Legal Backgrounder

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# FOUR MYTHS ABOUT FEDERAL PREEMPTION OF STATE TORT CLAIMS

by

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When the U.S. Supreme Court ruled last March in *Wyeth v. Levine*, 129 S. Ct. 1187 (2009), that the Federal Food, Drug, and Cosmetic Act (FDCA) does not preempt prescription drug failure-to-warn claims, the American Association for Justice (AAJ, formerly known as the Association of Trial Lawyers of America) proclaimed that the "Court reaffirmed the principle that state lawsuits perform a valuable and important function in ensuring accountability in uncovering drug hazards [and] rejected the FDA's attempts . . . to provide complete immunity to drug manufacturers." Public Citizen Litigation Group, announcing that it was "extremely gratified," declared that "legal immunity for the drug manufacturers - as called for by the drug companies and the Bush administration - would have been a huge mistake. . . . [T]he civil justice system . . . helps support, FDA authority to make drugs as safe and effective as possible." And *The New York Times*, in an editorial entitled "A Win for Injured Patients," predicted that

> [t]he 6-to-3 decision will benefit consumers at the expense of drug manufacturers.
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> It demolished the notion that federal regulatory rulings automatically pre-empt the states from enforcing even tougher standards on drugs. It also exposed as a sham the Bush administration's strenuous efforts to protect its allies in industry with phony pre-emption claims.
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> The decision to permit state damages suits . . . should force the manufacturers to exercise greater care in production and labeling.

These and similarly exaggerated pronouncements on the significance of *Wyeth* perpetuate the numerous myths surrounding federal preemption of product liability claims. The purpose of this LEGAL BACKGROUNDER is to identify and address four of the principal fallacies.

***Myth # 1: In the wake of* Wyeth, *federal preemption of product liability suits is dead***. Although *Wyeth* is a setback for the FDA and drug manufacturers, it is only the latest piece of a multi-dimensional tort preemption puzzle that the Supreme Court has still not figured out how to solve: During the past two decades, the Court has issued a confusing, erratic succession of fragmented tort preemption decisions involving various types of federally regulated products and state-law causes of action. In some cases, the Court has found express or

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implied preemption of particular types of claims,[1] and in others, such as *Wyeth*, it has not.[2] Practicing attorneys, as well as judges and legal scholars, have found it virtually impossible to reconcile these decisions.

So have members of the Supreme Court. *See, e.g., Wyeth*, 129 S. Ct. at 1222 (Alito, J., dissenting) ("In its attempt to evade *Geier*'s applicability to this case, the Court commits both factual and legal errors."); *Altria Group*, 129 S. Ct. at 553, 556 (Thomas, J., dissenting) ("[*Cipollone*] produced three separate opinions, none of which reflected the views of a majority of Justices. . . . Like *Cipollone* before it, *Lohr* produced a fractured decision featuring three opinions.").

The multiple opinions comprising many of the Court's product liability preemption cases reflect the deep and continuing divisions among the Justices over fundamental federal preemption principles. For example, in *Wyeth*, Justice Thomas filed a separate opinion concurring in the judgment, but criticizing the frequently invoked implied preemption doctrine known as "obstacle" or "frustration of purpose" or "purposes and objectives" preemption. *See* 129 S. Ct. at 1205, 1211 (Thomas, J., concurring in the judgment) ("I write separately . . . because I cannot join the majority's implicit endorsement of far-reaching implied preemption doctrines. . . . This Court's entire body of 'purposes and objectives' pre-emption jurisprudence is inherently flawed.").

But the most vivid and recurring example of how the justices simply cannot agree on basic federal tort preemption principles is the role, if any, of the so-called "presumption against preemption" in express and/or implied preemption analysis. *See, e.g., Wyeth*, 129 S. Ct. at 1195 n.2 (Stevens, J.) ("[T]he dissent argues that the presumption against pre-emption should not apply to claims of implied conflict pre-emption at all . . . but this Court has long held to the contrary."); *id*. at 1229 n.14 ("[I]t is not true that 'this Court has long' applied a presumption against pre-emption in conflict pre-emption cases."); *Altria Group*, 129 S. Ct. at 558 (Thomas, J., dissenting) ("In light of *Riegel*, there is no authority for invoking the presumption against pre-emption in express pre-emption cases."); *Riegel*, 128 S. Ct. at 1014 (Ginsburg, J., dissenting) ("Federal laws containing a preemption clause do not automatically escape the presumption against preemption.").

*Wyeth*, therefore, cannot be read in isolation, as if it were some beacon of clarity in the dense fog of Supreme Court product liability preemption jurisprudence. Furthermore, it is crucial to understand that *Wyeth* is limited to the doctrine of implied conflict preemption, since the FDCA's prescription drug provisions (unlike that statute's medical device provisions) do not include an express preemption clause. Only a year earlier, in *Riegel*, which involved a Class III medical device subject to intensive FDA premarket review, an 8-1 majority (including Justice Stevens) found express FDCA preemption of design and labeling defect claims.

