a direct interest in the resolution of the federal preemption issue here in that the State has potential claims against drug companies, including Pfizer, relating to the sale of prescription drugs. The State is a very large purchaser of prescription drugs because of the various prescription drug benefit and insurance programs the State funds and administers,[2] and often litigates monetary claims against the drug industry to recoup the costs of some of these drugs. Any such claims could be adversely affected by a preemption finding in this case.[3] The State may also have potential claims in some circumstances to recover the money it has paid through various benefit programs, such as Medicaid, and through various State-funded employee and retiree health insurance programs, to treat Minnesota citizens injured by various prescription drugs.[4] These potential State claims could also be adversely affected by a preemption finding in this case.

## ARGUMENT

The following Argument is divided into five parts. The first part discusses the federal preemption doctrine and the appropriate legal framework for evaluating federal preemption defenses of the sort Pfizer has asserted here. The second and third parts respectively discuss why

[2] For example, the State currently pays close to a billion dollars every year for prescription drugs just for its Medicaid fee-for-service program recipients.

[3] For example, the State could have potential common law and consumer fraud claims to recoup the money it paid for purchasing certain prescription drugs based on an argument that the drug company manufacturers lied about the efficacy and side effects of these drugs.

[4] Such potential claims involving prescription drug injuries could be similar to the claims the State successfully prosecuted to recover the costs its Medicaid program incurred to treat those harmed by tobacco products. *See State of Minnesota v. Philip Morris*, No. C1-94-8565 (Ramsey Cty. Dist. Ct.).

the FDCA does not expressly or impliedly preempt the Plaintiff's state law tort claims. The fourth part discusses why the FDA's statements and opinions relied upon by Pfizer also do not constitute grounds for federal preemption of the Plaintiff's claims. Finally, the fifth part discusses and summarizes why the Court should not recognize a new, and largely unprecedented, federal preemption defense to state common law product liability claims involving prescription drugs and why the Court should resolve all doubts about any such preemption defense here in favor of the Plaintiff and reject a defense such as this that would directly frustrate the public safety goal embodied in the FDCA.

## I. FEDERAL PREEMPTION DOCTRINE.

This part discusses core federal preemption doctrine principles, including the source of federal preemption, the types of federal preemption, and the historic and strong presumption against preemption of state laws, including, especially, the type of common law tort claims involved in this case.

### A. Source of Federal Preemption.

There is no agreement over the exact constitutional source of the federal preemption doctrine. *See* Richard C. Ausness, *Preemption of State Tort Law by Federal Safety Statutes: Supreme Court Preemption Jurisprudence Since Cippolone*, 92 Ky. L. J. 913, 914 (2003-04). Many courts and legal commentators believe that the federal preemption doctrine is based upon the Supremacy Clause of the U.S. Constitution, art. VI, cl. 2, which declares that the laws of the United States shall be the supreme law of the land. *Id.* & n.31-32.[5] Some legal commentators,

[5] *See also Chicago & N.W. Transp. Co. v. Kalo Brick & Tile Co.*, 450 U.S. 311, 317 (1981) (underlying rationale of the preemption doctrine is found in the Supremacy Clause). This Court
(footnote continued next page)

on the other hand, believe that the Supremacy Clause operates more like a "choice of law" provision that relates only to the supremacy of federal law that is in direct conflict with state law. *Id.* & n.36. Still other commentators believe that the doctrine is actually derived from other sources, such as Congress' enumerated powers in the Commerce or the Necessary and Proper Clauses of the federal Constitution. *Id.* & n.37 & 39. Ultimately, the precise basis for this doctrine is not critical here, given that the Plaintiff's state law tort claims are not preempted under any recognized basis for, or type of, federal preemption.

**B. Types of Federal Preemption.**

As this Court is well aware from its prior federal preemption rulings, there are several generally recognized categories of federal preemption, including: (1) express preemption; (2) implied conflict preemption; and (3) implied field preemption.[6] Implied conflict preemption is often further subdivided into impossibility and obstacle preemption. The key legal principles applicable to each of these preemption types are discussed below.

Federal preemption is also both "statute specific" and "claim specific." That is, some federal statutes preempt certain state law claims, while others do not.[7] Moreover, as the Supreme Court made clear in *Cippollone v. Liggett Group, Inc.,* 505 U.S. 504 (1992), the preemption analysis must be applied to each state law claim at issue. *Id.* at 524-29 (federal cigarette labeling

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noted that the "[t]he preemption doctrine derives from the Supremacy Clause" in *Thunderbird Mining Co. v. Ventura*, 138 F. Supp. 2d 1193, 1196 (D. Minn. 2001).

[6] *See, e.g., Thunderbird Mining Co.*, 138 F. Supp. 2d at 1196. The Eighth Circuit has also recognized these traditional types of federal preemption. *See, e.g., Northern Natural Gas Co. v. Iowa Utilities Bd.*, 377 F.3d 817, 821 (8th Cir. 2004).

[7] *See* Jean Macchiaroli Eggen, *Shedding Light on the Preemption Doctrine in Products Liability Actions: Defining the Scope of Buckman and Sprietsma*, 6 Del. L. Rev. 143, 174 ("[S]cope of preemption is very much a function of the particular federal statute at issue in the case.").

statute preempted state common law warning and advertising claims, but not state common law claims based on research and testing, misrepresentation and breach of warranty).

**1. Express preemption.**

Express preemption exists when a federal statute specifically excludes state regulation in a particular area. *See Cipollone*, 505 U.S. at 520-24 (federal statute compelled specific warning labels on packages of cigarettes). When Congress expressly preempts state law, the only remaining question is the extent of the preemption.

There are two types of clauses relevant to an express preemption analysis. The first, a "preemption clause," describes the extent to which a federal statute preempts state law. The second, a "savings clause," provides that compliance with the statute does not exempt someone from liability under state common law. Some federal statutes have both clauses, some have one or the other, and some, like the provisions of the FDCA at issue here, have neither.

**2. Implied Preemption.**

If a federal statute is silent regarding any preemptive effect, it may still preempt state law in a particular area under the implied preemption doctrine.[8] As noted above, the implied preemption doctrine encompasses both field and conflict preemption. Because Pfizer is not asserting a field preemption defense,[9] Pfizer Memo at 17, n.6, the State will limit its discussion

[8] Some courts and commentators assert that there can be no implied preemption if a federal statute contains express preemption language. The Eighth Circuit applied this analysis in rejecting a preemption defense just a few months ago in *Boerner v. Brown & Williamson Tobacco Co.*, 394 F.3d 594, 600 (8th Cir. 2005).

