IN THE SUPREME COURT FOR THE
STATE OF GEORGIA

AMERICAN HOME PRODUCTS CORP. d/b/a/ WYETH, et al.,	:	**CASE NO. S0761708**
Appellants,	:	
v.	:	
MARCELO A. FERRARI, et al.,	:	
Appellees.	:	

BRIEF OF *AMICI CURIAE* CHAMBER OF COMMERCE OF THE UNITED STATES OF AMERICA AND CROPLIFE AMERICA IN SUPPORT OF APPELLANTS

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Pursuant to Rule 23, the Chamber of Commerce of the United States of America ("the Chamber") and CropLife America are filing this *amicus curiae* brief in support of the Appellants to urge this Court to reverse the decision of the Court of Appeals, *Ferrari v. American Home Products Corp.*, 650 S.E.2d 585 (Ga. Ct. App. 2007). That decision is predicated upon a misreading of *Bates v. Dow AgroSciences LLC*, 544 U.S. 431 (2005). The Supreme Court's most recent opinion on federal preemption of product liability claims, *Riegel v. Medtronic, Inc.*, 128 S. Ct. 999 (2008), demonstrates that the Court of Appeals erred by reading *Bates* to have fundamentally altered the way that courts interpret federal statutes' preemption provisions.

IDENTITY AND INTEREST OF *AMICI CURIAE*

The Chamber of Commerce of the United States of America is the world's largest business federation, representing an underlying membership of three million businesses and organizations of every size, in every industry, and from every sector of the nation. The Chamber's mission includes representing its members' interests by filing *amicus curiae* briefs in federal and state appeals involving issues that are important to the American business community. For example, over the years the Chamber has submitted to federal and state courts a substantial number of *amicus* briefs regarding the proper interpretation and

application of federal statutes that preempt product liability claims involving products whose safety and use are regulated by the Federal Government.

CropLife America is the national trade association for the plant science industry. Its member companies develop, produce, sell, and distribute virtually all of the agricultural crop protection pesticides used by American farmers. Those pesticide products are comprehensively regulated by the United States Environmental Protection Agency (EPA) pursuant to the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"), 7 U.S.C. §§ 136-136y. As the nation's leading voice on federal and state issues affecting the pesticide industry, CropLife America has filed numerous *amicus* briefs involving FIFRA preemption of product liability claims that undermine EPA's regulation of pesticides.

Of particular interest in this appeal, in November 2004 both the Chamber and CropLife America submitted *amicus* briefs to the U.S. Supreme Court in *Bates v. Dow AgroSciences LLC*, 544 U.S. 431 (2005), a pesticide-related product liability case limited to interpreting the scope of FIFRA's express preemption provision, 7 U.S.C. § 136v(b). More recently, in October 2007, both the Chamber and CropLife America submitted *amicus* briefs to the Supreme Court in *Riegel v. Medtronic, Inc.*, 128 S. Ct. 999 (2008), a product liability case which involved interpretation and application of the express preemption provision contained in the

Federal Food, Drug, and Cosmetic Act's Medical Device Amendments of 1976 ("MDA"), 21 U.S.C. § 360k(a).

The Chamber and CropLife America are submitting an *amicus* brief in this appeal because the Court of Appeals of Georgia predicated its opinion upon the erroneous premise that a fragment of *dicta* in *Bates* is "pivotal language" that "drastically changes traditional preemption analysis" in a way that "applies to the analysis of any express preemption statute" and imposes upon courts "a *duty to accept* the reading of an express preemption statute that disfavors preemption," even where, as is the case here, there is "clear legislative history to the contrary." *Ferrari v. Am. Home Prods. Corp.*, 650 S.E.2d 585, 589, 590, 590 n.10 (Ga. Ct. App. 2007). In essence, the Court of Appeals misread *Bates* as requiring courts, when construing the scope of a federal statute's express preemption provision, to apply an *unrebuttable* presumption against preemption (i.e., to conclude that state law is not preempted) whenever an interpretation that disfavors preemption is "plausible."

