NOS. 09-993, 09-1039, 09-1501

In The Supreme Court of The United States

PLIVA, INC., *ET AL.*, *Petitioners*,
v.
GLADYS MENSING, *Respondent*.

ACTAVIS ELIZABETH LLC, *Petitioner*,
v.
GLADYS MENSING, *Respondent*.

ACTAVIS INC., *Petitioner,*
v.
JULIE DEMAHY, *Respondent*.

On Writs of Certiorari to the United States Courts of Appeals for the Eighth Circuit and for the Fifth Circuit

BRIEF FOR ADMINISTRATIVE LAW AND CIVIL PROCEDURE SCHOLARS AS *AMICI CURIAE* IN SUPPORT OF RESPONDENTS

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INTEREST OF *AMICI CURIAE*

Amici are scholars who teach and write about civil procedure and federal preemption of state law.[1] We file this brief to address the relationship between preemption doctrine and procedural rules. The arguments made by petitioners and their *amici* blur this relationship and obscure the traditional role that preemption plays in the adjudicative process. *Amici* write to clarify the basic principle that federal preemption of a state-law tort claim is a defense that must be pled and proven by the defendant. Reaffirming this principle is appropriate as a matter of preemption law, basic pleading doctrine, and this Court's longstanding precedent regarding the scope of jurisdiction under 28 U.S.C. § 1331.

Our scholarly interest in preemption and procedure arises from teaching and writing in a variety of related fields, including constitutional law, administrative law, and civil procedure. Edward J. Brunet is the Henry J. Casey Professor of Law at Lewis & Clark Law School where he teaches Civil Procedure. William W. Buzbee is a Professor of Law at Emory University School of Law, where he teaches Administrative Law. Robert L. Glicksman is the J.B. and Maurice C. Shapiro Professor of

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[1] Counsel for all parties have consented to the filing of this brief, and those consents are on file with the Clerk of the Court. Pursuant to Rule 37.6, *amici* affirm that no counsel for a party authored this brief in whole or in part, that no such counsel or party made a monetary contribution to the preparation or submission of this brief, and that no person other than *amici* and their counsel made such a monetary contribution.

Environmental Law at George Washington University Law School where he teaches Administrative Law. Thomas O. McGarity holds the Joe R. and Teresa Lozano Long Endowed Chair in Administrative Law at the University of Texas, where he teaches Environmental Law and Torts. Nina A. Mendelson is a Professor of Law at the University of Michigan Law School, where she teaches Administrative Law and Environmental Law. Alexander A. Reinert is an Associate Professor of Law at the Benjamin N. Cardozo School of Law, where he teaches Civil Procedure and Constitutional Law. Sidney Shapiro is the University Chair in Law at Wake Forest University School of Law, where he teaches Administrative Law. Adam Steinman is a Professor of Law at Seton Hall University School of Law, where he teaches Civil Procedure.

SUMMARY OF ARGUMENT

Preemption doctrine is typically associated with substantive federalism concerns. It serves to demarcate the boundaries of state and federal enforcement power, encouraging federal actors to speak clearly when invading the police powers traditionally reserved to the States, thereby ensuring that principles of federalism are maintained as much as possible in favor of State autonomy. This case, however, implicates the procedural dimensions of preemption doctrine. It presents the difficult question of the proper role for a court resolving a preemption defense at the motion to dismiss stage.

Petitioners and their *amici* maintain that plaintiffs in a state law tort action must plead facts establishing an absence of preemption before proceeding past the motion to dismiss stage.[2] *See* Br. for Pet'rs Pliva *et al.* 29 (arguing that to prove causation, respondents must prove that FDA "would have exercised its exclusive authority to implement the suggested warnings in a timely fashion."); *id.* 50 (terming FDA's "independent action" an "essential element in the causal chain"); Br. for Pet'rs Actavis *et al.* 17 (treating FDA action as causal element); *id.* 28-29; Br. for *Amici Curiae* Morton Grove Pharm., Inc. *et al.* 26-27 (arguing that FDA action is critical to causation and burden rests on respondents). Absent such pleading, they suggest, the plaintiff has failed to state a claim for relief. *See*, *e.g.*, Br. for Pet'rs Pliva *et al.* 51-52; Br. for Pet'rs Activa *et al.* 28-29; Br. for *Amici Curiae* Morton Grove Pharm., Inc. *et al.* 26-27. Although petitioners and their *amici* are less than clear regarding the source of this rule, their argument implies that plaintiffs are obliged to plead and prove a negative – the non-existence of preemption – even though this Court and lower federal courts have consistently treated preemption as an affirmative defense. Petitioners' suggestion is inconsistent with basic pleading

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[2] Actavis and Pliva filed motions to dismiss in the *Mensing* case, *see Mensing v. Wyeth, Inc.*, 588 F.3d 603, 605 (8th Cir. 2009), and Actavis filed a motion to dismiss in *Demahy*, *see Demahy v. Actavis, Inc.*, 593 F.3d 428, 430 (5th Cir. 2010). Although other defendants below filed motions styled as motions for summary judgment, these were made on legal, not factual grounds. *See* Br. for Resp'ts. 5 & n.4. Thus, as a practical matter, the cases below were resolved at the motion to dismiss stage.

doctrine, ignores the presumption against preemption, and would undermine the delicate balance of federal subject matter jurisdiction that this Court has maintained for nearly a century.