[9] Field preemption exists where Congress legislates in a field in which the federal interest is so extensive and detailed that it leaves no room for the states to act. *See, e.g., Florida Lime & Avocodo Growers, Inc. v. Paul*, 373 U.S. 132, 142 (1963).

here to the legal principles applicable to the two sub-categories of conflict preemption -- namely, impossibility and obstacle preemption.

**a. Impossibility Conflict Preemption.**

This preemption doctrine applies when a federal requirement and a state requirement are contradictory and it is impossible to comply with both requirements. *See Florida Lime*, 373 U.S. at 142-43. This doctrine requires an "actual" conflict. Mere contradictory requirements in federal and state law are not enough. For example, if a person can comply with both sets of law by refraining from doing an act covered by one set, there is no impossibility conflict preemption. *See Gade v. Nat'l Solid Wastes Mgmt. Ass'n*, 505 U.S. 88, 110 (1992) (J. Kennedy, concurring) ("The existence of a hypothetical or potential conflict is insufficient to warrant preemption of the state statute.").

An example of this type of preemption is found in *McDermott v. Wisconsin*, 228 U.S. 115 (1913), which involved a conflict between the FDCA and a Wisconsin labeling law relating to syrup. The defendant was able to show that syrup imported from another state that met federal labeling law requirements would be considered misbranded under Wisconsin's labeling law and that compliance with the state statute would result in liability under federal law. Because it was impossible for the defendant to comply with both sets of law, the Court found the state statute preempted. *Id.* at 127-37.

**b. Obstacle Conflict Preemption.**

This preemption doctrine arises when a state law stands as an obstacle to the full realization of the purposes of Congress in enacting a federal statute. *See Hines v. Davidowitz*, 312 U.S. 52, 67 (1941). The mere fact that Congress enacts a law "does not automatically imply that Congress wants to displace all state law that gets in the way of those purposes." Caleb

Nelson, *Preemption,* 86 Va. L. Rev. 225, 281 (2000).[10] The Supreme Court applied this doctrine in *Geier v. Am. Honda Motor Co.*, 529 U.S. 861 (2000), ruling that a state tort action based on an auto manufacturer's failure to install air bags was preempted by a federal administrative agency's safety standards which deliberately provided the manufacturer with a range of choices among passive restraint devices. The Court reasoned that a state tort rule requiring airbags "would have presented an obstacle to the variety and mix of devices that the federal regulation sought." *Id.* at 881.[11]

### C. The Presumption Against Preemption.

There is a very strong historic presumption against preemption that properly influences any preemption analysis. This presumption is derived from important federalism concerns.

#### 1. Courts should not find federal preemption absent a clear statement of Congress' intent to preempt the applicable state law.

Courts have consistently stated that the preemption analysis "start[s] with the assumption that the historic police powers of the State were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress." *City of Columbus v. Ours Garage and Wrecker Serv.*, 536 U.S. 424, 432-33 (2002) (quoting *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947), *Hillsborough County v. Automated Med. Labs, Inc.*, 471 US 707, 715 (1985).

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[10] *See also* Henry H. Drummonds, *The Sister Sovereign States: Preemption in the Second Twentieth Century Revolution in the Law of the Workplace*, 62 Fordham L. Rev. 469, 532-33 (1993) ("Too often, the courts use the rubric of fidelity to use the "full purposes and objectives" of Congress to justify judicial activism in the preemption field. Such judicial policy-making violates both the presumption against preemption and the constitutional scheme of federalism that gives rise to that presumption.").

[11] The Supreme Court has made it clear in a subsequent federal preemption case, *Sprietsma v. Mercury Motors*, 537 U.S. 51 (2002), that a state tort law action should not be preempted on the mere ground that a federal statute is aimed at fostering uniformity in certain product standards. *Id.* at 70.

This requirement that preemption be the "clear and manifest purpose of Congress" is known as the "presumption against preemption." It is also sometimes referred to as the plain or "clear statement rule,"[12] meaning that state laws should be presumed not preempted unless Congress makes a clear statement that they are.[13]

As courts have made clear, congressional intent is the "touchstone" of federal preemption analysis.[14] This presumption against preemption applies not only to the question of the *existence* of preemption in a given case, but also to the question of the *scope* of any preemptive effect. *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996).

This strong presumption against preemption is grounded in important federalism principles. Precluding state regulation in an area of state sovereignty is a grave act that should not be attributed to Congress absent clear evidence that this was, in fact, Congress' intent. As Professor Laurence Tribe has explained, the presumption:

> further[s] the spirit of *Garcia* [*v. San Antonio Metro. Transit Auth.*, 469 U.S. 528 (1985)] by requiring that decisions restricting state sovereignty be made in a deliberate manner by Congress, through explicit exercise of its lawmaking power to that end. . . . [T]o give the state-displacing weight of federal law to mere

[12] In *Gregory v. Ashcroft*, 501 U.S. 452 (1991), the Supreme Court noted that the intention of Congress to preempt must actually be "unmistakably clear" in the language of the federal law. *Id.* at 453.

[13] This clear statement rule is based on the logic that when Congress intends to preempt state law, it has the power to say so, and, since Congress presumably is aware of state regulations in areas it is considering, the likelihood is that Congress will, in fact, say so if that is indeed what it truly intends.

[14] This Court has also recognized that congressional intent is the touchstone of federal preemption analysis. *See Thunderbird Mining Co.*, 138 F. Supp. 2d at 1196; *see also Agre v. Rain & Hail LLC*, 196 F. Supp. 2d 905, 911 (D. Minn. 2002) (congressional intent is the touchstone of complete preemption analysis for purposes of remand motion). *Accord Boerner*, 394 F.3d at 600. Some scholars have likewise proclaimed that statutory interpretation is, therefore, the "cornerstone" of federal preemption analysis. *See* David G. Owen, *Federal Preemption of Products Liability Claims*, 55 S.C. L. Rev. 411, 414 (2003).

> congressional *ambiguity* would evade the very procedure for lawmaking on which *Garcia* relied to protect states' interests.

Laurence H. Tribe, *American Constitutional Law* §6-28, at 1175-76 (3d ed. 2000).

