Federal Preemption at the Supreme Court

*By Daniel E. Troy & Rebecca K. Wood**

> This Constitution, and the Laws of the United States... shall be the supreme Law of the Land; and the Judges in every State shall be bound thereby, any Thing in the Constitution or Laws of any State to the Contrary notwithstanding.
>
> - U.S. Constitution, art. VI, cl. 2

It has been a striking time for federal preemption at the Supreme Court. Last term, the Court heard six preemption cases, deciding four in favor of federal preemption by large margins, one against preemption, and coming to a draw in the sixth case, in which Chief Justice Roberts did not participate.[1] In the coming term, the Court is poised to hear two additional significant preemption cases.[2] Although the number of preemption cases considered by the Court this term is actually somewhat below the historical average, the Court does appear to be deciding in favor of preemption somewhat more often than usual, and by greater margins.[3] This term's preemption decisions tended to reflect broad agreement, with a series of nine-, eight-, and seven-Justice majorities—often joining together some of the Court's most liberal and conservative members. The following Table illustrates the point.

October 2007 Term: Cases Involving Federal Preemption

Case	***Vote***			***Preemption Upheld***	***Express Preemption***
	Majority (* wrote)	Concur	Dissent		
Rowe v. N.H. Motor Trans. Ass'n	9 *Breyer*, Roberts, Stevens, Kennedy, Souter, Thomas Ginsburg, Alito, Scalia (in part)*	2 *Ginsburg, Scalia (in part)*	0	Yes	Yes
Riegel v. Medtronic	8 *Scalia*, Roberts, Kennedy, Souter, Thomas, Breyer, Alito, Stevens (in part)*	1 *Stevens (in part and in judgment)*	1 *Ginsburg*	Yes	Yes
Preston v. Ferrer	8 *Ginsburg*, Roberts, Stevens, Scalia. Kennedy, Souter, Breyer, Alito*	0	1 *Thomas*	Yes	Functionally (see discussion)
Exxon Shipping Co. v. Baker	8 (on this point) *Souter*, Roberts, Scalia, Kennedy, Thomas, Stevens, Ginsburg, Breyer (Alito took no part)*	2 *Scalia, Thomas*	0	No	Yes
Chamber of Commerce v. Brown	7 *Stevens*, Roberts, Scalia, Kennedy, Souter, Thomas, Alito*	0	2 *Breyer, Ginsburg*	Yes	Functionally (see discussion)
Warner-Lambert v. Kent	4 *unreported (Roberts took no part)*	0	4 *unreported*	*no opinion*	No

Critics from a variety of perspectives contend that the Court has "display[ed] a troubling trend" in favor of federal preemption that is inconsistent with the Court's supposedly traditional presumption against preemption.[4] We unpack this charge and offer several observations that may help explain where the Court is coming from and where it is going.

From the outset, it is worth pausing to review some preemption fundamentals. Simply stated, preemption is the power of federal law to trump state law in certain circumstances. Of course, preemption is nothing new. It is rooted in the Supremacy Clause of the Constitution, which establishes that the federal "Constitution, and the Laws of the United States... shall be the supreme Law of the Land; and the Judges in every State shall be bound thereby, any Thing in the Constitution or Laws of any State to the Contrary notwithstanding."[5] Under well-known standards, federal preemption may be "expressed or implied" in the pertinent federal regime.[6] Express preemption involves discerning the meaning of an explicit preemption provision. There are "at least two types of implied pre-emption: field pre-emption... and conflict pre-emption."[7] Field preemption recognizes limited, but exclusive, areas of federal domain even in the absence of an explicit preemption provision from Congress.[8] Conflict preemption tends to paint with a narrower brush and applies to particular issues "where it is impossible for a private party to comply with both state and federal law,"[9] or where state law "'stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress'" or of a federal agency acting within the scope of its congressionally delegated authority.[10]

Preemption debates can make for odd coalitions that appear to defy conventional Left/Right, liberal/conservative analysis.[11] On the one hand, plaintiffs' counsel, consumer groups, and state officials may contend that federal preemption improperly displaces the states' traditional police power to protect their citizens, particularly in matters involving public health and safety. On the other hand, federal agencies and

*Mr. Troy is Senior Vice President and General Counsel of GlaxoSmithKline. Until recently, he was a partner in the Life Sciences and Appellate practices at Sidley Austin LLP, and before that was former chief counsel of the Food and Drug Administration. Ms. Wood is a partner in the Appellate and Products Liability practices at Sidley Austin LLP. Mr. Troy and Ms. Wood have represented the party or amicus curiae in each of the three cases involving federal preemption in the prescription drug and medical device contexts at the Supreme Court in the last year (Warner-Lambert v. Kent, Riegel v. Medtronic, Inc., and Wyeth v. Levine). The views expressed here are solely their own. *Sidley Austin LLP also filed amicus briefs in two other cases discussed in this article: Exxon Shipping Co. v. Baker and Rowe v. N.H. Motor Trans. Ass'n. The authors would like to thank Carter G. Phillips and Eamon P. Joyce, their colleagues at Sidley Austin LLP, and Will Adams, a 2008 summer associate at Sidley Austin LLP and law student at Harvard Law School, for contributing to this article. A version of this article also will appear in the Cato Supreme Court Review.*

entities regulated by those agencies may urge that preemption is a necessary bulwark "against unwarranted and inconsistent state interferences with the national economy and against aggressive trial lawyers and attorneys general who upset carefully crafted regulatory compromises."[12] Even advocates of federalism, within its proper sphere, may recognize a profound need to protect regulated entities from contrary state-law liabilities when conduct is closely regulated and mandated by federal government action. Indeed, although their voting records are still emerging, it may well be that notwithstanding a general sympathy towards federalism (at least where the federal government is intervening in areas beyond its proper domain), Chief Justice Roberts and Justice Alito—both of whom were federal executive and judiciary branch officials for years before being elevated to the Court—are comfortable with upholding the exercise of federal power, at least when it occurs within its properly delegated realm. Indeed, they both joined the pro-preemption majority in each of the four preemption decisions they both participated in this term.