The Supreme Court did not adopt such an extreme new rule. Cases after as well as prior to *Bates* reflect sharp disagreement within the Court as to whether even a *rebuttable* presumption against preemption should apply to interpretation of an express preemption provision. In particular, the Supreme Court's recent 8-1 decision in *Riegel*, holding that § 360k(a) of the MDA expressly preempts the

plaintiffs' medical device product liability claims, demonstrates that the Court of Appeals misread *Bates*. *Amici* believe that it is important for this Court to pointedly and explicitly reject the lower court's misinterpretation of *Bates* before it is relied upon by any other court either within or outside Georgia.

ARGUMENT

AS DEMONSTRATED BY THE U.S. SUPREME COURT'S RECENT OPINION IN *RIEGEL v. MEDTRONIC*, THE COURT OF APPEALS MISINTERPRETED *BATES*

A. *Bates* Is a Narrowly Focused Opinion

Bates v. Dow AgroSciences does not warrant the "landmark" status assigned to it by the Court of Appeals in its opinion below, *Ferrari*, 650 S.E.2d at 588. To be sure, *Bates* is the only U.S. Supreme Court case to address the applicability of FIFRA's express preemption provision, 7 U.S.C. § 136v(b), to pesticide-related product liability claims. But as demonstrated by the Court's 8-1 decision in *Riegel v. Medtronic*, the *Bates* decision did not effect the jurisprudential sea change to which the Court of Appeals claimed to be bound in holding that Appellees' vaccine-related design defect claims are not expressly preempted by the National Childhood Vaccine Injury Compensation Act, 42 U.S.C. § 300aa-22.

Section 136v(b) of FIFRA provides that a "State shall not impose any requirements for [pesticide] labeling or packaging in addition to or different from those required under [FIFRA]." 7 U.S.C. § 136v(b). Consistent with a multitude of pre-*Bates* pesticide decisions, *see, e.g.*, *Banks v. ICI Americas, Inc.*, 450 S.E.2d

671, 676 (Ga. 1995) (citing *Papas v. Upjohn Co.*, 985 F.3d 516 (11th Cir. 1993)), *Bates* held that § 136v(b) "reaches beyond positive enactments, such as statutes and regulations, to embrace common-law duties," but affords pesticide manufacturers only limited immunity from product liability suits. *Bates*, 544 U.S. at 443. Quoting FIFRA-specific language, the Court held that § 136v(b) preempts "a particular state rule" only if it satisfies two conditions: "First, it must be a requirement '*for labeling or packaging*,'" and "[s]econd, it must impose a labeling or packaging requirement that is '*in addition to or different from* those required under [FIFRA].'" *Id.* at 444 (quoting 7 U.S.C. § 136v(b)). Applying the first prong of this test for express preemption under § 136v(b), the Court held that unlike the petitioners' "fraud and negligent-failure-to-warn claims," which "are premised on common-law rules that qualify as 'requirements for labeling or packaging,'" *id.* at 446, their "claims for defective design, defective manufacture, negligent testing, and breach of express warranty are not pre-empted," *id.* at 444, because "[n]one of these common-law rules requires that manufacturers label or package their products in any particular way," *ibid.*

In the section of *Bates* which the Court of Appeals found to be "pivotal" and "outcome determinative" to interpretation of the Vaccine Act's preemption provisions, and indeed, "to the analysis of any express preemption statute, *Ferrari*, 650 S.E.2d at 589, 590, 590 n.10, the Supreme Court addressed the second prong

of its two-part test for preemption of pesticide-related product liability claims under § 136v(b) of FIFRA. More specifically, the Court interpreted the meaning of the phrase "in addition to or different from" in § 136v(b)—a phrase which nowhere appears, or has an analog, in § 300aa-22 of the Vaccine Act. *See Bates*, 544 U.S. at 447-48. The Court adopted a "'parallel requirements' reading of § 136v(b)" that excludes from preemption "a state-law labeling requirement . . . if it is equivalent to, and fully consistent with, FIFRA's misbranding provisions." *Id.* at 447.