The Supreme Court explained the many benefits of federalism underlying the presumption against preemption in *Gregory*. The federalist structure of joint sovereigns: (1) assures a more decentralized government that is more sensitive to the needs of a heterogeneous society; (2) increases opportunity for citizen involvement in democratic processes; (3) allows for more government experimentation and innovation; (4) makes government more accountable by making states compete for a mobile citizenry; and (5) provides an important check on abuses of government power.[15] 501 U.S. at 458-59. As Professor Tribe also observed, the presumption against preemption should result in more thoughtful deliberation in the federal lawmaking process as Congress must carefully consider any potential preemptive effect of its laws.

This strong presumption against preemption is consistent with the recent resurgence, over the last decade, of judicial recognition of the principles of federalism in other related legal areas. For example, the once largely dormant Tenth Amendment has been revitalized in recent years. The Supreme Court has struck down several federal laws as violating federalism principles embodied in the Tenth Amendment.[16] Likewise, the Supreme Court has recently resurrected the

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[15] As the Court explained, the "twin powers" of the federal and state governments will act as mutual restraints against the abuse of power only if both are credible: "In the tension between federal and state power lies the promise of liberty." *Id.* at 459.

[16] For example, the Court in *Printz v. United States*, 521 U.S. 898, 935 (1997), held that Congress could not mandate that state officials conduct background checks on handgun purchasers under the Brady Violence Protection Act. In *New York v. United States*, 505 U.S. 144, 174-77 (1992), the Court held that Congress may not force states to enact legislation providing for the disposal of radioactive waste generated within their borders or take title to the

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notion that the Commerce Clause does not grant unlimited power to the federal government.[17] These developments demonstrate the increasing breadth of the presumption against federal preemption.[18]

**2. The presumption against preemption applies with particular strength in the area of state regulation of public health and safety.**

The presumption against preemption is strongest where the federal regulatory scheme intrudes upon a "field which the States have traditionally occupied," such as any field involving the "historic police powers of the States." *Santa Fe Elevator Corp. v. Illinois Commerce Comm'n*, 331 U.S. 218, 230 (1947). These historic police powers include the regulation of health and safety, an area that the Supreme Court has termed "primarily, and historically, a matter of local concern." *Hillsborough County v. Automated Med. Labs., Inc.*, 471 U.S. 707, 719 (1985); *see also Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996) (noting "the historic primacy of state regulation of matters of health and safety").[19] Accordingly, courts will not infer, simply

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waste. As the Court noted in *New York*, the Tenth Amendment has morphed from a mere "tautology" to a revitalized state shield against federal authority.

[17] In *United States v. Lopez*, 514 U.S. 549 (1995), the Court struck down the federal Gun-Free School Zones Act of 1990 as beyond the enumerated powers of Congress, discussing at length the federalism principles underlying its decision. Similarly, five years later in *United States v. Morrison*, 529 U.S. 598 (2000), the Court held that a section of the Violence Against Women Act exceeded Congress' power under the Commerce Clause.

[18] Some legal scholars have suggested that this presumption against preemption might be more appropriately viewed as a rule of statutory interpretation to construe ambiguous federal statutory language narrowly. *See, e.g.,* Owen, *supra*, at 418. This distinction is not important for purposes of this case because, as discussed further herein, when this presumption, even if considered a rule of statutory interpretation, is applied in this case, the conclusion is inescapable that Congress has *never* evinced a clear and manifest intent to preempt the state common law tort claims in the Plaintiff's Complaint.

[19] This Court, in *In re St. Jude Medical, Inc. Silzone Heart Valves Prods. Liab. Litig.*, No. MDL 01-1396, 2004 WL 45503 (D. Minn. Jan. 5, 2004), also recently observed that federal preemption

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because of the comprehensiveness of a federal regulatory scheme, that Congress intended to preempt state health and safety regulations. *Hillsborough County*, 471 U.S. at 718.[20] The presumption, rather, is that "state and local regulation related to matters of health and safety can normally coexist with federal regulations." *Id.*

The common law tort system, which imposes duties and standards of care on manufacturers and others, forms an integral part of the state regulation of health and safety, and as such is strongly presumed not to be preempted by federal regulations but to coexist with them. Preemption of state tort law would produce "a serious intrusion into state sovereignty." *Medtronic*, 518 U.S. at 488. Moreover, because the tort system also compensates citizens injured by breaches of common law duties and standards of care, preemption would effectively strip citizens of state remedies for violations of state health and safety regulations. *Id.* at 488-89. Courts will not presume that Congress intended legislation to have such draconian consequences. *See, e.g., Sprietsma v. Mercury Marine*, 537 U.S. 51, 64 (2002) (stating that it would be "perfectly rational for Congress not to pre-empt common-law claims, which -- unlike most administrative and legislative regulations -- necessarily perform an important remedial role in compensating accident victims").

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is especially disfavored in areas of historic importance to the states' police powers, including public health and safety. *Id.* at *5.

[20] Citing *Hillsborough County*, this Court, in *Kociemba v. G.D. Searle & Co.*, 680 F. Supp. 1293 (D. Minn. 1988), observed that while the defendant IUD manufacturer made a strong case that the FDA had undertaken a "comprehensive effort" to regulate the development, manufacturing, labeling, and distribution of IUDs, including the particular IUD at issue in the action, the defendant could not point to statutory or regulatory language or legislative history that established that Congress intended to exclude state tort law. 680 F. Supp. at 1298.

### 3. The presumption against preemption is also especially strong where the alleged preemptive effect would deny injured plaintiffs any remedy and the federal law does not provide its own damages remedy.

Where the federal regulatory scheme itself fails to provide a remedy for harm, such as under the FDCA, then preemption would leave injured citizens without any recourse, state or federal.[21] The Supreme Court has emphatically declared that such a situation runs counter to fundamental principles of justice. *Id.* at 487 (stating that it would be "implausible" for Congress, in enacting regulatory legislation, to bar consumers from any remedy for injuries caused by the regulated products). Preemption under such circumstances will be found only if the federal regulation contains an express preemption clause. *See, e.g., Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238, 251 (1984) ("It is difficult to believe that Congress would, without comment, remove all means of judicial recourse for those injured by illegal conduct."). Here, the presumption against preemption is especially compelling given Pfizer's argument that the preemptive effect of the FDCA is to preclude not only the Plaintiff's failure to warn claim, but also *all* other of the Plaintiff's claims,[22] thereby leaving the Plaintiff without any remedy.