If the argument by petitioners and their *amici* were accepted, it would create irreconcilable tension in various strands of this Court's preemption jurisprudence. Indeed, petitioners and their *amici* disregard the equilibrium that this Court has struck through its preemption jurisprudence. The longstanding presumption against preemption, reaffirmed only two years ago in *Wyeth v. Levine*, 129 S. Ct. 1187 (2009), forms the backdrop for important aspects of both pleading jurisprudence and subject matter jurisdiction principles that would be substantially undermined by the arguments of petitioners and their *amici*. On the question most directly implicated in this case, the presumption against preemption explains precisely why preemption is an affirmative defense that a plaintiff need not anticipate to state a claim for relief at the motion to dismiss stage. Indeed, when this Court has considered the relationship between pleading and preemption it has consistently held that preemption is only considered after a plaintiff's complaint has stated a claim for relief. *See Franchise Tax Board of California v. Construction Laborers Vacation Trust*, 463 U.S. 1, 13-14 (1983). Moreover, the presumption mandates that the defendant show that a particular state law action is preempted by federal law. At the motion to dismiss stage, the defendant can only do so by showing an entitlement to dismissal on preemption grounds

based on the allegations that appear on the face of the complaint. Here, the complaint cannot be read to support a defense of preemption on its face.

The coherence of this approach is only amplified when one turns to consider subject matter jurisdiction, where the presence of a putative preemption defense has never been the basis for federal subject matter jurisdiction, except for narrow exceptions not applicable here, because it is not considered part of the plaintiff's "well pleaded complaint." *See Louisville & Nashville R. Co. v. Mottley*, 211 U.S. 149 (1908) (articulating rule). If petitioners are correct that facts necessary to rebut preemption must be pleaded and proved by the plaintiff, some actions in which preemption is a potential defense would arguably "arise under" federal law, permitting the exercise of federal subject matter jurisdiction under 28 U.S.C. § 1331. Decades of case law has established the opposite proposition – the presence of affirmative defenses with federal roots, like preemption, is insufficient to justify the exercise of "arising under" jurisdiction. In sum, pleading principles establish that a plaintiff is not expected to anticipate the defense of preemption in the pleadings; principles of federal subject matter jurisdiction go further, by labeling as "artful pleading" a plaintiff's attempt to incorporate preemption issues into her complaint.

Petitioners and their *amici* are indifferent to this finely calibrated approach, insisting that the possibility of a preemption defense creates a need for a plaintiff to incorporate facts rebutting preemption

into her cause of action. Thus, under petitioners' version, the presumption against preemption has no weight and the normal pleading rules regarding affirmative defenses are inapplicable. Moreover, if this Court accepts petitioners' argument, federal subject matter jurisdiction could be appropriate in any state-law case that touches on a conceivable federal regulatory concern that might cause a defendant to raise preemption as an affirmative defense. In addition, by proposing that the potential for preemption creates additional elements for a state law cause of action that must be pleaded by the plaintiff, petitioners and their *amici* misunderstand the elements of a plaintiff's failure to warn claim and the nature of the causation inquiry. For all of these reasons, the arguments made by petitioners and their *amici* should be rejected and the decisions below affirmed.

ARGUMENT

I. Respondents Need Not Anticipate the Affirmative Defense of Preemption in Their Pleadings

A. Petitioners' Argument Is Undermined By Basic Pleading Rules

To understand the conflict between petitioners' argument and well-established pleading principles, it is necessary to connect some of the assumptions that go unstated in petitioners' briefing. First, *Wyeth* made clear that one key issue in