In its "parallel requirements" discussion, the Court noted that "[c]onspicuously absent from the submissions by [Respondent] Dow and the [*amicus curiae*] United States is any plausible alternative interpretation of 'in addition to or different from' that would give that phrase meaning." *Id.* at 448. The Court then further indicated, in what only can be described as *dicta*, that "[e]ven if Dow had offered us a plausible alternative reading of § 136v(b) -- indeed, even if its alternative were just as plausible as our reading of that text -- *we would nevertheless have a duty to accept the reading that disfavors pre-emption.*" *Id.* at 449 (emphasis added).

B. *Bates* Does Not Require Courts To Interpret Express Preemption Provisions In a Manner That Disfavors Preemption

According to the Court of Appeals, "[t]he emphasized language above drastically changes traditional preemption analysis." *Ferrari*, 650 S.E.2d at 589. More specifically, the Court of Appeals asserted that

> [t]he pivotal language in *Bates* changed traditional preemption analysis in two ways: (1) There is no longer a rebuttable *presumption* against preemption, but a *duty to accept* the reading of an express preemption statute that disfavors preemption; and (2) preemption analysis ends with an examination of the statutory language alone. Under this approach, it appears that legislative history should no longer be examined to discern Congressional intent when an express preemption clause has two plausible alternative readings.

Ibid.

This radical interpretation of *Bates* is demonstrably incorrect. "*Bates* does not require a court to automatically accept a plausible interpretation of a statute which disfavors preemption. . . . the *Ferrari* holding takes only one part of the *Bates* ruling out of its context, and gives it broader scope than is appropriate." *Bruesewitz v. Wyeth, Inc.*, 508 F. Supp. 2d 430, 444 (E.D. Pa. 2007), *appeal docketed*, No. 07-3794 (3rd Cir. Sept. 24, 2007).

The Court of Appeals erroneously transformed a fragment of *dicta* from *Bates* into a Supreme Court "pronouncement" that supposedly is "outcome determinative" and "drastically changes" the manner in which courts must interpret

"any express preemption statute." *Ferarri*, 650 S.E.2d at 589, 590, 590 n.10. In reality, the *dicta* at issue merely refers to, and does not alter, the *rebuttable* "presumption against preemption"—a controversial feature of federal preemption jurisprudence which the U.S. Supreme Court has invoked sporadically when interpreting express preemption provisions. *See generally Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947) ("[W]e *start with the assumption* that the historic police powers of the States were not to be superseded by the Federal Act *unless that was the clear and manifest purpose of Congress*.") (emphasis added); *but see United States v. Locke*, 529 U.S. 89, 108 (2000) ("As *Rice* indicates, an 'assumption' of nonpre-emption is *not triggered* when the State regulates in an area where there has been *a history of significant federal presence*.") (emphasis added).

As further discussed below, for many years there has been sharp disagreement within the Supreme Court regarding whether even a *rebuttable* presumption against preemption should apply to interpretation of an express preemption provision, which normally "provides a reliable indicium of congressional intent with respect to state authority." *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 517 (1992). In view of the nature of this controversy, and contrary to the opinion of the Court of Appeals, *Bates* did not suddenly replace what at most is a *rebuttable* presumption against preemption with what amounts to

an *unrebuttable* presumption mandating that every express preemption provision, regardless of its legislative history or congressional intent, be construed against preemption of state law whenever such an interpretation is "plausible."

1. The majority opinion in *Bates*, which was authored by Justice Stevens, indicated that there is no "plausible alternative" to the "'parallel requirements' reading of § 136v(b)" of FIFRA. *Bates*, 544 U.S. at 447, 448. The opinion then proceeded to suggest that the Court still would have adopted its "parallel requirements" reading of § 136v(b) (i.e., a reading which "disfavors pre-emption" of state-law failure-to-warn claims that "parallel" federal pesticide requirements) "*[e]ven if* Dow [the pesticide manufacturer] had offered . . . a plausible alternative reading . . . indeed, *even if* its alternative were just as plausible as [the Court's] reading of that text." *Id.* at 449 (emphasis added). This *dicta*, which the Court of Appeals mistakenly elevated into a major doctrinal change, was nothing more than a hypothetical application of the general rebuttable presumption against preemption. Indeed, in quoting *Bates*, the Court of Appeals' opinion, 650 S.E.2d at 589, omits the Supreme Court's citations to, and reliance upon, its own precedents regarding the rebuttable presumption against preemption. *See Bates*, 544 U.S. at 449 (quoting *Rice*, 331 U.S. at 230 (classic statement of the presumption against preemption)); *ibid.* (citing *Medtronic, Inc. v. Lohr*, 518 U.S.