The tendency towards lopsided majorities that emerged in this term's preemption cases may be part of a more general and self-conscious effort by the Court to produce less fractured decisions and may also reflect several features about those cases. We make three general observations about the Court's current preemption cases:

First, there is a significant focus on statutory interpretation, rather than grand constitutional conflicts, such as federalism. Although not completely silent, the lurking federalism debate was largely quiet this term, especially where Congress had spoken in an express preemption provision or federal policy was otherwise clear. Indeed, a majority of the Court's cases involved express preemption—which requires discerning the meaning of an express statutory provision, rather than divining Congress's intent through the application of implied conflict preemption principles—or some functionally similar form of federal statutory analysis. This is not to suggest that implied preemption arguments are weaker as a doctrinal matter,[13] but the absence of text as a focal point may lead to a tendency to fracture and open the door to more controversial aspects of a preemption analysis. Unless one posits that the statutes at issue this term were simply unusually clear—a point that seems questionable given that the Court accepted review to answer disputes in the lower courts about their meaning—there seems to be something else going on. One answer is that they reflect a concerted and self-conscious effort, under the guidance of the new Chief Justice, to build consensus, even if it means issuing narrower rulings.

At his confirmation hearing, Chief Justice Roberts expressed a commitment to working towards increased clarity and uniformity in decisions: "one of the things that the Chief Justice should have as a top priority is to try to bring about a greater degree of coherence and consensus in the opinions of the court" because "we're not benefited by having six different opinions in a case."[14] In keeping with this goal, there has been some apparent movement towards narrower opinions that avoid hot-button, controversial issues in favor of a narrower position more justices can join. Although it is too soon to tell whether this will be a hallmark of the Roberts Court, a noticeable feature overall this term has been a decrease in 5-4 decisions. Overall, only 11 of the 67 signed opinions (16.4%) were decided 5-4; last term, in contrast, there were 24 split decisions in 69 signed opinions (34.3%).[15] In addition, the Court's business cases appeared to produce a higher level of agreement than non-business cases: though these cases accounted for less than 30% of the overall caseload, nearly half were decided by 9-0 or 8-1 margins.[16] For those living under these decisions, of course, this development may be something of a two-edged sword. On the one hand, increased clarity and certainty of legal rules as embodied in a single majority opinion may make it easier to appreciate and plan for risk—at least in fact patterns that closely resemble the case the Court decided. On the other hand, extremely narrow consensus opinions that hew closely to the circumstances in the given case may offer scant guidance beyond the four corners of the circumstances presented. Paradoxically, this may actually leave parties with less certainty and necessitate more litigation to unpack the outer boundaries of the Court's decision.

Second, other things being equal, the Court appears more inclined towards preemption where a case involves matters of special national interest or where an expert federal agency has issued a calibrated judgment that is threatened by contrary state action. The Court seems receptive to the plight of regulated entities that, absent preemption, would be subjected to a patchwork of dueling state and federal burdens. Of course, as detailed below, the perspective from which one begins this analysis—that of the regulating federal agency or the state—may influence where one ends up.

Third, a related point: the Court appears to take some comfort in the reality of a federal agency having applied its expert judgment within the scope of its delegated power and urging that there be preemption. It generally did so, however, without expressly wading into a formal—and sometimes divisive—analysis of the nature or degree of deference due to the agency.

I. Focus on Statutory Interpretation

A significant feature of this term's preemption cases is that rather than explicitly turning on sweeping philosophical debates about the merits of federal power-versus-federalism (sometimes embodied in presumptions about preemption)[17] or wading into administrative law battles about the degree of deference due federal agencies, many opinions hewed closely to the text of the federal statute, with a practical nod to the federal interests at stake in the overall federal scheme relating to that subject matter. Critics of judicial overreaching can take some comfort in this approach for interpretations that more closely follow the statutory text tend to give the political branches greater control.

Perhaps as a result of this tailored approach, this term's cases tended to produce significant pro-preemption majorities. Indeed, on the same day in February 2008, the Court issued a trio of preemption decisions in which it spoke in nearly one voice:[18] *Rowe v. New Hampshire Motor Transportation Association*[19] was unanimous on the core holding (with two justices also writing separate concurrences); *Riegel v. Medtronic, Inc.*[20] and *Preston v. Ferrer*[21] each had only one dissenter (with

one justice in *Riegel* also separately concurring in part with the majority). As detailed below, each of these cases turned on a federal statute with an express preemption provision—or at least a federal provision that operated very much as such. The Court embraced a textual approach, conscious of the overall statutory setting in which the provision arose, rather than engaging in a broader inquiry into any potential congressional purpose less readily reflected in the statutory language itself. Put another way, even if "[t]he purpose of Congress is the [Court's] ultimate touchstone" in judging preemption,[22] where that purpose can be discerned from text and statutory context, the justices appear to have been able to assemble larger coalitions in favor of preemption, without delving into perhaps more controversial discussions of legislative intent or other hot-button methods for decision-making.

Indeed, in both *Rowe* and *Riegel*, the Court's interpretation of the statutes' preemption clauses stayed close to the language of the express preemption provision—even though a minority of justices expressed doubt about whether Congress actually intended the preemption that resulted from this reading. For example, as Justice Stevens put it in his separate concurrence in *Riegel*, even though the "significance" of the express preemption provision perhaps "was not fully appreciated until many years after it was enacted" and "[i]t is an example of a statute whose text and general objective cover territory not actually envisioned by its authors," nevertheless, "'it is ultimately the provisions of our laws rather than the principal concerns of our legislators by which we are governed.'"[23] Thus, although Justice Stevens "agree[d]" with the "description of the actual history and principal purpose of the pre-emption provision at issue in this case" articulated in Justice Ginsburg's dissent, he—like the remaining seven justices—was "persuaded that its text *does* preempt."[24]

In contrast, as detailed below, where the preemption analysis did not principally involve construing an express preemption provision, the justices tended to be more fractured.

A. Rowe v. New Hampshire Motor Transport Association

In *Rowe*, the Court rejected a State's intent-based policy arguments about what the pertinent federal regime meant. Instead, the Court parsed the express preemption clause and focusing on precedent interpreting similar statutory language. At issue was an express preemption provision of the Federal Aviation Administration Authorization Act of 1994 (FAAAA) that prohibits states from enacting "any law 'related to' a motor carrier 'price, route, or service.'"[25] In the face of this provision, Maine enacted a law requiring companies shipping tobacco products into the state to use a delivery service that assured recipients were at least eighteen years old.[26] Invoking its earlier interpretation of similar preemption language in the Airline Deregulation Act of 1978, the Court began its analysis with the general principle of statutory interpretation that "'when judicial interpretations have settled the meaning of an existing statutory provision, repetition of the same language in a new statute indicates, as a general matter, the intent to incorporate its judicial interpretations as well.'"[27] Although the Court acknowledged that the Maine provision, in referencing "shippers" rather than "carriers," "is less 'direct' than it might be," even so, the effect is the same: "carriers will have to offer tobacco delivery services that differ significantly from those that, in the absence of [state] regulation, the market might dictate."[28] Accordingly, it is preempted.[29]