determining whether state failure to warn claims are preempted in the drug labeling context is whether the FDA would have rejected more stringent warnings had the manufacturer sought its approval for the warnings. 129 S. Ct. at 1197-98. Second, *Wyeth* also clarified that the party seeking to invoke preemption had the burden of showing that the agency would not have approved such warnings, even had additional information been provided justifying the new warnings. *Id.* at 1196-98 (referring to Wyeth's "burden" to establish preemption and its failure to provide "clear evidence" that the FDA would have rejected a proposed warning). Petitioners and their *amici*, however, suggest that it is respondents who must show that the agency would have acted had it been provided with the critical information, because it is incorporated into the element of causation in plaintiffs' tort claims. *See* Br. for Pet'rs Pliva *et al.* 29, 50 (arguing that to prove causation, respondents must show that FDA would have exercised its authority); Br. for Pet'rs Actavis *et al.* 17, 28-29 (same); Br. for Amici Curiae Morton Grove Pharm. *et al.* 26-27 (same). Petitioners and their amici suggest that this case is different because here, unlike in *Wyeth*, a generic drug manufacturer does not have the power to propose unilaterally a labeling change through the "changes being effected" regulations.[3] Therefore, the argument goes, FDA action is more critical here than in *Wyeth*. *See*, *e.g.*, Br. for Pet'rs Pliva *et al.* 51-52. Accepting for the purposes of argument that this correctly describes the regulatory

[3] 21 C.F.R. § 314.70(c).

regime for generic drug manufacturers, petitioners' contention only goes to the strength of their preemption defense, and not the party that bears the burden regarding preemption. Respondents may be forced to shoulder the burden of pleading and proving how the FDA would have acted only if they also have the burden of disproving preemption. As we discuss below, imposing any such burden on respondents would be inconsistent with rules of pleading and this Court's precedents regarding the allocation of burdens for raising and establishing affirmative defenses.

The Federal Rules of Civil Procedure set forth the circumstances under which a plaintiff's complaint will pass the minimal threshold to discovery. *See* Fed. R. Civ. P. 8(a); 12(b)(6). The Rules provide that affirmative defenses must be set forth in an answer. *See* Fed. R. Civ. P. 8(c)(1). Thus, just as a plaintiff must set forth her claims with a "short and plain statement," Fed. R. Civ. P. 8(a)(2), the defendant "must . . . state in short and plain terms its defenses to each claim." Fed. R. Civ. P. 8(b)(1)(A). Nearly one hundred years ago, this Court clarified that in the "orderly course, the plaintiffs were required to state their own case in the first instance, and then to deal with the defendants' after it should be disclosed in the answer." *Taylor v. Anderson*, 234 U.S. 74, 75 (1914). The adoption of the Federal Rules did not alter this rule and this Court has consistently "refused to change the Federal Rules governing pleading by requiring the plaintiff to anticipate" an affirmative defense. *Crawford-El v. Britton*, 523 U.S. 574, 595 (1998); *see*

also Jones v. Bock, 549 U.S. 199, 215-16 (2007); *Gomez v. Toledo*, 446 U.S. 635, 639-40 (1980).

The Court has made this division of pleading responsibilities clear in the context of qualified immunity, *Crawford-El*, 523 U.S. at 595, *Gomez*, 446 U.S. at 640, *Siegert v. Gilley*, 500 U.S. 226, 231 (1991), exhaustion of administrative remedies, *Jones*, 549 U.S. at 215-16, statute of limitations, *Zenith Radio Corp. v. Hazeltine Research, Inc.*, 401 U.S. 321, 334 (1971), and most importantly, preemption. *E.g.*, *Wyeth*, 129 S. Ct. at 1196-98; *Hillsborough County, Fla. v. Automated Medical Laboratories, Inc.*, 471 U.S. 707, 716 (1985) (referring to the showing that party seeking to establish preemption must make). Thus, the invocation of preemption *after* a complaint is filed cannot affect the standard by which the sufficiency of a complaint is judged under Rules 8 or 12.

This rule has specific implications when an affirmative defense turns on factual determinations. Most importantly, a plaintiff is not required to plead facts tending to rebut an affirmative defense to defeat a motion to dismiss at the pleading stage. *Jones*, 549 U.S. at 215-16. Nor may a court rely on a factual determination to resolve a motion to dismiss based on an affirmative defense without running afoul of the Seventh Amendment. *See Byrd v. Blue Ridge Rural Elec. Co-op, Inc.*, 356 U.S. 525, 531-32 (1958). In the Title VII context, for instance, an employer may take up the burden of persuading the factfinder that it would have imposed the same adverse employment action on an employee absent

an illicit motive. *See* 42 U.S.C. § 2000e-2(m) (approving of limited liability in mixed-motive cases); *id.* § 2000e-5(g)(2)(B) (requiring an employer to "demonstrat[e] that [it] would have taken the same action in the absence of the impermissible motivating factor" in order to limit its liability to solely declaratory relief, specified injunctive relief, and attorneys' fees and costs). This Court has never suggested, however, that such a defense can be resolved in the ordinary course at the motion to dismiss stage. *Cf. Desert Palace, Inc. v. Costa*, 539 U.S. 90, 98-99 (2003) (holding that plaintiff bears no special burden in mixed motive cases); *Swierkiewicz v. Sorema, N.A.*, 534 U.S. 506, 511-12 (2002) (describing minimal pleading burden for Title VII plaintiffs).