470, 485 (1996) (product liability case invoking the presumption against preemption)).

2. Subsequent Supreme Court decisions demonstrate that Justice Stevens' majority opinion in *Bates* neither eliminated the general rebuttable presumption against preemption nor replaced it with the strict, slanted rule of construction which the Court of Appeals read into *Bates*. For example, in a banking-related federal preemption case decided last year, Justice Stevens, joined by Chief Justice Roberts and Justice Scalia, authored a dissenting opinion which referred to "our presumption against preemption - a presumption I do not understand the Court to reject," as "basic rule, central to our federal system." *Watters v. Wachovia Bank, N.A.*, 127 S.Ct. 1559, 1578-79 (2007) (Stevens, J., dissenting). And in *Merrill Lynch, Pierce, Fenner & Smith v. Dabit*, 547 U.S. 71 (2006) (holding that a federal securities statute preempted certain state-law class-action claims brought by securities holders), Justice Stevens, writing for a unanimous Court, referred both to "the general 'presum[ption] that Congress does not cavalierly pre-empt state-law causes of action,'" *id.* at 87 (quoting *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996)), and *Bates*' observation "that a 'long history' of state-law tort remedy 'add[ed] force' to the presumption against pre-emption," *id.* at 88 (quoting *Bates*, 544 U.S. at 449). *See also Nat'l Ass'n of State Utility Consumer Advocates v. FCC*, 457 F.3d 1238, 1252 (11th Cir. 2006)

(applying the "presumption against preemption . . . to determine whether Congress granted the Commission authority to preempt the state regulation of line item billing" for cellular wireless services).

Most recently, Justice Ginsburg, in her dissenting opinion in *Riegel v. Medtronic* (a case which is discussed more fully later in this brief), invoked the presumption against preemption in discussing why, in her view, § 360k(a) of the MDA does not preempt product liability claims involving medical devices that have undergone the Food and Drug Administration's rigorous premarket approval process. *See Riegel*, 128 S. Ct. at 1013-14 (Ginsburg, J., dissenting). According to Justice Ginsburg, "[f]ederal laws containing a preemption clause do not automatically escape the presumption against preemption." *Id.* at 1014 (citing *Bates*, 544 U.S. at 449). As part of this discussion about the rebuttable presumption against preemption, Justice Ginsburg, quoting *Bates*, asserted that

> [a] preemption clause tells us that Congress intended to supersede or modify state law to some extent. In the absence of legislative precision, however, courts may face the task of determining the substance and scope of Congress' displacement of state law. Where the text of a preemption clause is open to more than one plausible reading, *courts ordinarily "accept the reading that disfavors pre-emption."* *Bates*, 544 U.S. at 449.

Riegel, *id.* at 1014 (emphasis added). Thus, Justice Ginsburg, quoting the very language at issue in this appeal, indicated that *Bates*' reference to "accept[ing] the reading that disfavors pre-emption" is simply another way of stating that, in her

view, a presumption against preemption "ordinarily" should apply to questions involving the scope of express preemption provisions that are susceptible to more than one interpretation. *See also id.* at 1016 n.9 (Ginsburg, J., dissenting) (referring to "the presumption against preemption operative even in construing a preemption clause").

3. Justice Ginsburg's dissenting opinion in *Riegel*—which nowhere asserts that *Bates* changed the manner in which federal preemption provisions should be interpreted—is the latest installment in the long ongoing debate within the Supreme Court regarding whether, in lieu of the ordinary rules of statutory construction, even a *rebuttable* presumption against preemption should apply to questions concerning the scope of an express preemption provision. That debate is reflected in *Bates* and earlier product liability preemption cases, as well as in *Riegel*. *See Bates*, 544 U.S. at 457 (Thomas, J., concurring in the judgment in part and dissenting in part) ("[T]he majority states that the presumption against pre-emption requires choosing the interpretation of § 136v(b) that disfavors pre-emption. . . . That *presumption does not apply*, however, *when Congress has included within a statute an express pre-emption provision*. . . . our task is to determine which state-law claims § 136v(b) pre-empts, *without slanting the inquiry* in favor of either the Federal Government or the States.") (emphasis added); *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996) ("[D]issenting Justices have