Maine urged that there should be an implied public health exception to the express preemption provision because its law "help[s] it prevent minors from obtaining cigarettes" and "federal law does not pre-empt a State's efforts to protect its citizens' public health, particularly when those laws regulate so dangerous an activity as underage smoking."[30] The state contended that an implied public health exception could be discerned based on legislative history and a separate federal enactment denying federal funds to states that refuse to forbid tobacco sales to minors.[31] Criticizing Maine's proposed exception as amorphous and without apparent limits, the Court made quick work of rejecting these arguments. Surveying the statute's list of express exceptions to the preemption provision, it found that none resembled the state's theory and refused to read into the statute exceptions that were not made explicit.[32] The Court likewise readily concluded that neither the legislative history nor a separate federal enactment answered the question presented.[33]

More broadly, the Court emphasized that a state's traditional interest in public health does not solve the preemption question here because "'[p]ublic health' does not define itself" and may depend on the "kind and degree" of the applicable risk. [34] Here, if all states individually could regulate carrier services, national uniformity would be undermined:

> Given the number of States through which carriers travel, the number of products, the variety of potential adverse public health effects, the many different kinds of regulatory rules potentially available, and the difficulty of finding a legal criterion for separating permissible from impermissible public-health-oriented regulations, Congress is unlikely to have intended an implicit general "public health" exception.[35]

Justice Ginsburg, who might be expected to be more receptive to arguments that sound in Congress's ultimate purpose, concurred in the result, even though she wrote separately to note that Congress probably did not intend a preemption outcome.[36] Noting that at the time of the FAAAA's passage there was a strong federal policy in favor of restricting minors' access to tobacco, she encouraged Congress to fill the "perhaps overlooked" regulatory gap FAAAA created.[37]

B. Riegel v. Medtronic

The Court continued its focus on the text of an express preemption provision in *Riegel*. There, the Court held that the express preemption provision of the Medical Device Amendments of 1976 (MDA) to the Federal Food, Drug, and Cosmetic Act (FDCA) barred certain state-law claims regarding the 1% of medical devices to which FDA had extended pre-market approval (PMA). The PMA process is FDA's most rigorous level of review, in which it determines the safety and effectiveness of a specific medical device after many hundreds or thousands of hours of agency review and imposes parameters on every aspect of the device, including its design and labeling.[38] The MDA prohibits States from enforcing any "requirement" for medical devices that is "different from, or in addition to, any [federal] requirement applicable... to the device."[39]

Riegel followed from the logic of *Medtronic, Inc. v. Lohr*,[40] in which FDA's generally less vigorous oversight of so-called 510(k) medical devices was held insufficient to impose federal "requirements" within the meaning of the express preemption provision. In so doing, *Lohr* juxtaposed the 501(k) process against the "rigorous" PMA process, observing that "[t]he § 510(k) notification process is by no means comparable to the PMA process."[41] It concluded that 501(k) review is "quite unlike a case in which the Federal Government has weighed the competing interests relevant to the particular requirement in question, reached an unambiguous conclusion about how those competing considerations should be resolved in a particular case or set of cases, and implemented that conclusion via a specific mandate on manufacturers or producers."[42] In the wake of *Lohr*, the vast majority of lower courts had recognized preemption in the PMA context.[43]

Riegel echoed this analysis.[44] See § III, *infra*. After concluding that PMA review imposed federal "requirements," the Court relied on a line of precedent to hold that state law claims—including common law claims and jury verdicts—constitute state "requirements" under the provision.[45] Because the state requirements plaintiff sought to enforce were different from the federal requirements, they were preempted under the terms of the express preemption provision.[46]

The sole *Riegel* dissenter, Justice Ginsburg, failed to persuade any other justice to withhold preemption based on a reading of what Congress may have intended when it enacted the MDA. Indeed, Justice Scalia, writing for the eight-justice majority, emphasized that its decision turned on the plain text of the statute and that it "is not [the Court's] job to speculate upon congressional motives."[47] In contrast, in dissent, Justice Ginsburg recounted the history surrounding the legislation's enactment, emphasizing that Congress passed the MDA around the time of the Dalkon Shield litigation, which had resulted in hundreds of lawsuits.[48] Given this context, the dissent opined that Congress was familiar with common law suits over medical devices and would have preempted common law claims more clearly if it had intended to do so.[49] As noted, this view failed to sway even one other justice, notwithstanding a nod from Justice Stevens to Justice Ginsburg's historical examination, in the face of the statutory enactment.

C. Preston v. Ferrer

Although there is some debate about whether it involves an express preemption provision as such, Preston provides another example of a large majority of Justices coalescing around the text of a federal provision that expressly privileges arbitration elected by private contract over court-based adjudication.[50] As all but one justice agreed, the Federal Arbitration Act (FAA) "declares a national policy favoring arbitration of claims that parties contract to settle in that manner" that "forecloses state legislative attempts to undercut the enforceability of arbitration agreements."[51] Indeed, "[t]he FAA's displacement of conflicting state law is now well-established and has been repeatedly affirmed."[52]

This case involved a contract between a television personality (Judge Alex) and his talent agent that required the parties to arbitrate "'any dispute... relating to the terms of [the contract] or the breach, validity, or legality thereof... in accordance with the rules [of the American Arbitration Association].'"[53] Judge Alex challenged the validity of the contract, urging that such matters must be heard by the state labor commissioner.[54] Justice Ginsburg, writing for an 8-1 majority, observed that the "best way to harmonize" the competing provisions was for the arbitrator, not the state labor commissioner, to decide the contract's validity under state law.[55] Even though the state eventually would have allowed arbitration to occur following the labor commissioner's review, such a delay in final resolution would be contrary to the FAA's purpose, to speed dispute resolution.[56] Alone in dissent, Justice Thomas did not expressly critique the majority's interpretation of the FAA, but wrote briefly to adhere to his position that the FAA does not apply to state proceedings.[57]

D. Chamber of Commerce v. Brown

Although the National Labor Relations Act (NLRA) contains no express preemption provision as such, a seven-Justice majority seized on language in a recent NLRA amendment, concluding that it "forcefully buttresses the pre-emption analysis," rendering preemption "both implicit and explicit" and making this case even "easier" than prior NLRA cases on point.[58]

At issue in *Brown* were provisions of California law that forbid employers that received state funds from using those funds to "assist, promote, or deter union organizing."[59] The Court held that Congress "implicitly mandated" preemption of certain matters "necessary to implement federal labor policy," including that "certain zones of labor activity be unregulated."[60] Although the NLRA prohibits employers from "interfer[ing] with, restrain[ing], or coerc[ing]" employees in their decisions whether to organize,[61] a later amendment to the Act clarified that an employer's "express[ion] of any views, argument, or opinion" about organizing that contains no threat of reprisal or a promise of benefit is not prohibited.[62] The Court focused on this amendment, calling it "explicit direction from Congress"[63] that employers and employees both should be allowed to enter a "free debate" about unionization.[64] Because the California statute curtailed this debate, the NLRA preempted it.