Recognizing that an issue is properly considered an affirmative defense necessarily implies that the party seeking to invoke it bears both the burden of production and persuasion on that issue. *See, e.g., Meacham v. Knolls Atomic Power Laboratory*, 554 U.S. 84 (2008) (holding that exemption from liability for disparate impact claim under ADEA for employer actions based on reasonable factors other than age creates an affirmative defense); *Pennsylvania State Police v. Suders*, 542 U.S. 129, 152 (2004) (noting that plaintiff might "elect to allege facts relevant to mitigation in her pleading . . . but she would do so in anticipation of the employer's affirmative defense, not as a legal requirement").[4] Of course, affirmative

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[4] This burden of pleading carries over to evidentiary stages of the case. *See, e.g., Meacham*, 554 U.S. at 101-02 (where

defenses may be dispositive at the motion to dismiss stage, but to do so the entitlement to the defense must be obvious from the face of the complaint. Thus, in *Jones*, *supra*, the Court analogized to the statute of limitations context, observing that if the limitations bar is shown by the allegations of the complaint, dismissal is proper. 549 U.S. at 215. The key point is that "[w]hether a particular ground for opposing a claim may be the basis for dismissal for failure to state a claim depends on *whether the allegations in the complaint suffice to establish that ground*, not on the nature of the ground in the abstract." *Id.* (emphasis added); *see also Leveto v. Lapina*, 258 F.3d 156, 161 (3d Cir. 2001) ("[A] complaint may be subject to dismissal under Rule 12(b)(6) when an affirmative defense ... appears on its face" (internal quotation marks omitted)) (cited with approval by *Jones*, 549 U.S. at 215); *Accord Goodman v. Praxair, Inc.*, 494 F.3d 458, 464 (4th Cir. 2007) (en banc) (affirmative defense may be resolved by Rule 12(b)(6) motion in "the relatively rare circumstances where facts sufficient to rule on an

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exemption from liability is "in the orthodox format of affirmative defense," Court is compelled to hold that defendant must convince factfinder of exemption's applicability); *see also* James Bradley Thayer, A PRELIMINARY TREATISE ON EVIDENCE 368-369 (1898) ("In general, he who seeks to move a court in his favor, whether as an original plaintiff . . . or as a defendant . . . must satisfy the court of the truth and adequacy of the grounds of his claim, both in point of fact and law."). Even in the unusual circumstance in which the plaintiff has better access than the defendant to the information relevant to an affirmative defense, this Court has declined to alter the usual rule of pleading and proof. *See Taylor v. Sturgell*, 553 U.S. 880, 907 (2008).

affirmative defense are alleged in the complaint"); *EPCO Carbon Dioxide Prods., Inc. v. JP Morgan Chase Bank, N.A.*, 467 F.3d 466, 470 (5th Cir. 2006) (defense must appear on face of the complaint); *McKenna v. Wright*, 386 F.3d 432, 436 (2d Cir. 2004) (at motion to dismiss stage, plaintiff is entitled to all reasonable inferences that both support his claim and rebut the affirmative defense); *Jacobs v. City of Chicago*, 215 F.3d 758, 775 (7th Cir. 2000) (Easterbrook, J., concurring in part and concurring in the judgment) (noting that Rule 12(b)(6) is a poor fit for resolving affirmative defenses that are based on factual determinations); 5B WRIGHT & MILLER, FEDERAL PRACTICE AND PROCEDURE: CIVIL 3D § 1357, at 708-10 (2004).

This general observation about affirmative defenses is reflected in this Court's preemption case law. Although this Court has considered preemption defenses at many different procedural stages, it has never dismissed on preemption grounds at the motion to dismiss stage when the defense, as in the instant case, hinges on historical facts that are subject to resolution by a traditional factfinder. At the motion to dismiss stage, preemption can only succeed as a defense when the complaint itself establishes the facts upon which the preemption defense rests. Accordingly, when a preemption defense implicates only legal considerations, as in complete preemption, this Court has not hesitated to resolve such issues at the pleading stage. *See Rush Prudential HMO, Inc. v. Moran*, 536 U.S. 355, 374-375 (2002) (resolving express preemption claim at complaint stage). This Court, however, has yet to

resolve an implied conflict preemption case in favor of the party seeking preemption at the motion to dismiss stage, where a factual inquiry was necessary to determining the existence of preemption. *See Geier v. American Honda Motor Co., Inc.*, 529 U.S. 861, 865 (2000) (decided after summary judgment); *California v. ARC America Corp.*, 490 U.S. 93, 99 (1989) (decided after settlement); *Hillsborough County,* 471 U.S. at 711 (decided after bench trial); *cf. Wyeth*, *supra* 129 S. Ct. at 1193 (decided after jury trial).[5] And many of the express preemption cases have also been resolved at advanced procedural stages. *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996) (summary judgment); *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504 (1992) (jury trial); *Fidelity Federal Sav. & Loan Ass'n v. de la Cuesta*, 458 U.S. 141 (1982) (summary judgment).