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[21] Commentators have recognized that the lack of any private right of action in the FDCA is a reason for courts to reject an FDCA federal preemption defense. *See, e.g.,* Betsy J. Grey, *Make Congress Speak Clearly: Federal Preemption of State Tort Remedies*, 77 B.U. L. Rev. 559, 561 (1997) ("Whether to allow this preemption defense is of critical importance to accident victims, because, if the defense is upheld, they may be left without recourse to a damages remedy.").

[22] Pfizer argues that all of the Plaintiff's claims "are merged into a single [preempted] product liability claim." Pfizer Memo. at 29.

## II. THE FDCA DOES NOT EXPRESSLY PREEMPT THE PLAINTIFF'S STATE COMMON LAW TORT CLAIMS IN THIS CASE.

There is no express preemption clause in the FDCA pertaining to prescription drugs, nor has there ever been one.[23] In fact, the legislative history of the FDCA reveals that Congress considered, and specifically rejected, the potential preemptive effect of the FDCA on state common law tort claims when first debating the legislation in 1938. Congress specifically rejected a proposal to include a private right of action for damages caused by products regulated under what would become the FDCA on the grounds that such a right already existed under state common law. *See* Hearings Before Subcomm. Of Comm. On Commerce On S. 1944, 73d Cong., 2d Sess. 400, 403 (1933); Robert S. Adler & Richard A. Mann, *Preemption and Medical Devices: The Courts Run Amok*, 59 Mo. L. Rev. 895, 924, n.130 (1994).[24]

Despite numerous amendments to the FDCA in the 67 years since Congress first enacted the statute, Congress has *never* seen fit to add an express preemption clause regarding state regulation of prescription drugs, nor to include an express preemption clause barring state tort claims for injuries to consumers from any FDCA-regulated product. Moreover, Congress' refusal to preempt state law claims involving prescription drugs cannot be ascribed to its ignorance. Congress has shown that it can and will add an express preemption clause to the

[23] Although Pfizer does not put forth an express preemption defense, Pfizer Memo. at 17, n.6, the majority of cases it relies upon for its conflict preemption defense involve federal statutes containing express preemption clauses.

[24] While Pfizer acknowledges that it has no express preemption defense in this case, Pfizer Memo. at 17, n.6, the absence of an express preemption provision is evidence that Congress also did not intend to impliedly preempt state common law tort claims involving prescription drugs, as Pfizer argues here. *See Caraker v. Sandoz Pharm. Corp.*, 172 F. Supp. 2d 1018, 1035 (S.D. Ill. 2001).

FDCA when it deems one necessary, as it has done for the labeling of medical devices and over-the-counter drugs. *See infra* at 21.[25]

## III. THE FDCA DOES NOT IMPLIEDLY PREEMPT THE PLAINTIFF'S STATE COMMON LAW TORT CLAIMS IN THIS CASE.

There is also no evidence that Congress ever intended the FDCA to impliedly preempt state regulation of prescription drugs, including state regulation through labeling requirements imposed by common law duties. In *Hill v. Searle Labs.*, 884 F.2d 1064 (8th Cir. 1989), the Eighth Circuit expressed the overwhelming majority view: "FDA approval is not a shield to liability. FDA regulations are generally minimal standards of conduct unless Congress intended to preempt common law, which Congress has not done in this area [i.e., in the area of prescription drugs]." *Id.* at 1068 (citations omitted).[26] In *Kociemba*, this Court expressed the same view: "The mere fact [of] FDA approval does not, by itself, indicate that Congress impliedly intended to preclude state tort actions against prescription drug manufacturers. This is especially true in light of the widely held view that FDA regulation of prescription drugs

[25] In another context, the Eighth Circuit, two months ago, found that a federal agency's approval of product labeling was entitled to preemptive effect where, unlike in the FDCA, the federal law -- the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA") -- expressly provided for preemption by prohibiting any state law imposing labeling requirements "in addition to or different from" those required by the federal law. *Hardin v. BASF Corp.*, 397 F.3d 1082, 1085 (8th Cir. 2005). As is clear from *Hurley*, Pfizer's reliance on *Nat'l Bank of Commerce v. Dow Chem. Co.*, 165 F.3d 602 (8th Cir. 1999), is misplaced, given that the federal law at issue in that case (FIFRA) expressly prohibited any deviation from the approved product labeling.

[26] Last year, in a case arising out of the U.S. District Court for the District of North Dakota, the Eighth Circuit was again presented with the issue of whether there is a federal preemption defense in the context of a product liability suit involving prescription drugs, but did not address the issue because it resolved the appeal on another ground. *See Ehlis v. Shire Richwood, Inc.*, 367 F.3d 1013, 1019 (8th Cir. 2004). In other contexts, the Eighth Circuit has recognized that "a *minimum* safety standard will rarely, if ever, impliedly preempt more rigorous safety obligations" and that such standards do not preempt common law tort liability for the failure to provide greater protection. *Harris v. Great Dane Trailers*, 234 F.3d 398, 401 (8th Cir. 2000).

establishes *minimum* standards, both as to design and warning." 680 F. Supp. at 1299 (emphasis in original). Numerous other courts that have addressed this issue have concurred that there is no such preemption defense.[27] So too have the major treatises.[28] Even, at one point, has the FDA.[29]

As courts have consistently recognized, there is nothing in the FDCA that prohibits drug companies from strengthening warnings regarding their drugs without prior FDA approval. *See, e.g., Caraker,* 172 F. Supp. 2d at 1033-39. In fact, as the *Caraker* court discussed, the FDA's

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[27] *See Caraker,* 172 F. Supp.2d 1018, 1033 (*citing Wells v. Ortho Pharm. Corp.*, 788 F.2d at 746 (11th Cir. 1986)) ("An FDA determination that a warning is not necessary may be sufficient for federal regulatory purposes but still not be sufficient for state tort law purposes.). *Caraker* contains a very thorough and well-reasoned analysis of this issue. *See also Mazur v. Merck & Co.*, 742 F. Supp. 239, 247 (E.D. Pa. 1990) ("[M]ere compliance with FDA suggestion, or for that matter, regulation or order, does not mean that state tort law becomes irrelevant. . . . Compliance with an FDA regulation may establish that the manufacturer met the appropriate minimum standards of due care, but compliance does not necessarily absolve the manufacturer of all liability. . . . Manufacturers must meet state safety requirements, whether codified or embodied in the common law, in addition to satisfying initial FDA requirements."); *Edwards v. Basel Pharm.*, 933 P.2d 298 (Okla. 1997) ("it is the widely held view that the FDA sets minimum standards for drug manufacturers as to design and warning. We conclude that compliance with these minimum standards does not necessarily complete the manufacturer's duty. . . . The common law duty to warn is controlled by state law."); *Feldman v. Lederle Labs.*, 625 A.2d 1066, 1070 (N.J. 1993) ("FDA regulations were simply 'minimum standards' -- compliance with them was mandatory, but they did not preclude Lederle from taking additional action."); *Savina v. Sterling Drug, Inc.*, 795 P.2d 915, 931 (Kan. 1990); *MacDonald v. Ortho Pharm. Corp.*, 475 N.E.2d 65, 70 (Mass. 1985) ("The regulatory history of the FDA requirements belies any objective to cloak them with preemptive effect.); *Feldman v. Lederle Labs.*, 479 A.2d 374, 391 (N.J. 1984).