In dissent, Justices Breyer and Ginsburg urged that the case for preemption in the NLRA's text was not nearly as clear as the majority suggested. For one thing, the state statute did not explicitly regulate employers' speech. Employers that received state funds still could have expressed their opinion about union organizing; the state statute only said not to "do so on [the state's] dime."[65] The dissent charged that the majority's reliance on the state statute's preamble implicitly recognized this deficiency given that it was the preamble, rather than the statute's text, that detailed the state's policy "not to interfere with an employee's choice" about whether to unionize.[66] A reading of the statute more sympathetic to the state's position would have been that the state was merely trying to control how its money was spent and wanted to disengage from aiding one side in a labor dispute, in harmony with federal labor policy. But the presence of express language from Congress appeared to tip the balance for the majority.

E. Exxon Shipping Co. v. Baker

Although the focus of the *Exxon* case was punitive damages, the Court also had occasion to address briefly whether an express preemption provision of the Clean Water Act (CWA) preempts the availability of maritime punitive damages under federal common law.[67] The pertinent statutory provision protects "navigable waters... , adjoining shorelines, ... [and] natural resources," of the United States, subject to a savings clause that reserves "obligations... under any provision of law for damages to any publicly owned or privately owned property resulting from a discharge of any oil."[68] Although the Court struggled to discern the company's precise preemption theory, all eight justices participating in the decision found it "too hard to conclude that a statute expressly geared to protecting 'water,' 'shorelines,' and 'natural resources' was intended to eliminate *sub silentio* oil companies' common law duties to refrain from injuring the bodies and livelihoods of private individuals."[69] The Court also found "untenable" the argument that the CWA "somehow preempts punitive damages," but not compensatory damages.[70] Although the Court's preemption analysis is minimal, this appears to join the general trend of large majorities of justices coalescing around a specific statutory provision—this time all agreeing there was no preemption under the text.

F. Warner-Lambert v. Kent

In *Kent*—the sole exclusively implied preemption case the Court heard last term—the vote fractured 4-4.[71] Although there is no opinion from which reliably to discern what animated the different justices' votes, in contrast to the super-majorities witnessed in the five decisions in which the Court coalesced around an express (or pseudo-express) preemption provision, the absence of an express provision may have made consensus more difficult. This is not to suggest that the case for implied preemption is necessarily weaker in a given case than in the express preemption context—indeed, as detailed below, there was a strong case for implied preemption in *Kent*—but only that the absence of an express statute may open the door to additional doctrinal issues that make it harder for the Court to reach broad agreement. We address some of those currents below.

II. Federal and State Interests

Although the presence of express preemption provisions in a majority of the Court's cases allowed it to avoid focusing—or fracturing—on federal-versus-state power issues, there still appears to be a tendency to uphold preemption where the issue at hand was thought to be fundamentally federal. Indeed, although the Court sometimes has recognized a presumption *against* preemption in matters traditionally "reserved" to the states,[72] the rationale for any such thumb-on-the-scale evaporates when the federal government acts in an area in which it has "exclusive, or at least plenary, authority to regulate"[73] or where there is a conflict between federal and state law because "one can assume that Congress or an agency ordinarily would not intend to permit a significant conflict" between federal and state law.[74]

Historically, for example, the Court has been particularly willing to preempt state laws that touch on foreign affairs.[75] This approach is echoed in other federal contexts in which Congress, or an expert federal agency to which Congress delegated decision-making authority, see § III, *infra*, already has balanced and resolved competing policy objectives.[76] Indeed, despite the overall focus on statutory analysis, this theme played out in this term's decisions in which the Court noted established national policies governing motor carrier transportation (*Rowe*),[77] regulation of complex medical devices (*Riegel*),[78] arbitration of private disputes (*Preston*),[79] and labor law (*Brown*)[80] which the state laws at issue would undermine.

There also was a strong argument for the uniquely federal nature of the question at issue in *Kent*. That case involved a product liability suit filed against a pharmaceutical company alleging personal injuries caused by taking a prescription medication. Michigan, where the patients filed the suit, provides a statutory defense to suits against manufacturers of prescription drugs that were approved by FDA and in compliance with FDA requirements.[81] The state statute creates an exception to this defense, however, which requires the state fact-finder to speculate whether (1) the manufacturer intentionally withheld or misrepresented information to FDA that was required to be submitted under various provisions of federal law (2) that would have materially affected FDA's decision to approve the drug for nationwide marketing or withdraw it.[82] Although the plaintiffs asserted that this exception applied, FDA itself never found any violation of its federal disclosure requirements or took any action to withdraw the product because of fraud on the agency.[83] The Solicitor General and the company contended that determining whether there had been proper disclosures to a federal agency and how an agency would respond to any fraud on it was a matter exclusively reserved to the agency itself.[84] Indeed, the Court had previously held in *Buckman Company v. Plaintiffs' Legal Committee* that "[s]tate-law fraud-on-the-FDA claims inevitably conflict with the FDA's responsibility to police fraud consistently with the Administration's judgment and objectives" and are therefore preempted.[85]

The Second Circuit below, however, procedurally distinguished the claims in *Kent* from *Buckman*, ruling that the claims here were not for fraud-on-the-FDA per se, but "sound[ed] in traditional state tort law."[86] As the Solicitor General and the company pointed out, however, this is a distinction without a difference. Consistent with *Buckman*, "the relationship between a federal agency and the entity it regulates is inherently federal in character because the relationship originates from, is governed by, and terminates according to federal law" and "[p]olicing fraud against federal agencies is hardly a field which the States have traditionally occupied."[87] The Court's divide in *Kent* may stem from a difference of opinion in whether to view the question presented as sounding in traditional state tort law or in federal law. Where you start may be where you end up.