If there were any doubt upon whom the burden rests in a case like this, it is resolved by *Wyeth*, in which the Court stated it would not find impossibility preemption "absent clear evidence that the FDA would not have approved a change to Phenergan's label." 129 S. Ct. at 1198. That the evidence had to be supplied by Wyeth and not raised at the pleading stage by the injured consumer is

[5] One case in which the Court resolved preemption on an implied preemption theory at the motion to dismiss stage, *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001), is notable both for its application solely to fraud on the FDA claims and for basing its holding solely on legal conclusions, not on any factual dispute. *Id.* at 348-49 (holding that FDCA created "comprehensive scheme" that displaced state law); *id.* at 352 (limiting reach of decision to "fraud –on-the-agency" state law claims).

further confirmed by the Court's emphasis that "Wyeth has offered no such evidence," that it "cannot credit Wyeth's contention that the FDA would have prevented it from adding a stronger warning," and that "Wyeth has failed to demonstrate" an entitlement to the "demanding defense" of impossibility preemption. *Id.* at 1198-99. Similarly, when discussing Wyeth's alternative argument for implied preemption based on a frustration of Congressional purpose, the court found that "Wyeth has not persuaded us that failure-to-warn claims like Levine's obstruct the federal regulation of drug labeling." *Id.* at 1204. Petitioners and their *amici* claim that the instant case is different because here, in contrast to *Wyeth*, any action by the FDA is purely speculative and therefore cannot be established by the plaintiff, but this begs the question of who bears the burden of establishing this element of the preemption defense. As the foregoing discussion makes clear, it is inconsistent with pleading doctrine to place that burden on a plaintiff.[6]

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[6] Consistent with the view that preemption is an affirmative defense, this Court has treated the defense as one that can be waived or forfeited if not raised below, although an appellate court has discretion to consider a late-raised argument. *See Exxon Shipping Co. v. Baker*, 554 U.S. 471, 486-87 (2008) (considering preemption argument even though it had been raised in an untimely manner). The Court has treated preemption as jurisdictional only when the federal law purports to displace entirely state court jurisdiction by providing exclusive federal jurisdiction over the dispute. *See International Longshoremen's Ass'n, AFL-CIO v. Davis*, 476 U.S. 380, 393 (1986).

B. Petitioners' Argument Is In Irreconcilable Tension with Decades of Subject Matter Jurisdiction Jurisprudence

The standard pleading rule imposing on defendants the burden of raising an affirmative defense and not requiring plaintiffs to anticipate such a defense in the complaint is not simply a rule borne of administrative convenience regarding which party is in the best position to plead a particular set of facts. In addition, the Court's subject matter jurisdiction jurisprudence makes clear that the allocation of pleading burdens is necessary to vindicate the federalism concerns that inform the division of jurisdiction between the state and federal systems. This Court has consistently taken these concerns into account by holding that the facts rebutting preemption play no role in the plaintiff's affirmative case. Petitioners pay no heed to this long-standing precedent.

Although the cases at bench are amenable to federal jurisdiction because of diversity of citizenship, petitioners' argument, if accepted, would have radical consequences for "arising under" jurisdiction pursuant to 28 U.S.C. § 1331. The Court has stated multiple times that plaintiffs cannot create federal question subject matter jurisdiction under 28 U.S.C. § 1331 by including as part of their affirmative claim allegations that anticipate the preemption defense – it is a long established application of the "well pleaded complaint rule." *See Caterpillar, Inc. v. Williams*, 482 U.S. 386, 393

(1987) (describing "settled law" that arising under jurisdiction cannot be based on preemption defense); *Franchise Tax Board of California v. Construction Laborers Vacation Trust*, 463 U.S. 1 (1983) (declining to exercise Section 1331 jurisdiction where federal issue only arose through preemption defense); *see also Louisville & Nashville R. Co. v. Mottley*, 211 U.S. 149 (1908) (introducing well-pleaded complaint rule); *Grable & Sons Metal Products, Inc. v. Darue Engineering & Mfg.*, 545 U.S. 308, 315 (2005) (applying well-pleaded complaint rule to quiet title action). Under this Court's rulings, first the plaintiff establishes a claim for relief and then the preemption defense comes into play. *See Franchise Tax Board*, 463 U.S. at 13-14. Accepting petitioners' argument, however, would imply that plaintiffs bringing state tort law claims that implicate preemption defenses would necessarily have to include facts rebutting such defenses to plead their cause of action. To hold that plaintiffs not only may but must plead facts tending to rebut the preemption defense would entirely undermine longstanding case law regarding limited federal subject matter jurisdiction and the Court's refusal to tolerate "artful pleading" to expand subject matter jurisdiction.