One possible way to try to make sense of *Riegel* and *Wyeth* is to infer that the current Court is placing increased emphasis on express preemption, at the expense of implied preemption, in the product liability arena. Indeed, Justice Scalia, who authored the *Riegel* opinion, explicitly placed Congress on notice that when it enacts an express preemption provision prohibiting imposition of state requirements, "[a]bsent other indication, reference to a State's 'requirements' includes its common-law duties." 128 S. Ct. at 1008. In view of the solid majority in *Riegel*, there is no reason to think that *Wyeth* suddenly signals the end to preemption of product liability claims, especially where Congress has enacted a relatively clear express preemption provision. Indeed, even *Wyeth* "recognize[d] that some state-law claims might well frustrate the achievement of congressional objectives." 129 S. Ct. at 1204.

***Myth # 2: Federal preemption provides manufacturers with complete immunity from suit, and therefore, leaves injured plaintiffs without a remedy***. In a recent statement, AAJ thanked President Obama, "[o]n behalf of the thousands of people whose cases have been affected by *complete preemption immunity*" (emphasis added), for issuing a memorandum that purports to curtail federal departments and agencies from preempting state and local law (including state common law). No Supreme Court preemption decision, however, affords "complete" or "blanket" immunity to manufacturers in product liability cases. Instead, since *Cipollone* the Court has followed a claim-by-claim approach to analyzing federal preemption of damages actions. *See*

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[1] *See, e.g., Cipollone v. Liggett Group, Inc.*, 505 U.S. 504 (1992) (cigarettes); *Geier v. American Honda Motor Co.*, Inc., 529 U.S. 861 (2000) (automobiles); *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001) (medical devices); *Bates v. Dow AgroSciences*, LLC., 544 U.S. 431 (2005) (pesticides); *Riegel v. Medtronic, Inc.*, 128 S. Ct. 999 (2008) (medical devices).

[2] *See, e.g., Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996) (medical devices); *Sprietsma v. Mercury Marine*, 537 U.S. 51 (2002) (recreational boats); *Altria Group, Inc. v. Good*, 129 S. Ct. 538 (2008) (cigarettes); *Wyeth v. Levine* (prescription drugs).

*Cipollone*, 505 U.S. at 523 ("[W]e must look to each of petitioner's common-law claims to determine whether it is in fact pre-empted.").

For example, in *Bates*, the Court held that under the federal pesticide statute, failure-to-warn and fraud claims which are based on state-law duties that diverge from federal labeling requirements are expressly preempted. *See* 544 U.S. at 446-47. But the Court also held that claims for design and manufacturing defects, negligent testing, and breach of express warranty fall outside the scope of the statute's express preemption provision. *Id*. at 444. As another example, in *Riegel*, Justice Scalia, writing for the majority, indicated that the FDCA medical device preemption provision "does not prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations; the state duties in such a case 'parallel,' rather than add to, federal requirements." 128 S. Ct. at 1011; *see also Medtronic, Inc.* v. *Lohr*, 518 U.S. at 486 (rejecting any argument that "the statute pre-empts any and all common-law claims brought by an injured plaintiff against a manufacturer of medical devices").

To be sure, a successful federal preemption defense precludes a plaintiff from pursuing certain state-law causes of action. But in many cases, federal preemption does *not* deprive a particular plaintiff of all judicial recourse, for example, where a manufacturer is alleged to have produced an "off-spec" product containing a manufacturing flaw, or has failed to distribute a product with the labeling specified by a federal regulatory agency. In *Wyeth*, the plaintiff sued, and ultimately settled with, the medical clinic that botched the intravenous administration of a prescription drug, in addition to targeting the "deep pocket" drug manufacturer. Further, as in the case of the National Childhood Vaccine Injury Compensation Act, 42 U.S.C. § 300aa-1 *et seq*., Congress knows how to pair a federal compensation remedy with an express preemption provision when it deems that necessary and appropriate.

***Myth # 3: State tort suits complement federal regulation of potentially hazardous products***. From a public policy viewpoint, this myth is at the front line of the still ongoing tort preemption battle. Tort preemption opponents and their allies on the Supreme Court, such as Justice Stevens, contend that liability suits are a complementary form of state regulation because they (supposedly) provide a necessary incentive for manufacturers to design, test, and label their federally regulated products in a way that minimizes risks to consumers. *See*, *e.g.*, *Wyeth*, 129 S. Ct. at 1202 ("The FDA has limited resources to monitor the 11,000 drugs on the market. . . . State tort suits uncover unknown drug hazards and provide incentives for drug manufacturers to disclose safety risks promptly.").

Preemption proponents, however, argue that Congress has placed regulation of potentially hazardous products into the hands of expert federal agencies such as the FDA and the U.S. Environmental Protection Agency; that national uniformity of regulation promotes safety; and that allowing juries in liability suits to second-guess federal regulatory agencies' careful balancing of product risks vs. benefits necessarily undermines, and thus conflicts with, a federal regulatory scheme. *See*, *e.g.*, *id*. at 1222, 1229, 1230 (Alito, J., dissenting) ("[D]rug labeling by jury verdict undermines [the] workability of the federal drug-labeling regime. . . . By their very nature, juries are ill-equipped to perform the FDA's cost-benefit balancing function. . . . [T]he FDA conveys its warnings with one voice, rather than whipsawing the medical community with 50 (or more) potentially conflicting ones."); *see also Riegel*, 128 S. Ct. at 1008 ("A jury . . . sees only the cost of a more dangerous design, and is not concerned with its benefits; the patients who reaped those benefits are not represented in court.").