Whether the Court begins from the perspective of the federal or state interest may partly explain the outcome in the other preemption cases as well. In *Brown*, for example, the state argued for its prerogatives in controlling how its own state treasury funds were used. But the Court viewed *Brown* as primarily implicating federal labor policy instead of a state's control over its funds. Nor was the Court receptive to arguments

that the state statute actually was consistent with and furthered federal labor policy. Indeed, the *Brown* dissent argued that Congress had even used language identical to the state statute to prevent employers from using federal funds to interfere with union organizing.[88] What was good for the federal goose, California argued, was good for the state gander. Nevertheless, the Court reasoned that the state statute improperly implicated "federal labor policy" because Congress intended to strike a balance on employer speech that neither violated the employers' First Amendment rights nor coerced employees.[89] That balance prevented states such as California from "opening the door to a [fifty]-state patchwork of inconsistent labor policies."[90]

The Court used similar language to describe the nature of the federal interest in *Riegel* and *Buckman*. In *Riegel*, the Court noted that state tort law threatens the federal agency's cost-benefit analysis.[91] See § III, *infra*. In *Buckman*, a state tort law finding that the manufacturer had made false statements to FDA was preempted because of the "delicate balance" FDA must strike in evaluating submissions from regulated entities and the need to prevent a "deluge of information" from being submitted to the agency during the approval process out of nothing more than a self-protective desire to avoid potential state tort liability rather than for a legitimate federal regulatory purpose.[92] Thus, even though the justices may be more apt to fracture in the absence of an express preemption provision, a properly defined federal interest may still bode well for preemption.

III. Federal Agency Expertise and Review

The rise of the administrative state has brought with it heavy federal regulation. Compliance costs can burden regulated entities, particularly as they endeavor to meet local, state, federal, and international demands. This can put regulated entities in inconvenient or even untenable positions as they cope with regulations that may impose competing and even mutually exclusive requirements. These realities have resulted in an apparent increase in *actual* deference to the federal agency in at least two senses.

First, although the Court has not been enthusiastic about undertaking formal administrative deference analyses—and detailing what degree of deference various agency interpretations of the statutes, regulations or other matters they author or administer are entitled to under the well-known but often divisive frameworks of *Chevron*, *Auer*, and *Skidmore*[93]—in practice, the Court nonetheless has tended to follow the agency's position on whether there should be preemption. For example, as one commentator has observed, in all but one of the recent preemption cases involving product liability issues, the Court has *in fact* followed the federal agency's preemption position (be it pro or con in a given case), even though the Court generally did not engage in a formal agency deference analysis.[94]

In *Lohr*, for instance, the Court simply stated that the agency's interpretation—in that case, against preemption for the less heavily regulated medical devices at issue in that case—"substantially informed" its reading of the express preemption statute.[95] Similarly this term, Justice Scalia, writing for the majority in *Riegel*, again picked up on this "substantially informed" language with respect to the agency's position that the more heavily regulated devices at issue in that case implicated federal "requirements" within the meaning of the preemption provision; but the Court did not explicitly cite agency deference doctrine or provide further explanation.[96] Indeed, on another point, the Court sidestepped deciding the case on administrative law grounds even though they may have supported the majority's view. The plaintiffs had pointed to an FDA regulation that limited the pertinent statute's preemptive scope where "state or local requirements [were] of general applicability" to argue against preemption.[97] FDA interpreted its own regulation only to withhold preemption from general duties such as fire codes or rules about trade practices, not the tort duties at issue in *Riegel*.[98] There is a strong argument that the agency's reading of its own regulation was entitled to substantial deference under *Auer*. Yet Justice Scalia "[n]either accept[ed] nor reject[ed]" FDA's interpretation, avoiding the matter and concluding that the regulation was unnecessary to the outcome of the case.[99]

Second, as noted above, the Court has a history of crediting federal agency balancing of complicated policy issues when contrary state law threatens to disrupt that balance. Where an expert federal agency has considered an issue within the proper bounds of its authority, the Court appears to give significant deference to the agency about the proper solution. One possibility is that the Court may extend actual deference to an agency's view where the Court is convinced about the rigor of the process Congress or the agency has devised for reviewing a particular policy issue. This review of the regulator may be born of a growing recognition of the agencies' comparative competency to make decisions in highly technical areas.

In *Riegel*, for example, the Court assessed the comparative advantage of having an expert agency make technical public health judgments about the safety and effectiveness of complex medical devices, instead of a jury. The majority opinion, while disclaiming reliance on anything but the controlling statutory text, took care to detail FDA's extensive process for determining whether certain medical devices are safe and effective. The opinion devoted numerous pages of discussion to FDA's "rigorous regime of premarket approval" in which "FDA spends an average of 1,200 hours reviewing each application" and reviews a "multivolume application" that includes "a full description of the methods used" in manufacturing and processing the device."[100]

As between a jury and FDA, the former is likely to be less competent at determining trade-offs between a device's safety and effectiveness because the 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."[101] It would "make little sense" for Congress to have intended dual FDA and jury determinations of medical device safety, the opinion concluded, because where those determinations conflict they would expose device manufacturers to contradictory obligations.[102] Consistent with this approach, in the earlier *Lohr* case, the Court also had looked to the rigor of the federal agency review to aid in deciding whether state actions were preempted. Observing that the review at issue in *Lohr* merely judged a device's "*equivalence* [to other devices], not safety" and did "not in any way denote official FDA approval of [the] device" the Court came to the opposite conclusion,

that no preemption was warranted for the different category of devices at issue in *Lohr*.[103]

In the upcoming term, the Wyeth prescription drug preemption case provides the Court with an opportunity to revisit its actual deference to agency expertise and an agency's call for preemption.[104] In *Wyeth*, although Congress charged FDA with determining the appropriate warnings for prescription drugs marketed in the United States—and even though the agency was "fully aware of the risk" ultimately visited on the plaintiff and approved calibrated warning language alerting prescribers to that potential risk[105]—the plaintiff challenged the warning as inadequate and told the jury "we don't rely on the FDA to... make the safe[ty] decision" or determine "the extent to which [a company] should have warned" because "FDA doesn't make the decision, you do."[106]

The plaintiff's argument ignores the federal regulatory process for approving prescription drugs for marketing on the nationwide market—an issue reserved to FDA and its statutory predecessors for over a century[107]—and may become a focus of the analysis if the Court adheres to the interpretive methods discussed above. The United States and other amici detail FDA's extensive labeling review process.[108] In striking parallel to the PMA process at issue in *Riegel*, FDA's review process for prescription drugs is "expert" and "rigorous," "scrutiniz[ing] everything about the drug," and the goal of which is to "strike a balance" between notifying prescribing physicians and their patients about a drug's potential dangers and overwarning (which may lead to prescribing physicians avoiding treatments whose potential benefits would outweigh their potential risks for a particular patient out of unsubstantiated fears).[109] Indeed, this balance is peculiarly difficult in the context of prescription drugs because the potential for harm is often inseparable from the potential for benefit.[110]

Justice Breyer appeared to foreshadow this core issue in *Wyeth* when questioning plaintiffs' counsel at the *Kent* oral argument:

> You came up and began and said this drug has side effects that hurt people. And that's a risk when you have a drug, and it's a terrible thing if the drug hurts people. There's a risk on the other side. There are people who are dying or seriously sick, and if you don't get the drug to them they die. So there's a problem. You've got to get drugs to people and at the same time the drug can't hurt them. Now, who would you rather have make the decision as to whether this drug is, on balance, going to save people or, on balance, going to hurt people? An expert agency, on the one hand, or 12 people pulled randomly for a jury rol[l] who see before them only the people whom the drug hurt and don't see those people who need the drug to cure them?[111]

Thus, even where there is no express preemption provision, there is a powerful argument to defer to federal expertise at least where a matter is one of proper federal concern and the agency is acting well within the proper scope of its congressionally delegated power. The alternative is to disregard congressional design and place regulated entities between the rock of federal mandates and the hard place of trying to comply with a patchwork of different and competing state-law standards.

