

## WHAT *RIEGEL* PORTENDS FOR FDA PREEMPTION OF STATE LAW PRODUCTS LIABILITY CLAIMS

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### INTRODUCTION: PREEMPTION CASES IN SEARCH OF A FRAMEWORK

In *Riegel v. Medtronic, Inc.*, the U.S. Supreme Court held that a federal statute governing regulation of medical devices expressly preempts, or displaces, state tort law claims when a device has received FDA premarket approval.<sup>1</sup> A month after the Court issued this opinion, Justice Scalia inveighed against the news media coverage of *Riegel* (an opinion that he authored) at a meeting convened by the Food and Drug Law Institute:

Scalia said news organizations often fail to focus on the text of the laws the Court interprets. . . . The media often make it appear as though the court is reaching policy judgments on its own rather than basing its decisions on the text of the law at issue in a case. . . . In some instances, said Scalia, the news media leave the impression that no ruling based on the text of a law “is even possible.”<sup>2</sup>

Scalia’s majority opinion can indeed be fairly characterized as a “narrow, textual interpretation” of the preemption clause of the congressionally enacted Medical Devices Amendments of 1976 (MDA) to the Federal Food Drug and Cosmetics Act (FDCA).<sup>3</sup> Express preemption cases, at least in theory, can begin and end with statutory text.

But it is rare to find a products liability preemption case where, in Justice Scalia’s words, “the statute itself speaks clearly to the point at issue.”<sup>4</sup> Far more typically, disagreements erupt among the Justices over whether

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<sup>1</sup> *Riegel v. Medtronic, Inc.*, 128 S. Ct. 999 (2008) (link).

<sup>2</sup> *Scalia Criticizes News Media*, Associated Press, Mar. 27, 2008, available at [http://www.breitbart.com/article.php?id=D8VM047O4&show\\_article=1](http://www.breitbart.com/article.php?id=D8VM047O4&show_article=1) (link).

<sup>3</sup> Robert Barnes, *Supreme Court Shields Medical-Device Makers*, WASH. POST, Feb. 21, 2008, at D1, available at <http://www.washingtonpost.com/wp-dyn/content/article/2008/02/20/AR2008022001140.html> (quoting Catherine Sharkey, Professor of Law, New York University School of Law) (link). The MDA expressly preempts state requirements that are “different from, or in addition to” certain federal requirements. 21 U.S.C. § 360k(a) (2008) (link).

<sup>4</sup> *Riegel*, 128 S. Ct. at 1009. Indeed, even with respect to the MDA, the Court interpreted the very same preemption clause in *Medtronic, Inc. v. Lohr*, where it found substantial “ambiguity in the statute.” 518 U.S. 470, 496 (1996) (citation omitted) (link). See *infra* note 21 and accompanying text.

statutory language is in fact clear. Often congressional legislation touches on some aspects of federal regulation of consumer products, motor vehicles, or recreational boats (to name a few examples), without clearly specifying the interrelationship with state common law tort claims. In such legislation, Congress often creates confusion by including *both* a preemption clause, which mandates displacement of competing or conflicting state law standards, and a savings clause, which purports not to upend existing state common law liability.<sup>5</sup>

Where the language of the preemption and savings clauses points in opposite directions, or where Congress has been cryptic or silent on the matter, Justice Scalia's ode to text will ring hollow. Courts will have to decide on the basis of implied conflict preemption (as opposed to express preemption), looking at the entire statutory and regulatory framework to determine whether state laws either "make it 'impossible' for private parties to comply with both state and federal law,"<sup>6</sup> or, more broadly, whether state laws frustrate or "stand[] as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress."<sup>7</sup> Justice Ginsburg's lone dissent in *Riegel* may well portend the true battleground in implied conflict preemption challenges to come: "In the absence of legislative precision . . . courts may face the task of determining the substance and scope of Congress' displacement of state law."<sup>8</sup> Where statutory text is indeterminate, where are courts to look?

Several options present themselves. First, courts may resort to the "presumption against preemption" statutory canon to raise the bar against interpretations favoring preemption absent clear language by Congress.<sup>9</sup> While this approach retains some appeal for judges and academic commentators,<sup>10</sup> it has receded of late in the imagination of the Supreme Court Jus-

<sup>5</sup> See National Traffic and Motor Vehicle Safety Act of 1966, 15 U.S.C. § 1392(d) (1988) (current version at 49 U.S.C. § 30103(b) (2000) (link)) (preemption clause); *id.* § 1397(k) (current version at 49 U.S.C. § 30103(e) (2000) (link)) (savings clause); Consumer Product Safety Act, 15 U.S.C. § 2075(a) (2000) (preemption clause) (link); *id.* § 2074(a) (savings clause) (link); Federal Boat Safety Act of 1971, 46 U.S.C. § 4306 (2000) (preemption clause) (link); *id.* § 4311(g) (savings clause) (link).