It is black letter law that a federal court lacks "arising under" jurisdiction via 28 U.S.C. § 1331 over a claim unless the federal issue is placed on the face of the well-pleaded complaint, as defined by the elements of the cause of action. The rule respects federalism by permitting the state in the first instance to apportion the pleading burden and by

ensuring that the federal courts will remain a limited forum, preventing an influx of state law claims into federal court simply because federal law provides a basis for a particular defense. *See Grable & Sons Metal Products*, 545 U.S. at 313-14 (finding arising under jurisdiction over state law claims "always raises the possibility of upsetting the state-federal line drawn . . . by Congress"); *Healy v. Ratta*, 292 U.S. 263, 270 (1934) (noting that federal jurisdiction is limited because of "[d]ue regard for the rightful independence of state governments"); Arthur R. Miller, *Artful Pleading: A Doctrine in Search of Definition*, 76 TEX. L. REV. 1781, 1783 (1998) ("artful pleading" doctrine respects power of state courts "to articulate and develop their own substantive law even when a federal issue may constitute an ingredient of a case").

This issue has arisen numerous times in the context of the defense of preemption, and the Court has consistently held, with limited exceptions having to do with "complete" preemption, that federal jurisdiction will not turn on whether preemption analysis will play a role in resolving a plaintiff's claim. The case upon which the "well pleaded" complaint rule rests, *Mottley*, is itself a precursor to preemption cases, and confirms that the defense of preemption is not part of the plaintiff's complaint. In *Mottley*, the federal issue that was claimed to form the basis for "arising under" jurisdiction was the plaintiffs' expectation that the defendants would argue that they could not comply with a contract to provide free rail transportation because doing so would directly conflict with a federal statute. 211

U.S. at 150. In other words, *Mottley* was an early example of conflict preemption, and the Court found that jurisdiction was not proper despite the fact that the parties agreed that the construction and validity of the federal law was a critical aspect of the dispute.

More recently, in *Franchise Tax Board*, the Court found that there was no federal subject matter jurisdiction over a California state law claim that the defendants claimed was preempted by ERISA. 463 U.S. at 13-14. California law established the elements of the claim "without reference to federal law" and therefore "federal law becomes relevant only by way of a defense to an obligation created entirely by state law, and then only if appellant has made out a valid claim for relief under state law." *Id.* at 13. This was precisely the situation for which the well-pleaded complaint rule was adopted, despite the fact that all parties agreed that preemption analysis would ultimately resolve the dispute in question. *See id.* at 12; *accord Caterpillar, Inc.*, 482 U.S. at 393.

The Court has articulated only two exceptions to this rule, neither of which applies here. First are those cases in which Congress explicitly provides for jurisdiction over state law claims in federal court, such as in the Price-Anderson Act, 42 U.S.C. § 2014(hh). *See Beneficial Nat. Bank v. Anderson*, 539 U.S. 1, 6 (2003); *El Paso Natural Gas Co. v. Neztsosie*, 526 U.S. 473, 484-485 (1999). There is no basis for finding this exception to apply here. The second exception is when a federal statute completely preempts a state law action; that is

where "federal statutes at issue provide[] the exclusive cause of action for the claim asserted and also set forth procedures and remedies governing that cause of action." *Beneficial Nat. Bank*, 539 U.S. at 8. In this circumstance the state law claim is said to be "recharacterized" as a federal claim, because federal law provides the relevant and exclusive cause of action. *See Metropolitan Life Ins. Co. v. Taylor*, 481 U.S. 58, 64 (1987) (finding that some state tort claims were completely preempted by ERISA); *Avco Corp. v. Aero Lodge No. 735, Intern. Ass'n of Machinists and Aerospace Workers*, 390 U.S. 557, 560-561 (1968) (finding complete preemption of some state law claims by Labor Management Relations Act). It is noteworthy that this Court has applied this recharacterization analysis in only two circumstances, for some claims implicating ERISA and the LMRA. Indeed, the tension between *Franchise Tax Board* and the line of authority that began with *Avco* has been criticized, with some Justices arguing that the *Avco* line is an unwarranted exception to the "well-pleaded complaint rule." *See Beneficial Nat. Bank*, 539 U.S. at 12-13 (Scalia, J., dissenting). In any event, no one maintains here that the FDCA creates a cause of action that displaces the state law failure to warn claims at issue here.