CONCLUSION

Perhaps in keeping with the new Chief Justice's expressed goal of forging consensus opinions, there was considerable uniformity in the justices' votes in this term's preemption cases. The Court's text-based approach to interpreting express preemption provisions provided a pivot point for securing broad consensus and avoiding perhaps more controversial issues of federalism and agency deference. Although reluctant to wade into formal federalism debates, the Court seemed particularly sympathetic to preemption where the matter at hand was significantly federal. With the exception of foreign affairs, however, it may be difficult to predict with certainty whether a given matter that may have both federal and state law features will be viewed principally from a state or federal vantage point. Finally, the Court has tended to preempt state laws when federal agencies make considered, often technical judgments with respect to highly regulated matters within their congressionally delegated expertise. In according *actual* deference to the procedural and substantive judgments of expert agencies, though, the Court generally avoided wading into formal, and often divisive, administrative law analysis.

Endnotes

1 See Table, *infra*. The pro-preemption decisions are: Chamber of Commerce v. Brown, 128 S. Ct. 2408 (2008); Preston v. Ferrer, 128 S. Ct. 978 (2008); Riegel v. Medtronic, Inc., 128 S. Ct. 999 (2008); and Rowe v. N.H. Motor Trans. Ass'n, 128 S. Ct. 989 (2008). The Court rejected preemption in *Exxon Shipping Co. v. Baker*, 128 S. Ct. 2605 (2008), see note 67, *infra*, and divided 4-4 in *Warner-Lambert v. Kent*, 128 S. Ct. 1168 (2008) (per curiam), with the Chief Justice recusing. See note 71, *infra*.

2 *See* Wyeth v. Levine, No. 06-1249 (filed Mar. 12, 2007) (addressing preemption of state-law challenges to prescription drug warnings approved by FDA) (to be argued Nov. 3, 2008); Altria Group v. Good, No. 07-562 (filed Oct. 26, 2007)) (addressing preemption of state-law challenges to statements in cigarette advertising authorized by the Federal Trade Commission) (to be argued Oct. 6, 2008).

3 From 1983 to 2003, the Court decided on average more than 6.3 preemption cases per term, and upheld federal preemption in about half of them. *See* Note, *New Evidence On The Presumption Against Preemption: An Empirical Study of Congressional Responses To Supreme Court Preemption Decisions*, 120 Harv. L. Rev. 1604, 1613 (2007). Last term, the Court upheld federal preemption in four of six cases. *See* Table, *infra*.

4 *See, e.g.,* Erwin Chemerinsky, *Troubling Trend in Preemption Rulings*, 44 JTLA Trial 62 (2008) ("One would expect that a conservative Court, committed to protecting states' rights, would narrow the scope of federal preemption. After all, a good way to empower state governments is to restrict the federal government's reach. Restricting pre-emption gives state governments more autonomy. But there is every indication that the Roberts Court, although unquestionably conservative, will interpret pre-emption doctrines broadly when businesses challenge state and local laws.").

5 U.S. Const. art. VI, cl. 2.

6 *E.g.,* Gade v. Nat'l Solid Wastes Mgmt. Ass'n, 505 U.S. 88, 98 (1992).

7 *Id.*

8 *See, e.g.,* Cipollone v. Liggett Group, Inc., 505 U.S. 504, 516 (1992) (plurality opinion).

9 *Id.*

10 *E.g.,* Capital Cities Cable, Inc. v. Crisp, 467 U.S. 691, 698-99 (1984) (citation omitted); *see also* Hillsborough County, Fla. v. Automated Med. Labs., Inc., 471 U.S. 707, 713 (1985).

11 *See, e.g.,* Richard A. Epstein & Michael S. Greve, "Introduction: Preemption in Context," 1-21 *in* Federal Preemption: States' Powers, National Interests (Epstein & Greve, eds., 2007).

12 *Id.* at 1.

13 *See generally* Buckman Co. v. Plaintiffs' Legal Comm., 531 U.S. 341, 352 (2001) ("[N]either an express pre[]emption provision nor a savings clause '[b]ars the ordinary working of conflict pre[]emption principles.'") (quoting Geier v. American Honda Motor Co., 529 U.S. 861, 869 (2000)).

14 Confirmation Hearing on the Nomination of John G. Roberts, Jr. to be Chief Justice of the United States: Hearing Before the S. Comm. on the Judiciary, 109th Cong. (2005), *available at* 2005 WL 2237124.

15 *See generally* Jason Harrow, Measuring "Divisiveness" in OT06, SCOTUSblog.com, July 2, 2007 http://www.scotusblog.com/wp/measuring-divisiveness-in-ot06/; Charles Lane, *Narrow Victories Move Roberts Court to Right*, Wash. Post, June 29, 2007, at A4.

16 *See generally* Harrow, *supra* note 15; Lane, *supra* note 15, at A4. Overall, the number of unanimous decisions was 17.9% in the 2007 Term, down from 37.7% in the 2005 Term and 23.9% in the 2006 Term. *See generally* Rupal Doshi, Georgetown Univ. Law Ctr. Sup. Ct. Inst., Supreme Court of the United States October Term 2006 Overview 4 (2007).

17 The notion of a presumption *against* preemption arose in the context of field preemption. *See generally* Rice v. Santa Fe Elevator Corp., 331 U.S. 218, 230 (1947) (discussing the "assumption" that the "historic police powers of the States" are not superseded where "Congress legislate[s]... in [a] field which the States have traditionally occupied" unless Congress makes its intent to do so "clear and manifest"). Although the Court's decisions have not always been consistent, there is a strong argument that no such presumption applies in the face of an express preemption provision. Indeed, in *Riegel*, the notion of a presumption against preemption garnered only a single dissenting vote. *See* 128 S. Ct. at 1006-07, 1013-14; *see also* Sprietsma v. Mercury Marine, 537 U.S. 51, 62-63 (2002) (concluding that the Court's "task of statutory construction must in the first instance focus on the plain wording of the [express preemption] clause, which necessarily contains the best evidence of Congress' pre-emptive intent"); CSX Transp., Inc. v. Easterwood, 507 U.S. 658, 664 (1993) (same).