<sup>6</sup> *Geier v. American Honda Motor Co.*, 529 U.S. 861, 873 (2000) (link).

<sup>7</sup> *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941) (link).

<sup>8</sup> *Riegel*, 128 S. Ct. at 1014 (Ginsburg, J., dissenting); see also *Lohr*, 518 U.S. at 505 (Breyer, J., concurring) ("Congress must have intended that courts look elsewhere for help as to just which federal requirements pre-empt just which state requirements, as well as just how they might do so.")

<sup>9</sup> The presumption harkens back to mid-twentieth century, when the Court asserted that "the historic police powers of the States [a]re not to be superseded . . . unless that was the clear and manifest purpose of Congress." *Riegel*, 128 S. Ct. at 1013 (Ginsburg, J., dissenting) (alterations in original) (quoting *Rice v. Sante Fe Elevator Corp.*, 331 U.S. 218, 230 (1947)).

<sup>10</sup> See, e.g., Brief of Amicus Curiae Constitutional and Administrative Law Scholars in Support of Respondents at 3–4, *Philip Morris USA Inc. & Altria Group, Inc. v. Good*, No. 07-562 (U.S. June 18, 2008), 2008 WL 2489869, at \*3–4 ("[S]tatutory rules like this Court's 'presumption against preemption' are the most critical component of this Court's federalism doctrine. . . . [and] suggest a lens through which this Court should view preemption disputes.") (citation omitted).

tices. In fact, this canon was not even mentioned by the majority in *gel*.<sup>11</sup>

Second, perhaps—consistent with the media suggestion about *Riegel*—the Justices simply vote their policy preferences in these matters.<sup>12</sup> If so, then we would expect even more room for judicial policymaking in implied preemption cases, where Congress has not restricted courts’ interpretive sphere with constraining statutory language. In one sense, preemption decisions always entail policy choices. After all, the decision that a federal standard ousts a competing state standard entails a choice that regulation should take place exclusively at the federal level, and a concomitant embrace of the view that state tort law is a regulatory competitor. *Riegel* subscribes to this ascendant law-and-economics inspired view of the regulatory role of tort law;<sup>13</sup> the opposing “tort as compensation” view is nowhere engaged.<sup>14</sup>

Justice Scalia’s majority opinion goes even further down this road, casting aspersions on the jury’s competence to engage in cost-benefit analysis, relative to that of the FDA.<sup>15</sup> And in a passage distinctly out of place in

<sup>11</sup> Nor can its absence be explained by the fact that *Riegel* is an *express* preemption case, for so was *Lohr*, and there, the Court trotted out the trusted presumption as the opening salvo of its preemption analysis. *Lohr*, 518 U.S. at 485 (“[B]ecause the States are independent sovereigns in our federal system, we have long presumed that Congress does not cavalierly pre-empt state-law causes of action.”). In fact, to date, the Court has—paradoxically—applied the presumption in the express preemption products liability cases, but not in the implied ones. See Catherine M. Sharkey, *Products Liability Preemption: An Institutional Approach*, 76 GEO. WASH. L. REV. 449, 458 (2008) [hereinafter Sharkey, *Products Liability Preemption*] (noting that the Court invoked the presumption in *Bates v. Dow Agrosiences LLC*, 544 U.S. 431 (2005), *Lohr*, and *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504 (1992)—all decided on express preemption grounds—but not in *Sprietsma v. Mercury Marine*, 537 U.S. 51 (2002), or *Geier*—the seminal implied preemption cases) (link).

<sup>12</sup> The standard attitudinal model used by political scientists posits that Justices vote their policy preferences. See JEFFREY A. SEGAL & HAROLD J. SPAETH, *THE SUPREME COURT AND THE ATTITUDINAL MODEL REVISITED* 86 (2002); see also SAUL BRENNER & HAROLD SPAETH, *STARE INDECISIS: THE ALTERATION OF PRECEDENT ON THE SUPREME COURT, 1946–1992*, at 109 (1995).

<sup>13</sup> *Riegel*, 128 S. Ct. at 1008 (“[W]hile the common-law remedy is limited to damages, a liability award ‘can be, indeed is designed to be, a potent method of governing conduct and controlling policy.’”) (citing *Cipollone*, 505 U.S. at 521).

<sup>14</sup> Justice Stevens, champion of the remedial function of tort law in *Lohr*, see 518 U.S. at 487–89, though conceding that “the overriding purpose of the [FDCA] was to provide additional protection to consumers,” says nothing further about the disappearance of the tort-as-compensation model in *Riegel*. See 128 S. Ct. at 1011–13 (Stevens, J., concurring in part and concurring in the judgment). Nor does Justice Kennedy, who dissented in *Cipollone*, in part on the ground that on the ground that “tort law has an entirely separate function—compensating victims—that sets it apart from direct forms of regulation,” 505 U.S. at 537, express any hesitation on that front in joining the *Riegel* majority.