Petitioners' position would thus not only conflict with basic pleading doctrine, it also would turn principles of "arising under" jurisdiction on their head. Accepting petitioners' argument would require plaintiffs not only to anticipate the affirmative defense of preemption in their

complaints, but would actually turn the facts rebutting preemption into an element of the plaintiffs' substantive legal claim. What once was "artful pleading" would now be considered required pleading. Perhaps more troubling, the principles of federalism which call for limited federal subject matter jurisdiction would no longer be operative in the preemption context.

II. The Presumption Against Preemption Squarely Places the Burden of Showing Preemption on Petitioners

The need for defendants to plead and prove their entitlement to a preemption defense is consistent not only with basic rules of pleading and subject matter jurisdiction principles, but it also is the most coherent way to integrate the background presumption against preemption into the pleading context. Although Petitioners' *amici* have questioned whether the presumption against preemption applies here, *see* Br. for *Amici Curiae* Morton Grove Pharm., Inc., *et al.* 18-19, this Court only two years ago reaffirmed the presumption in a similar context. *See Wyeth*, 129 S. Ct. at 1194-95; *see also Lohr*, 518 U.S. at 485. This presumption is particularly applicable in the field of state tort law, including failure to warn claims, where a preemption defense would implicate the "historic police powers of the States." *Wyeth* at 1194-95. Thus, the presumption against preemption operates to require that an important national governmental interest be shown to justify infringing on the traditional state law power to regulate products based on health and

safety concerns. In the field of drug law, then, the presumption against preemption ensures that consumers will be protected as much as possible by their own states' laws, except when it conflicts with a very important national interest.

To the extent that the presumption has ever been called into question, it is in areas that do not implicate federalism concerns, such as fraud-on-the-agency claims. *See Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341, 351-52 (2001) (distinguishing traditional state tort law claims from a fraud-on-the-agency claim). *Wyeth* made this crystal clear when it rejected a similar argument to abandon the presumption against preemption for all implied preemption cases, terming any reliance on *Buckman* "especially curious, as that case involved state-law fraud-on-the-agency claims, and the Court distinguished state regulation of health and safety as matters to which the presumption does apply." 129 S. Ct. at 1195 n.3.

The reason for the presumption against preemption jibes well with the federalism concerns that inform principles of federal subject matter jurisdiction articulated above: absent "the clear and manifest purpose of Congress," this Court will not construe federal acts to override the powers of the State to regulate within its traditional police powers. *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947). Generally, principles of federalism permit both federal and state authorities to regulate health and safety issues; the question in preemption cases is whether Congress has left room for the States to

operate as they traditionally have. Adhering to the presumption is necessary so that federal activity displaces as little state law as possible. *See* Stephen A. Gardbaum, *The Nature of Preemption*, 79 CORNELL L. REV. 767, 806-07 (1994).

Therefore, if Congress' intent is ambiguous, preemption must be rejected so as to protect state autonomy – to do otherwise "would evade the very procedure for lawmaking on which *Garcia* [*v. San Antonio Metro. Trans. Auth.*, 469 U.S. 528 (1985)] relied to protect states' interests." *Gregory v. Ashcroft*, 501 U.S. 452, 464 (1992) (internal quotation marks omitted). Petitioners and their *amici* would go beyond what was rejected in *Garcia* and *Gregory* – they ask this Court to hold that preemption is available simply because of the failure of plaintiff to plead facts tending to rebut the preemption defense. The procedural requirement that defendants show an entitlement to the preemption defense at the motion to dismiss stage by demonstrating that their entitlement appears on the face of the complaint is therefore the only way to operationalize the presumption against preemption in the pleading context. Any other result would leave state autonomy in the hands of the drafters of a plaintiff's complaints, depriving states of the protection afforded by requiring that Congress clearly indicate its intent to preempt state law claims. Needless to say, this turns the presumption against preemption on its head. Instead of the presumption operating to ensure that those with the most incentive to invoke preemption – regulated entities – plead and prove it, it leaves to individual

plaintiffs the burden of pleading and proving a lack of preemption. It would become a presumption in name only.

III. Petitioners' Reliance on the Element of Causation Cannot be Squared with the Elements of the Claim at Issue

Despite the requirements of pleading and preemption law, petitioners and their *amici* argue that for respondents to plead causation, they must allege the FDA would have approved a request for a more stringent warning had it been provided with relevant information about the safety of Metoclopramide from petitioners. Although petitioners attempt to couch this argument as somehow separate from preemption, for the reasons explained above, this is untenable. To the extent that petitioners seek to argue as a matter of state tort law that such a causation requirement exists, this contention is without merit for several reasons.