18 *See* Tony Mauro, *The Majority Flexes Its Muscles*, Legal Times, Feb. 25, 2008 (quoting Robin Conrad, U.S. Chamber of Commerce, referencing February 20, 2008 as "quite a hat trick" when the Court issued these three pro-preemption decisions in one day); Table, *supra*.

19 128 S. Ct. 989.

20 128 S. Ct. 999.

21 128 S. Ct. 978.

22 *Cipollone*, 505 U.S. at 516 (internal quotation omitted, first alteration original).

23 *Riegel*, 128 S. Ct. at 1011 (Stevens, J., concurring) (quoting Oncale v. Sundowner Offshore Servs., 523 U.S. 75, 79-80 (1998)).

24 *Id.* (emphasis added).

25 *Rowe*, 128 S. Ct. at 993 (quoting 49 U.S.C. § 14501(c)(1)).

26 *Id.* at 993-94.

27 *Id.* at 994 (quoting Merrill Lynch, Pierce, Fenner & Smith, Inc. v. Dabit, 547 U.S. 71, 85 (2006)).

28 *Id.* at 996.

29 *Id.* at 992.

30 *Id.* at 996.

31 *Id.* at 996-97.

32 *Id.*

33 *Id.*

34 *Id.* at 997.

35 *Id.*

36 *Id.* at 998-99 (Ginsburg, J., concurring).

37 *Id.* at 999.

38 *Riegel*, 128 S. Ct. at 1011.

39 *Id.* at 1003 (quoting 21 U.S.C. § 360k(a)).

40 518 U.S. 470 (1996).

41 *Id.* at 477-79.

42 *Id.* at 501.

43 *See, e.g.,* McMullen v. Medtronic, Inc., 421 F.3d 482 (7th Cir. 2005), *cert. denied,* 547 U.S. 1003 (2006); Cupek v. Medtronic, Inc., 405 F.3d 421 (6th Cir.), *cert. denied sub nom.* Knisley v. Medtronic, 546 U.S. 935 (2005); Horn v. Thoratec Corp., 376 F.3d 163 (3d Cir. 2004); Brooks v. Howmedica, Inc., 273 F.3d 785 (8th Cir. 2001) (en banc); Martin v. Medtronic, Inc., 254 F.3d 573 (5th Cir. 2001); *but see* Goodlin v. Medtronic, Inc., 167 F.3d 1367 (11th Cir. 1999).

44 *Riegel*, 128 S. Ct. at 1006-07.

45 *Id.* at 1007-08.

46 *Id.*

47 *Id.* at 1009.

48 *Id.* at 1014-15 (Ginsburg, J., dissenting).

49 *Id.*

50 The pertinent Federal Arbitration Act provision provides that "'a written provision in any… contract evidencing a transaction involving commerce to settle by arbitration a controversy thereafter arising out of such contract or transaction… *shall be valid, irrevocable, and enforceable*, save upon such grounds as exist at law or in equity for the revocation of any contract'" as a matter of general applicability. *Preston*, 128 S. Ct. at 983 (quoting 9 U.S.C. § 2) (emphasis added). To be sure, the Court previously observed that the FAA "contains no express pre-emptive provision," instead treating the statute as involving implied conflict preemption. Volt Info. Scis., Inc. v. Board of Trs. of Leland Stanford Junior Univ., 489 U.S. 468, 477 (1989). But Preston did not embrace this analysis, and otherwise held that reliance on Volt "is misplaced." *Preston*, 128 S. Ct. at 998.

51 *Id.* at 983 (internal quotation and alterations omitted).

52 *Id.* (internal quotation omitted).

53 *Id.* at 982 (quoting contract) (alterations and omissions in the original).

54 *Id.*

55 *Id.* at 989.

56 *Id.* at 986.

57 *Id.* at 989 (Thomas, J., dissenting).

58 *Brown*, 128 S. Ct. at 2414.

59 *Id.* at 2410-11 (quoting Cal. Gov't Code §§ 16645-16649 (West Supp. 2008)).

60 *Id.* at 2411-12.

61 *Id.* at 2413 (quoting 29 U.S.C. § 158(a)(1)).

62 *Id.* (quoting 29 U.S.C. § 158(c)).

63 *Id.* at 2414.

64 *Id.* at 2413.

65 *Id.* at 2420 (Breyer, J., dissenting).

66 *Id.* at 2411, 2415.

67 128 S. Ct. 2605, 2612-16 (2008). It should be noted that *Exxon* involved "preemption" in a somewhat different sense than that described above, in that the issue was whether an express statutory provision of federal law could preempt *federal* maritime common law claims.

68 *Id.* at 2618 (citing 33 U.S.C. § 1321(b) & (o)) (alteration and second omission in original).

69 *Id.* at 2619.

70 *Id.*

71 In *Kent*, the Chief Justice recused and the remaining eight justices divided 4-4. Consistent with its practice, the Court issued a per curiam opinion affirming the judgment below by an equally divided Court; it did not issue a substantive opinion or identify how any justice voted. Such dispositions effectively leave the legal landscape where the Court found it and are "not entitled to precedential weight." Rutledge v. United States, 517 U.S. 292, 304 (1996).

72 *See* note 17, *supra*.

73 Thomas W. Merrill, *Agency Preemption: Speak Softly, But Carry a Big Stick?,* 11 Chap. L. Rev. 363, 387 (2008) (arguing for a presumption in *favor* of preemption in matters within exclusive or plenary federal control); *see also* United States v. Locke, 529 U.S. 89, 108 (2000) (where a matter has long been subject to federal control, "there is no beginning assumption that concurrent regulation by the State is a valid exercise of its police powers").

74 *Geier*, 529 U.S. at 885; *see* Felder v. Casey, 487 U.S. 131, 138 (1988) ("Under the Supremacy Clause of the Federal Constitution, '[t]he relative importance to the State of its own law is not material when there is a conflict with a valid federal law,' for 'any state law, however clearly within a State's acknowledged power, which interferes with or is contrary to federal law, must yield.'") (citations omitted).

75 *See, e.g.,* Crosby v. Nat'l Foreign Trade Council, 530 U.S. 363, 377-78 (2000) (holding state law preempted because Congress had "calibrated [foreign] policy [in] a deliberate effort to steer a middle path" that left no place for competing state action) (internal quotation omitted).

76 *See, e.g., Geier,* 529 U.S. 861.

77 128 S. Ct. 989.