[28] *See, e.g.,* Am. L. Prod. Liab. 3d § 64:30 (updated August 2002): "Federal drug labeling requirements do not preempt state law claims based on inadequate warnings with respect to prescription drugs. . . . Furthermore, compliance with federal drug labeling regulations is merely the minimal standard."); Restatement (Third) of Torts: Product Liability § 4(a)(b) (1997).

[29] "In response to concerns raised by drug manufacturers that warnings required and drafted by the FDA might be deemed inadequate by juries, *the FDA commissioner specifically noted that the boundaries of civil tort liability for failure to warn are controlled by applicable State law*." *MacDonald*, 475 N.E.2d at 70 (*citing* 43 Fed. Reg. 4214 (1978)) (emphasis added). Similarly, as the *Caraker* court noted, the United States more recently in *Buckman* represented to the Supreme Court that while a fraud on the FDA claim is preempted, "if there is negligent design, negligent manufacturing, failure to warn, common law malpractice, all of those claims are available . . . . " 172 F. Supp. 2d at 1036-37 (quoting the oral argument of the Solicitor General).

own regulations contemplate that drug companies may add warnings without FDA approval. *Id.* at 1034-35.[30] This makes sense, since a prohibition on additional warnings would directly endanger the health of drug consumers, given that the discovery of dangers and side effects of drugs is necessarily a dynamic process. Labeling and warnings deemed adequate by the FDA at the time of initial approval of a drug may become inadequate upon a drug company's later discovery of unforeseen dangers based on later testing or adverse drug reaction reports. *Caraker*, 172 F. Supp. at 1033-34. In fact, the FDA allows drug manufacturers to take the initiative to revise their labeling and warnings "as soon as there is reasonable evidence of an association of a serious hazard with a drug." *Id.* at 1038 (quoting 21 C.F.R. § 201.57(e) (1996)).[31]

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[30] The *Caraker* court cited the preamble to the FDA's drug labeling regulations, numerous substantive provisions in the regulations relating to labeling and warnings, and the history of the FDA's regulations relating to warnings which show that the FDA actually eliminated its initial regulations that expressly prohibited drug companies from adding warnings without FDA approval. *Id. See also In re Tetracycline Cases*, 747 F. Supp. 543, 548-50 (W.D. Mo. 1989) (FDA regulations allow drug manufacturer to make additions to or changes to warnings regarding prescription drugs prior to FDA approval to supplement or complement the FDA's warnings).

[31] Here, the Plaintiff argues that Pfizer had more than sufficient evidence of an *association* between Zoloft and the akathisia that led to her husband's death. To prevail on her failure to warn claim, the Plaintiff need not, as Pfizer suggests, definitively establish that Zoloft *causes* akathisia or suicidality. The negligent lack of a warning of the association between the drug and this condition is enough for a jury to find liability based on the Plaintiff's warning claim. *See Dusek v. Pfizer, Inc.*, No. Civ.A. H-02-3559, 2004 WL 2191804, at *9 (S.D. Tex. Feb. 20, 2004) ("If Plaintiffs were advocating for a warning that simply stated that there was an association between Zoloft and suicide, or another warning that did not attest to the existence of a casual relationship, the change could be implemented prior to FDA approval, because a conflict would not exist."). Here, the Plaintiff contends that there is no evidence that the FDA ever considered and rejected the warning she claims should have been given and that Pfizer has, in fact, admitted as much. Plaintiff Memo. at 1, 9-10. The court found preemption in *Dusek* on the basis of the "unique circumstances" of that case because the FDA had specifically rejected the precise warning that the plaintiffs were advocating (that Zoloft *causes* suicide) and that formed the basis of their common law failure to warn claim. *Id.* at *10. Here, Pfizer repeatedly mischaracterizes the warning that the Plaintiff argues it should have given regarding Zoloft. Unlike in *Dusek*, the Plaintiff here is *not* contending that liability lies under state common law because Pfizer did not warn that Zoloft "causes" suicide. Plaintiff Memo. at 2, n.3; 12, n.11; and 13.

As the Plaintiff makes clear, and the FDA has admitted, there is also nothing in the law that confers on the FDA the power to require drug manufacturers to include stronger warnings regarding their drugs after the drugs are initially approved. Plaintiff Memo. at 5-6. Absent such authority, there can be no impermissible conflict between the stronger warning that the Plaintiff contends Pfizer should have given and any alleged FDA requirement regarding such a stronger warning.

Given the overwhelming weight of authority against federal preemption of such tort claims, and given Congress' reenactment of the FDCA without amendment to the sections of the Act pertaining to prescription drugs, Congress can be said to have ratified the case law holding that the FDCA sets only minimum standards and does not preempt state tort law. "Congress is presumed to be aware of an administrative or judicial interpretation of a statute and to adopt that interpretation when it re-enacts a statute without change." *Lorillard v. Pons*, 434 U.S. 575, 580-81 (1978). Indeed, when Congress amended the FDCA in 1997, it added an express preemption clause regarding labeling requirements *only* for over-the-counter drugs. Federal Food, Drug, and Cosmetic Act, 21 § 751(a) and (e), as amended, 21 U.S.C. § 379r(a)(e) ("The Food and Drug Administration Modernization Act of 1997").[32] Congress remained silent on prescription drugs.[33]

In arguing in favor of implied federal preemption of state common law tort claims, Pfizer erroneously relies on cases containing *express* preemption provisions: *Horn v. Thoratec Corp.*,

[32] Even then, Congress inserted a savings clause clarifying that "[n]othing in this section shall be construed to modify or otherwise affect any action or the liability of any person under the product liability law of any State." 21 U.S.C. § 379r, subd. (e) ("No effect on product liability law"); *see also* Sen. Rpt. No. 105-43, 1st Sess. (1997), at 66.