First, the question of whether such a requirement exists is solely a function of state substantive law, the content of which is not before this Court. Even so, as a matter of basic tort law in Louisiana and Minnesota, where respondents filed suit, the element of causation requires only that respondents show that but for an inadequate warning they would not have been injured. *Willett v. Baxter Int'l Inc.*, 929 F.2d 1094, 1098 (5th Cir. 1991) (in failure to warn case under Louisiana law, causation is established by showing that relevant decision-maker would have acted differently had an

adequate warning been provided); *Gray v. Badger Min. Corp.*, 676 N.W.2d 268, 276 (Minn. 2004) (holding that causation inquiry in failure to warn cases focuses on whether parties would have acted differently with adequate warning). Indeed, in *Wyeth*, the Court explicitly treated the question of causation – whether the plaintiff's injury would "have occurred if Phenergan's label had included an adequate warning" – to be a matter of tort law, separate from the question of preemption. 129 S. Ct. at 1194 & n.2 ("The dissent's frustration with the jury's verdict does not put the merits of Levine's tort claim before us, nor does it change the question we must decide-whether federal law pre-empts Levine's state-law claims."). Preemption cannot both be an affirmative defense and redefine the elements of a plaintiff's prima facie case. *Meacham*, 554 U.S. at 93; *Public Employees Retirement System of Ohio v. Betts*, 492 U.S. 158, 181 (1989), *superseded by statute on other grounds*, Public Law No. 101-433, 104 Stat. 978 (1990).

Second, to the extent that causation is in dispute, it is not a matter that can be resolved at the pleading stage. Causation is a fact-intensive inquiry that normally is resolved after discovery, at summary judgment or trial. *See*, *e.g.*, *Coray v. Southern Pac. Co.*, 335 U.S. 520, 523-24 (1949) (finding that issue of proximate cause in negligence case was question for jury); *Garnier v. Rodriguez*, 506 F.3d 22, 27 (1st Cir. 2007); *Bailey v. Floyd County Bd. of Educ. By and Through Towler*, 106 F.3d 135, 145 (6th Cir. 1997). Even in the context of Article III standing, which requires that a plaintiff

prove causation not only as an element of its claim but also to invoke federal jurisdiction, this Court has recognized that at the motion to dismiss stage, "general factual allegations of injury resulting from the defendant's conduct may suffice." *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 561 (1992) (recognizing that at summary judgment, plaintiff will have to put forward more specific evidence to establish standing); *Miccosukee Tribe of Indians of Florida v. Southern Everglades Restoration Alliance*, 304 F.3d 1076, 1081 (11th Cir. 2002) (finding injury-in-fact and causation sufficiently alleged at motion to dismiss stage)

Petitioners and their *amici* imply that preemption is required here not only because plaintiffs cannot show that the FDA would have approved more stringent warnings had it been provided with additional information, but also because even making the inquiry into what the FDA would have done conflicts with federal authority over drug regulation because it invites speculation about federal decisionmaking. *See* Br. of Petr's Pliva, *et al.* 53-55; Br. of *Amici Curiae* Morton Grove Pharm., Inc. *et al.* 27-28. Thus, the argument goes, focusing on the counterfactual question about what the FDA would or would not have done itself interferes with federal law and calls for preemption here. This argument is without merit. When one recognizes that the burden of establishing preemption falls on the party seeking to invoke the defense, it is clear that requiring regulated entities to show that the FDA would not have acted actually assists federal regulation. This rule puts the incentive to provide

information to the FDA on the proper parties – the regulated entities – thus ensuring that the FDA is regulating with the full slate of available information. *See Wyeth*, 129 S. Ct. at 1202 (noting FDA's limited resources and incentive provided by state tort actions). The alternative would leave the FDA in the position of regulating the field alone, with regulated entities having little to no incentive to provide new information to improve the quality of regulation. *See id.* at 1202-03 & n. 12; *Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 451-52 (2005) (noting that state law tort claims tend to reinforce agency regulation); Thomas O. McGarity, THE PREEMPTION WAR 1-17 (2008) (detailing Vioxx's regulatory history and the withholding of relevant safety data from the FDA).

This Court's decision in *Arkansas Louisiana Gas Co. v. Hall*, 453 U.S. 571 (1981) (*Arkla*), is not to the contrary. There the claim itself – not a defense – rested on a proposition about what the Federal Energy Regulatory Commission would have done had respondents sought a change in the contract price for natural gas. *Id.* at 574. Moreover, in *Arkla*, FERC had taken a formal position in opposition to respondents' claim and the operative statute directly conflicted with the basis for respondent's affirmative claim. *Id.* at 579-80. Finally, it is instructive that the respondents were a regulated entity in *Arkla* – thus the Court's decision operated to place on the *Arkla* respondents the same incentive that properly is placed on petitioners here: to cooperate with and provide new information to the relevant regulatory agency.

CONCLUSION

For the reasons set forth above and in respondents' brief, *amici* respectfully urge the Court to affirm the judgments below.

Respectfully submitted,

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