argued that this assumption should apply only to the question whether Congress intended any pre-emption at all, as opposed to questions concerning the *scope* of its intended invalidation of state law."); *Cipollone v. Liggett Group*, 505 U.S. at 545 (1992) (Scalia, J., concurring in the judgment in part and dissenting in part) ("[I]t seems to me that *assumption dissolves once there is conclusive evidence of intent to pre-empt in the express words of the statute itself*, and the only remaining question is what the *scope* of that pre-emption is meant to be.") (emphasis added).

In its opinion below, the Court of Appeals acknowledged that "[b]efore *Bates*, application of a presumption against preemption to questions concerning the *scope* of an express preemption clause was controversial." *Ferrari*, 650 S.E.2d at 589 (citing *Lohr* and *Cipollone*). It still is. The Court of Appeals illogically misread Justice Stevens' *dicta* in *Bates* as somehow resolving the debate over whether interpretation of express preemption provisions even should be subject to a *rebuttable* presumption against preemption by imposing what is tantamount to an *unrebuttable* presumption.

4. The Court of Appeals' notion that under *Bates*, "clear legislative history to the contrary" is immaterial to construing a preemption provision in a way that disfavors preemption, *Ferrari*, 650 S.E.2d at 590, makes its misreading of *Bates* even more problematic and improbable. It is axiomatic that "[t]he purpose of Congress is the ultimate touchstone of pre-emption analysis." *Cipollone*, 505

U.S. at 516 (internal quotation marks omitted). Thus, not surprisingly, the Supreme Court's opinion in *Bates* included a lengthy discussion of FIFRA's legislative history, *see* 544 U.S. at 437-41, 452 n.26, and analyzed the scope of the statute's preemption provision "[a]gainst this background," *id.* at 442. Subsequent to *Bates*, the Supreme Court has continued the practice of examining legislative history that conveys or reflects Congress' preemptive intent. *See, e.g., Mid-Con Freight Sys., Inc. v. Mich. Pub. Serv. Comm'n*, 545 U.S. 440, 449 (2005) ("Our reading of the [preemption provision's] text finds confirmation in historical context.").

5. Tracking the lower court's opinion, Appellees argue that under *Bates*, "if there is any rational interpretation of a federal statute that would permit the states to apply their own law to a case, the states are free to do so." Br. of Appellees at 17. If this were correct, it would be virtually impossible for Congress to enact a statute preempting state regulatory or tort law since any court that is disinclined to find preemption almost always could conclude that construing a preemption provision in a manner that excludes the state law at issue is a "plausible" or "rational" interpretation.

Appellees assert that the "justification for this approach is [that] it forces Congress *to be explicit* and politically accountable in drafting legislation that impinges on state authority." *Ibid.* (emphasis added). But Congress already knows

how to be explicit in drafting preemption provisions that express its intent regarding displacement of state law. In *Riegel*, for example, the Court found it unnecessary to rely upon FDA's position regarding the meaning of the MDA preemption provision because in view of "the broad language Congress chose in the MDA . . . the statute itself speaks clearly to the point at issue." 128 S. Ct. at 1008, 1009.

In contrast, under Appellees' unworkable approach to express preemption, Congress would have to anticipate every conceivable current and future type of state law (including every possible type of state-law product liability claim) that it intends to preempt, and then draft an incredibly precise preemption provision that *explicitly itemizes* each and every such law or claim. As Justice Scalia explained in a slightly different context, under such a rule

> [t]he statute that says *anything* about pre-emption must say *everything*; and it must do so with great exactitude, as any ambiguity concerning its scope will be read in favor of preserving state power. If this is to be the law, surely only the most sporting of congresses will dare to say anything about pre-emption.
>
> The proper rule of construction for express pre-emption provisions is . . . the one that is customary for statutory provisions in general: Their language should be given its ordinary meaning.