[33] In fact, in 2003, Congress failed to enact a proposed express preemption provision in H.R. 5.

376 F.3d 163 (3d Cir. 2004); *Brooks v. Howmedica, Inc.*, 273 F.3d 785 (8th Cir. 2001); *Martin v. Medtronic, Inc.*, 254 F.3d 573 (5th Cir. 2001); *Kemp v. Medtronic, Inc.*, 231 F.3d 216 (6th Cir. 2000); *Mitchell v. Collagen*, 126 F.3d 902 (7th Cir. 1997). The other cases Pfizer relies upon are no more helpful. For example, Pfizer cites the Fifth Circuit's decision in *Hurley v. Lederle Labs.*, 863 F.2d 1173 (5th Cir. 1988). As the court explained in *Motus v. Pfizer, Inc.*, 127 F. Supp. 2d 1085 (C.D. Cal. 2000), which involved the identical preemption issue before this Court, Pfizer's reliance on *Hurley is* misplaced, given that *Hurley* dealt with different federal regulations regarding vaccines that expressly precluded unapproved labeling. *Id.* at 1093.[34] These cases are simply irrelevant to the analysis here.[35]

The Supreme Court's implied federal preemption finding in *Buckman v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001), also does not help Pfizer's preemption argument. The Court in that case held that the plaintiff's "fraud on the FDA" claim was impliedly preempted. The Court reasoned that policing fraud against a federal agency is not a field which states have traditionally occupied and that the FDA had its own means to enforce claims of fraud perpetrated on the agency. *Id.* at 350.

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[34] The *Motus* court explained that, unlike in *Hurley*, it is "*not true"* that Pfizer could not change the language of its package insert without FDA approval and it is also "*not true"* that a manufacturer would otherwise be liable for strengthening an FDA-approved warning. 127 F. Supp. 2d at 1094. The *Motus* court also correctly rejected the argument that Pfizer made there and again makes here that stronger warnings for Zoloft will invariably result in over-deterrence. Not only did the court find that there is an absence of persuasive evidence that strengthening the warnings on Zoloft would have this result, and that the FDA has not found that this would occur, but it also noted that Pfizer presented no legislative history or testimony suggesting that in enacting the FDCA and creating the FDA Congress intended to prevent or even consider overdeterrence of drug use. *Id.* at 1097-98.

[35] Pfizer also mistakenly relies upon *Chicago & N.W. Transp. Co.,* just as it did in *Motus*. As the *Motus* court explained, that case is inapposite in that it was based on the pervasive and exclusive nature of the authority of the Interstate Commerce Commission and courts have held that FDA labeling determinations are not so broad or exclusive as to preempt state law claims. *Id.* at 1099.

In this case, the Plaintiff does not have a fraud on the FDA claim. Rather, her fraud claim is a state common law claim alleging that Pfizer defrauded prescription drug consumers, like the Plaintiff's deceased husband. It is clear that the federal preemption defense recognized in *Buckman* has no application to such claims of fraud on consumers. As the court in *Globetti v. Sandoz Pharm. Corp.*, No. CV98-TMP-2649-S, 2001 WL 419160 (N.D. Ala. Mar. 25, 2001), aptly explained:

> Defendant owed separate duties beyond simple full and fair disclosure to the FDA, duties not to market a defective and unreasonably dangerous product, not to misrepresent or suppress the facts needed by physicians and consumers to assess the safety of the product, and to adequately warn of the known risks associated with it. These duties existed irrespective of the FDCA. Thus, while plaintiff cannot recover simply because defendant defrauded a federal agency, nothing in Buckman suggests that she cannot recover where the misrepresentations or suppression were directed at her (through her physician) or when the warning given (even though FDA approved) inadequately disclosed the hazards of the product.

*Id.* at *2 (footnote omitted). *See also Dawson v. Ciba-Geigy Corp.*, 145 F. Supp. 2d 565, 573 (D.N.J. 2001) (same); *Caraker*, 172 F. Supp. 2d at 1039-41 (same).

Just last year, Judge John Tunheim employed this same reasoning in rejecting a medical device manufacturer's attempt to use *Buckman* to escape liability for the plaintiffs' state common law failure to warn claims. In *St. Jude Medical, Inc. Silzone Heart Valves Prods. Liab. Litig.*, Judge Tunheim concluded that the plaintiffs' warning claims were not preempted under *Buckman* in that the claims derived not from a fraud on the FDA theory, but rather from traditional tort causes of action that have been the exclusive province of the states. *Id.* at *13.[36]

[36] Judge Tunheim ruled that the plaintiffs' warnings claims were not preempted notwithstanding the fact that the FDA had determined that the product labeling constituted an adequate warning and that the FDA had approved of and even drafted some of the language. *Id.* at 12. In rejecting
(footnote continued next page)

The legal commentators are also in accord that the preemption defense is indeed very limited in scope and has no application to the types of state law product liability claims contained in the Plaintiff's Complaint.[37] Accordingly, there can be no implied federal preemption defense based on *Buckman* in the instant case.

## IV. THE COURT SHOULD AFFORD LITTLE, IF ANY, WEIGHT OR DEFERENCE TO THE FDA'S INFORMAL STATEMENTS AND LITIGATION AMICUS BRIEFS REGARDING THE PRESCRIPTION DRUG FEDERAL PREEMPTION ISSUE HERE.

Pfizer contends that the Court should find federal preemption here based upon various informal FDA statements regarding Zoloft and other antidepressants. Pfizer also relies upon some amicus litigation briefs filed on behalf of the FDA in other prescription drug product liability litigation articulating the FDA's views of the FDCA's preemptive effect. These statements simply do not justify a finding of implied preemption given the analysis above, including the fact that the FDCA does not prohibit state common law liability based upon the absence of additional warnings not required by the FDA and the fact that the decision as to whether state common law liability lies because of the absence of such additional warnings is not

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a preemption defense, Judge Tunheim reasoned that the plaintiffs had alleged that they could demonstrate that the FDA was unaware of certain risks as the labeling language was updated.