78 128 S. Ct. 999.

79 128 S. Ct. 978.

80 128 S. Ct. 2408.

81 *See* Mich. Comp. Laws § 600.2946(5).

82 *See* Mich. Comp. Laws § 600.2946(5)(a).

83 *See* Brief for the United States as Amicus Curiae Supporting of Petitioners at 5, 21, Warner-Lambert Co. v. Kent, No. 06-1498 (Nov. 28, 2008), 2007 WL 421889 ("U.S. Kent Br."); Desiano v. Warner-Lambert & Co., 467 F.3d 85, 87 (2d Cir. 2006), *aff'd by an equally divided court sub nom*., Warner-Lambert v. Kent, 128 S. Ct. 1168 (2008).

84 *See e.g.,* U.S. Kent Br. at 6-7 ("Michigan law is preempted to the extent it requires courts to determine whether a manufacturer defrauded FDA and whether FDA would have denied or withdrawn approval of a drug but for the fraud."); *Garcia v. Wyeth-Ayerst Labs*., 385 F.3d 961 (6th Cir. 2004) (same).

85 531 U.S. at 350.

86 *Desiano*, 467 F.3d at 94.

87 *Buckman*, 531 U.S. at 347 (internal quotation omitted); *see* U.S. Kent Br. at 9-10.

88 *See Brown*, 128 S. Ct. at 2420 (Breyer, J., dissenting).

89 *Id*. at 2412.

90 *Id*. at 2418.

91 *Riegel*, 128 S. Ct. at 1008.

92 *Buckman*, 531 U.S. at 348, 350-51.

93 *See* Chevron USA, Inc. v. Natural Res. Def. Council, Inc., 467 U.S. 837, 844 (1984) (recognizing the legally binding effect of formal and non-arbitrary interpretations of ambiguous statutory provisions by the agency charged with administering those provisions); Auer v. Robbins, 519 U.S. 452, 461 (1997) (recognizing that an agency's interpretation of its own ambiguous regulation is "controlling unless plainly erroneous or inconsistent with the regulation") (internal quotation omitted); Skidmore v. Swift & Co., 323 U.S. 134, 140 (1944) (recognizing some lesser degree of deference in other circumstances "depend[ing] upon the thoroughness evident in [the agency's] consideration, the validity of its reasoning, its consistency with earlier and later pronouncements, and all those factors which give it power to persuade").

94 *See* Catherine M. Sharkey, *Products Liability Preemption: An Institutional Approach*, 76 Geo. Wash. L. Rev. 449, 477 (Apr. 2008) ("Out of the preemption muddle, then, a glimmer of clarity emerges at least with respect to the products liability cases—the Court's final decisions line up with the positions urged by the agency."). Those cases are *Lohr*, 518 U.S. 470; *Geier*, 529 U.S. 861; *Buckman*, 531 U.S. 341; *Sprietsma*, 537 U.S. 51; and *Riegel*, 128 S. Ct. 999. The one outlier is *Bates v. Agrosciences LLC,* 544 U.S. 431 (2005), in which the Court rejected the agency's pro-preemption position. In *Kent*, the agency also favored the pro-preemption position, but the Court did not issue a precedential opinion addressing the issue. *See supra*. Thus, perhaps the lesson learned from these cases is that without the federal agency's support, preemption may be difficult; with it, preemption is likely, but not guaranteed.

95 *Lohr*, 518 U.S. at 495-96 (observing that FDA "is uniquely qualified to determine whether a particular form of state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress, and, therefore, whether it should be pre-empted") (internal quotation omitted); see *id.* at 506 (noting FDA's "special understanding of the likely impact of both state and federal requirements, as well as an understanding of whether (or the extent to which) state requirements may interfere with federal objectives") (Breyer, J., concurring). The *Lohr* majority perhaps did not go so far, however, as to "admit to deferring to [FDA's] regulations," and, to the dissent's mind at least, it was an open question whether "an agency regulation determining the pre-emptive effect of *any* federal statute [was] entitled to deference." *Id*. at 512 (O'Connor, J., concurring in part and dissenting in part).

96 *Riegel*, 128 S. Ct. at 1006.

97 *Id.* at 1010 (quoting 21 C.F.R. § 808.1(d)(1)) (alteration omitted).

98 *Id*.

99 128 S. Ct. at 1011.

100 See *id*. at 1003-05 (internal quotation omitted).

101 *Id*.

102 *See id.* at 1008.

103 *Lohr*, 518 U.S. at 493 (emphasis in original).

104 We will not repeat here the full case for FDA preemption in many prescription drug contexts, which has been developed extensively elsewhere. *See, e.g.,* Brief for the United States as Amicus Curiae Supporting Petitioner, Wyeth v. Levine, No. 06-1249 (June 2, 2008), 2008 WL 2308908 ("U.S. Levine Br.") (arguing that the Federal Food, Drug and Cosmetic Act (FDCA) preempts state tort claims that would impose liability for the use of labeling FDA approved after being informed of the relevant risk); Brief of DRI—The Voice of the Defense Bar as Amicus Curiae in Support of Petitioner, Wyeth v. Levine, No. 06-1249 (June 3, 2008) 2008 WL 2355772 ("DRI Levine Br.") (arguing that "[p]ermitting States—and lay fact-finders—to serve as quasi-regulators able to require additional warnings inconsistent with FDA's own judgments creates irreconcilable conflicts with federal law and thwarts the attainment of important [federal] public health objectives"); Daniel E. Troy, "The Case for FDA Preemption," 81-112 *in* Federal Preemption, *supra* (making case for preemption "to protect the FDA's mission and objectives, as defined by Congress, against independent threats emanating from state tort law").

105 U.S. Levine Br. at 1-7.

106 Joint Appendix at 211-12, 217, Wyeth v. Levine, No. 06-1249 (May 27, 2008), 2008 WL 2309484.

107 *See, e.g.,* Pure Food and Drug Act of 1906, Pub. L. No. 59-384, 34 Stat. 768 (1906); United States v. Walsh, 331 U.S. 432, 434 (1947) ("The [FDCA] rests upon the constitutional power resident in Congress to regulate interstate commerce" and Congress has regulated drugs "[t]o the end that the public health and safety might be advanced.").

108 *See, e.g.,* U.S. Levine Br. at 1-4, 11-15; DRI Levine Br. at 4-16.

109 U.S. Levine Br. at 11, 13, 17.

110 *E.g.,* U.S. Levine Br. at 8-9, 16-17; Troy, *supra* note 104, at 84.

111 Oral Argument Transcript at 30, Warner-Lambert Co. v. Kent, No. 06-1498 (Feb. 25, 2008), 2008 WL 495030.