Cipollone, 505 U.S. at 548 (Scalia, J., concurring in the judgment in part and dissenting in part).

C. *Riegel* Demonstrates That the Court of Appeals Misinterpreted *Bates*

On February 20, 2008 the U.S. Supreme Court issued its opinion in *Riegel v. Medtronic, Inc.*, 128 S. Ct. 999. *Riegel* addressed the question of whether the MDA's express preemption provision, 21 U.S.C. § 360k(a), "bars common-law claims challenging the safety and effectiveness of a medical device given premarket approval by the Food and Drug Administration (FDA)." *Id.* at 1002. Despite what Justice Ginsburg, in her dissenting opinion, considered to be a plausible contrary reading of that preemption provision, the Court held 8-1 that § 360k(a) expressly preempts such claims. *Riegel*, the first Supreme Court decision concerning federal preemption of product liability claims since *Bates*, demonstrates that the Court of Appeals misunderstood and misread *Bates*.

Section 360k(a) of the MDA provides in pertinent part that "no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use *any requirement*—which is *different from, or in addition to*, any requirement applicable under this chapter to the device." 21 U.S.C. § 360k(a) (emphasis added). In *Bates*, the Court noted, 544 U.S. at 447, that this MDA preemption provision is "similarly worded" to the FIFRA preemption provision interpreted in that case.

The majority opinion in *Riegel*, authored by Justice Scalia, indicates that "[s]afety and effectiveness are the very subjects of the Riegels' common-law

claims, so the critical issue is whether New York's tort duties constitute 'requirements' under the MDA." 128 S. Ct. at 1007. In holding that those tort duties are "requirements" within the meaning of the § 360k(a) preemption provision, the Court cited its earlier holdings, including in *Bates*, "that a provision pre-empting state 'requirements' pre-empted common-law duties." *Ibid.* The Court reiterated in *Riegel* that "[a]bsent other indication, reference to a State's 'requirements' includes its common-law duties." *Id.* at 1008. In other words, as confirmed by *Riegel*, and contrary to the position that Appellees are advocating here, Br. of Appellees at 17, the Supreme Court did *not* hold in *Bates* that a federal preemption provision must "explicitly" refer to common-law claims or duties in order to preempt them.

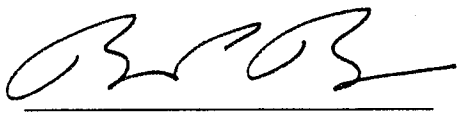
In her dissenting opinion, Justice Ginsburg set forth a detailed discussion as to why, in her view, it is plausible (indeed, necessary) to read § 360k(a) of the MDA in a manner that excludes preemption of common-law claims for defectively designed or inadequately labeled medical devices. To support that interpretation of the preemption provision, Justice Ginsburg recounted the MDA's legislative history. *See Riegel*, 128 S. Ct. at 1014-18. As discussed earlier in this brief, she also referred to the general rebuttable presumption against preemption, including by quoting the *Bates dicta* at issue in this appeal. *See id.* at 1013-14 (Ginsburg, J., dissenting). But Justice Ginsburg nowhere contended that *Bates* replaced the

rebuttable presumption against preemption with an inflexible new rule that would compel the Court to adopt her reading of § 360k(a). None of the other eight Justices of the Supreme Court, including Justice Stevens, who authored the *Bates* opinion, read *Bates* that way either.

CONCLUSION

The Court of Appeals erred by predicating its opinion on a misreading of *Bates*. This Court, therefore, should reverse the opinion of the Court of Appeals.

Respectfully submitted,



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CERTIFICATE OF SERVICE

I hereby certify that I have this day served counsel for appellants and appellees with the foregoing Brief of *Amici Curiae* Chamber of Commerce of the United States of America and Croplife America in Support of Appellants, by depositing copy of same in the U.S. Mail with adequate postage affixed and addressed as follows:

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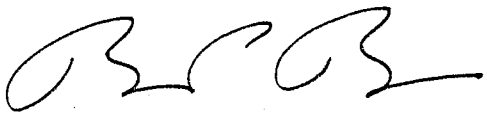

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March 3, 2008