[37] *See, e.g.,* Eggen at 163 ("*Buckman* was intended to apply narrowly to matters involving 'policing fraud against federal agencies,' and not to matters involving the manufacturer's direct relationship to the consumer."). As Eggen explains, *Buckman* should not be used, as some defendants have tried, to preempt all state common law tort claims under an implied preemption analysis. *Id.* at 163-68. *See also* Trent Kirk, *Fraud-on-the-FDA & Buckman -- The Evolving Law of Federal Preemption in Products Liability Litigation*, 53 S. C. L. Rev. 673, 691-92 (2002) ("The *Buckman* holding does not appear to imply that state claims other than fraud-on-the-FDA will be preempted. *Buckman* did not rule on any claims related to warning, manufacture, or design."). The United States also filed an amicus brief in *Buckman* implying that state law design-related claims should not be preempted. *Id.*

the FDA's to make. These FDA statements and amicus briefs also do not justify a finding of federal preemption for the many additional reasons discussed below.

While some litigants have advocated a federal "agency preemption" theory -- that federal agency action or statements should be given preemptive effect[38] -- the law is clear that the type of informal FDA pronouncements upon which Pfizer relies are not entitled to any preemptive effect. First, courts and commentators have correctly reasoned that federal preemption based upon agency action or pronouncements is suspect, given that federal agencies are a clear step removed from Congress and that their interpretations, therefore, should not constitute a substitute for a clear and unmistakable expression of *congressional* intent.[39] The relevant inquiry in federal preemption analysis is the clear and unmistakable intent of Congress -- *not* the intent of an unelected agency.[40]

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[38] The Supreme Court has recognized that federal agency regulations can also have a preemptive effect in certain circumstances. *See, e.g., City of New York v. F.C.C.*, 486 U.S. 57, 64 (1988); *Behrens v. United Vaccines, Inc.*, 189 F. Supp. 2d 945, 951 (D. Minn. 2002) (citing *New York*). However, just as a comprehensive federal statute dealing with an area does not justify preemption, as discussed above at 12, it is equally improper to infer federal preemption whenever an agency deals with an area comprehensively. *See Caraker*, 172 F. Supp. 2d at 1035 (such an inference "is virtually tantamount to saying that whenever a federal agency decides to step into a field, its regulations will be exclusive.").

[39] *See, e.g.,* Ausness, *supra*, at 975 (argument that undue weight should not be given to agency decisions is even more compelling when an unelected agency is seeking to diminish the historic police powers of the states, and an agency's interpretations of its authority should not be treated as a substitute for a clear expression of congressional intent).

[40] Under *Chevron U.S.A., Inc. v. Natural Res. Def. Council, Inc.*, 467 U.S. 837, 842 (1984), courts look at the intent of an agency only where a statute is ambiguous. If a statute is ambiguous as to its preemptive intent, however, the presumption against preemption should lead to a finding that Congress did not intend to preempt state law. *See* Bradford R. Clark, *Separation of Powers as a Safeguard of Federalism*, 79 Tex. L. Rev. 1321, 1436-38 (2001). Moreover, as the Supreme Court made clear in *Smiley v. Citibank (South Dakota), N.A.*, 517 U.S. 735 (1996), giving *Chevron* deference to an agency's interpretation of a substantive provision of a statute is quite different than giving such deference to an agency's interpretation of a statute's federal preemptive effect. In *Smiley*, the Court decided to defer to the OCC's substantive interpretation

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Courts and commentators have also correctly reasoned that federal preemption cannot be grounded in the type of informal federal agency statements upon which Pfizer relies here. Nor should these statements be entitled to any deference in the preemption analysis. As the Supreme Court made clear in *United States v. Mead Corp.*, 533 U.S. 218 (2001), the lack of formality, including the absence of compliance with formal notice and comment procedures, undermines any claim of federal preemption the agency may assert. *Id.* at 228.[41]

The Court should also decline to give any weight to the FDA's recent litigation amicus briefs dealing with the issue of federal preemption for numerous reasons. First, the mere statement of opinion of a federal agency in a litigation amicus brief falls short of the type of final and formal agency action necessary to support a federal preemption finding. As the United States government stated in its brief in *Sprietsma v. Mercury Marine*, 537 U.S. 51 (2002), "as a general matter, state law is not preempted by a mere expression of an opinion or statement of policy by a federal agency, untethered to any agency action that has legal effect in its own right. Brief for the United States as Amicus Curiae Supporting Petitioner at *23, *Sprietsma v. Mercury Marine*, 537 U.S. 51 (2002) (No. 01-706), *available at* 2002 WL 500643 (U.S.).

Second, this Court should not give any special weight to the FDA's statements regarding the existence or scope of any federal preemption defense asserted here, given that the FDA has

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of an ambiguous statutory term under *Chevron*, while explicitly rejecting any deference to the agency's regulation purporting to preempt state law directly. The Court explained that the argument that the OCC's regulation is entitled to *Chevron* deference "confuses the question of the substantive (as opposed to pre-emptive) *meaning* of a statute with the question of *whether* a statute is preemptive." *Id.* at 744. The Court noted that the latter decision "must always be decided *de novo* by the courts." *Id.*

[41] As the Court noted in *Mead*, the deference to be afforded to agency action and statements depends upon, *inter alia*, the consistency, formality and thoughtfulness of the agency's action. *Id.*

no specialized expertise in making legal determinations of this kind. This type of legal determination is the province of the courts. *See* Cass R. Sunstein, *Interpreting Statutes in the Regulatory* State, 103 Harv. L. Rev. 405, 469 (1989) (the scope of power delegated to an agency should be decide by an independent entity, such as a court, and not by the agency itself).

Third, the Court should refuse to find preemption based upon the FDA's opinions in its recent amicus briefs because the FDA's views in these briefs are inconsistent with other pronouncements by the agency and the United States government, as discussed in note 31 above. *See also Norfolk S. Ry. Co. v. Shanklin*, 529 U.S. 344, 356 (2000) (chiding agency for changing its position and contradicting the plain language of the text of the federal law at issue).

Fourth, the FDA incorrectly argues in favor of preemption in its amicus briefs because of the possibility that the agency might take some enforcement action against a drug company for including warnings which the FDA did not require or with which the FDA disagreed. Quite simply, the hypothetical possibility, or even the threat, of such an enforcement action is not sufficient to justify implied conflict preemption. As discussed above, federal preemption requires an actual, not a hypothetical conflict. *Rice*, 458 U.S. at 659. Moreover, the mere filing of an enforcement action does not guarantee that the FDA would prevail. No actual conflict would exist unless and until the FDA prevailed.