"Victims' rights" lawyers and legal activists frequently argue that manufacturers of federally regulated drugs, medical devices, pesticides, and other highly beneficial but potentially hazardous products need the "incentive" of potential tort liability to force them to design, test, and label their products in a safe manner, or to disclose newly discovered risks to federal regulatory agencies (disclosures that federal statutes typically make mandatory). This faulty argument assumes, without any empirical support, that most manufacturers of federally regulated products lack any sense of corporate social responsibility. For example, in its statement on *Wyeth*, the American Association for Justice asserted that the decision "proved that even if you are just one person, you can fight for justice and hold your *wrongdoer* accountable" (emphasis added). Not surprisingly, the Association's statement failed to note that the drug manufacturer had fully complied with FDA requirements by distributing its product with the precise, carefully considered labeling specified by that agency. *See Wyeth*, 129 S. Ct. at 1193.

The notion that state-law liability suits are, to use Justice Stevens' term, a "catalyst" for making federally

regulated products safer, *Bates*, 544 U.S. at 445, is dubious at best. In fact, elsewhere in *Bates*, Justice Stevens appears to contradict his own contention:

> A requirement is a rule of law that must be obeyed; an event, such as a jury verdict, that merely motivates an optional decision is not a requirement. The proper [preemption] inquiry . . . does not call for speculation as to whether a jury verdict will prompt the manufacturer to take any particular action (a question, in any event, that will depend on a variety of cost/benefit calculations best left to the manufacturer's accountants).

*Id*. at 445. Along the same lines, in a March 2007 *Trial* magazine article entitled "Why preemption proponents are wrong," Brian Wolfman, Director of Public Citizen Litigation Group, asserted that jury verdicts do not have the same regulatory effect as federal agency requirements:

> Large industry players generally react slowly, and sometimes not at all, to liability pressures. Most instances of liability are absorbed without a change in the manufacturer's conduct, or at least the kind of change that a regulator could bring about swiftly.
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> To the extent that tort law exerts a regulatory effect on a drug manufacturer, it does so only after repeated suits, settlements, and findings of liability — an even then the cause-and-effect relationship is rarely clear. . . . There is no reason to build a body of legal literature and judicial doctrine on the equivalency between tort and direct regulation when that equivalency is not remotely accurate.

Insofar as damage awards do not compel or even prompt manufacturers to change their products, they cannot function as a supplemental form of safety regulation. This is all the more reason to allow federal regulatory agencies to do their job, which is to regulate product risks and balance them against product benefits. Enabling myriad juries throughout the United States to second-guess federal regulatory agencies' product-specific risk/benefit determinations, such as what labeling and warnings should accompany a product, conflicts with that vital task. *See, e.g., Bates*, 125 S. Ct. at 452 ("[I]magine 50 different labeling regimes prescribing the color, font size, and wording of warnings. . . ."). Allowing juries to thwart nationally uniform safety regulation also may stifle innovative activity. *See Riegel*, 128 S. Ct. at 1009 ("[T]he solicitude for those injured by FDA-approved devices . . . was overcome in Congress's estimation by solicitude for those who would suffer without new medical devices if juries were allowed to apply the tort law of 50 States to all innovations.")

***Myth # 4: Federal tort preemption is an inherently polarizing issue***. Federal preemption is based directly on the Constitution's Supremacy Clause, Art. VI, cl. 2, which provides that federal law displaces state law when the two conflict. Thus, its application is rooted in federalism. To the extent that preemption provokes federalism, ideological, or policy issues, they should be resolved by Congress or the federal agencies to which regulatory authority has been delegated. The courts' proper role, of course, is to interpret the law, and in preemption cases, determine whether state law expressly or impliedly conflicts with federal law.

Furthermore, tort preemption opponents and proponents need not reflexively divide along traditional ideological (or political party) lines. "Conservatives" generally favor State's rights and oppose increased federal control over commerce or other economic activity. But conservatives nevertheless can and do support federal preemption of certain types of liability claims involving federally regulated products as a necessary restraint that helps to achieve the important goals of product safety and national regulatory uniformity.

"Liberals" traditionally support vigorous environmental, health, and safety protection through increased federal government regulation. But liberals can and should recognize that preemption of certain types of product liability claims fosters the role of the federal regulators on whom they rely, and also that state-by-state (or jury-by-jury) regulation of product safety can seriously undermine the efforts of those federal regulators.

If more focus were placed on regulatory realities, and less on ideologically or politically-tinged perceptions and myths, the result would be greater clarity on how federal preemption benefits regulators and consumers, as well as corporations confronted with product liability suits.

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