Finally, there is also good reason for the Court to refuse to afford deference to the FDA's opinions in its amicus briefs given the close ties the agency now has with the pharmaceutical industry. Just this month, a study was authored discussing the financial leverage and influence

that the drug industry has over the FDA and how the FDA's dependence on the industry has compromised its legitimacy and independence and jeopardized the health of Americans.[42]

## V. BECAUSE FEDERAL PREEMPTION IS AN AFFIRMATIVE DEFENSE, AND IN LIGHT OF THE PRESUMPTION AGAINST PREEMPTION, ANY DOUBTS AS TO THE PREEMPTIVE EFFECT OF THE FDCA SHOULD BE RESOLVED IN FAVOR OF THE PLAINTIFF AND IN FURTHERANCE OF THE GOALS OF PUBLIC SAFETY EMBODIED IN THE FDCA.

Federal preemption is an affirmative defense for which Pfizer bears the burden of proof. *See, e.g., Hawkins v. Leslie's Pool Mart, Inc.*, 184 F.3d 244, 256 (3d Cir. 1999); *Kociemba*, 680 F. Supp. at 1298. In light of this affirmative burden, the strong presumption against preemption, and the important federalism principles underlying this presumption, this Court should resolve *any* doubts it has about the existence of a federal preemption defense here in favor of the Plaintiff. In fact, the same general and important federalism concerns that underlie the presumption against preemption also support the analogous presumption against removal in federal removal jurisprudence. *See, e.g., Men's Assur. Co. of America*, 992 F.2d 181, 183 (8th Cir. 1993) (recognizing presumption in favor of state court jurisdiction and against

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[42] *See* Gary W. Lawson, *Impact of User Fees on Changes Within the FDA* (2005), *available at http://www.fdastudy.com*. Dr. Marcia Angell makes the same criticism of the financial ties between the FDA and the drug industry in her book, *The Truth About Drug Companies* (2004). In discussing the drug company user fees paid to the FDA under the Prescription Drug User Fee Act, Angell states that:

> "[P]ractice puts the FDA on the industry's payroll, drug by drug. The more drugs the agency reviews, the more money it gets from the industry. . . . This arrangement creates a powerful conflict of interest for the FDA. Moreover, the very notion that private companies "use" a public regulatory agency is wrong, since the FDA is there to serve the public, not drug companies."

*Id.* at 243. Dr. Angell concludes that the FDA "is too much in the thrall of the industry it regulates" and states that: *"The FDA needs to be strengthened as an independent agency.* It is now so dependent on the pharmaceutical industry that it has become the big pharma's handmaiden." *Id.* at 242-43 (emphasis in original).

removal); *State of Minnesota v. Worldcom, Inc.*, 125 F. Supp. 2d 365, 368 (D. Minn. 2000) (all doubts as to the propriety of removal are to be resolved in favor of remand).[43] As discussed above, there are numerous reasons why this Court should have doubts about the validity of a preemption defense in a case like this, any one of which alone would justify the Court in rejecting the defense.

Numerous legal scholars have appropriately cautioned against the unwarranted recognition of federal preemption in general, including the unwarranted recognition of such a defense against state common law product liability claims, especially those involving prescription drugs. This is yet an additional ground upon which this Court should resolve any doubts about the existence of such a defense in this case in favor of the Plaintiff. *See, e.g.,* Kenneth Starr, *et al.*, *The Law of Preemption* 47, 56 (1991) ("preemption diminishes the state sphere that federalism teaches us to protect"); Laurence H. Tribe, *American Constitutional Law* § 6-28, at 1175-76 (3d ed. 2000) (*see* quote, *supra,* at 10); Betsy J. Grey, *Make Congress Speak Clearly: Federal Preemption of State Tort Remedies*, 77 B.U. L. Rev. 559, 627 (1997) ("Our system of federalism demands that interference with states' policy decisions to give their citizens tort remedies should be the product of judgment and careful balancing, rather than an unintended result of congressional inattention or imprecision."); Owen, *supra*, at 441 (courts should be cautious about using preemption to foreclose state law rights to judicial remedies by persons injured by defective products since "there is in fact no reason, as a general matter, why product safety regulations and products liability litigation cannot comfortably co-exist."); Ausness, *supra*,

[43] Likewise, these federalism concerns also support the presumption in favor of concurrent federal and state jurisdiction to adjudicate claims arising under the laws of the United States. *See, e.g., Tafflin v. Levitt*, 493 U.S. 792, 795 (1990).

at 24 (greater protection to state police power interests against preemption is warranted in cases where the federal statutory language is ambiguous); Stacey A. Carroll, *Federal Preemption of State Products Liability Claims: Adding Clarity and Respect for State Sovereignty to the Analysis of Federal Preemption Defenses*, 36 Ga. L. Rev. 797, 819 (2002) (a more deferential preemption analysis should apply to common law products liability claims because compensating injured plaintiffs goes to the heart of traditional state police powers and such an analysis would leave fewer persons injured by defective products without a remedy); Drummonds, *supra*, at 532-33 (*see* quote *supra* at 8, n.11).

Finally, as courts and commentators have appropriately recognized, a federal preemption defense in the context of state law tort claims dealing with prescription drugs would actually frustrate the public safety goal embodied in the FDCA. As the court noted in *In re Paxil Litig.*, No. CV-01-07937, 2002 WL 31375497 (C.D. Cal. Oct. 18, 2002), which dealt with false advertising claims, it contravenes "common sense" to believe that when enacting the FDCA for the purpose of protecting public health, Congress not only declined to provide for a private cause of action, but also eliminated the availability of common law state claims. *Id.* at *1.[44] Potential state common law liability for inadequate warnings is only likely to encourage pharmaceutical manufacturers to make complete disclosure of the risks of their drugs, to strengthen existing warnings where necessary, and to deter and punish drug companies that put their interest in drug sales and profits above the paramount interest in public safety. It would be unconscionable to allow Pfizer, and the rest of the drug industry, to evade liability for their failure to take

[44] *See also Caraker*, 172 F. Supp. 2d at 1039 ("[T]his Court is wary to immunize the entire pharmaceutical drug industry which Congress itself believed needed to be better watched."); *Motus*, 127 F. Supp. 2d at 1099-1100 ("[T]he Court notes that permitting plaintiff's state law 'failure to warn' claims may complement the congressional purposes of FDA regulations.").

reasonable, simple, and responsible safety precautions consistent with the public safety goal of the FDCA.

## CONCLUSION

For the above-stated reasons, the State requests that this Court deny Pfizer's summary judgment motion in its entirety.

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Respectfully submitted,

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