<sup>15</sup> *Riegel*, 128 S.Ct at 1008 (“A jury, on the other hand, 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.”). See also Transcript of Oral Argument at 19, *Riegel*, 128 S. Ct. 999 (No. 06-179) [hereinafter *Riegel* Oral Argument], available at [http://www.supremecourt.us/oral\\_arguments/argument\\_transcripts/06-179.pdf](http://www.supremecourt.us/oral_arguments/argument_transcripts/06-179.pdf) (Scalia, J.) (“What’s going on is simply one jury has decided that in its judgment, there was a safer device that should have been used; and because of the judgment of that one jury, the manufacturer is placed at risk in selling a device that scientists at the FDA have said is okay. I find that extraordinary.”) (link).

an opinion whose outcome is ostensibly determined exclusively by statutory text, Justice Scalia, “speculat[ing] upon congressional motives,” finds a “suggest[ion] that the 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.”<sup>16</sup>

When such policy predilections undergird preemption decisions—even, as in *Riegel*, in the narrowest realm of express preemption based upon clear statutory text, let alone in the comparatively unbounded realm of implied preemption—it is time to consider alternative models to that of courts’ being left to their own devices under the guise of imputing congressional motives.

This Essay presents that alternative, building upon my previously articulated “agency reference model,” which provides a framework for courts to decide implied conflict preemption cases by seeking guidance from the relevant federal regulatory agency.<sup>17</sup> The basic question at the core of implied conflict preemption inquiries is whether or not state common law actions are irreconcilable with, or would stand as an obstacle to, or frustrate, the command of federal regulatory directives and goals. To answer this question, courts need a fine-grained account of the precise regulatory review conducted by the agency and evidence as to its compatibility with state law tort claims. The agency reference model aims, as a general matter, to facilitate input from federal agencies on these issues.

As the Court moves beyond *Riegel* and the realm of express preemption to tackle implied conflict preemption in the pharmaceutical context in the upcoming *Wyeth v. Levine* case,<sup>18</sup> the time is ripe to consider such a model. Indeed, where, by definition, statutory text alone will not resolutely decide the implied conflicts in products liability cases, articulation of an analytic framework for where the courts should turn is a pragmatic necessity. Drawing upon some suggestive gestures toward agency input in *Riegel*, this Essay applies the agency reference model to the concrete setting

<sup>16</sup> *Riegel*, 128 S. Ct. at 1009. Here, Justice Stevens jumped off the majority bandwagon, rejecting this “policy argument advanced by the Court, not by Congress.” *Id.* at 1012 (Stevens, J., concurring in part and concurring in the judgment).

<sup>17</sup> Sharkey, *Products Liability Preemption*, *supra* note 11, at 452–53, 477–502 (setting forth a functional institutional approach to implied conflicts products liability preemption whereby courts accord *Skidmore* deference to agency preemption determinations, conditioned on strong record evidence concerning regulatory cost benefit analysis and a reasoned determination of the need for a uniform national policy).

<sup>18</sup> 128 S. Ct. 1118 (No. 06-1249), *cert. granted*, 76 U.S.L.W. 3018 (U.S. Jan. 18, 2008) (to be argued October Term 2008). The Court will consider “[w]hether the prescription drug labeling judgments imposed on manufacturers by the [FDA] pursuant to FDA’s comprehensive safety and efficacy authority under the [FDCA] preempt state law product liability claims premised on the theory that different labeling judgments were necessary to make drugs reasonably safe for use.” Supreme Court of the United States, Question Presented for *Wyeth v. Levine*, *available at* <http://origin.www.supremecourtus.gov/qp/06-01249qp.pdf> (link).

of the regulation of pharmaceutical drugs and extends the model by specifying searching judicial review of evidence taken from the FDA's regulatory record (record evidence) to substantiate FDA findings of implied conflicts between state common law failure-to-warn claims and the federal regulation of the safety and efficacy of drugs.

## I. AGENCY INPUT

Judicial reliance on input from federal agencies in making preemption decisions is not as radical as it might at first seem. Indeed, although often barely acknowledged, reliance on agencies' views in regulatory preemption cases has been a staple of Supreme Court jurisprudence.<sup>19</sup> *Riegel* fits this pattern of cryptic reliance on agency positions. For, although ultimately decided as an express preemption case based on unambiguous statutory text, *Riegel* nonetheless gives a nod toward agency deference, suggesting that, had the statute been ambiguous, the Court would have taken into account the FDA's position on preemption.

*Riegel* provided the Court a second opportunity to interpret the preemption provision of the Medical Devices Amendments to the FDCA. The earlier case, *Medtronic v. Lohr*,<sup>20</sup> likewise an express preemption case, thus presents a foil to *Riegel*. To begin, the Court reached the opposite bottom line conclusion on preemption in *Lohr*, so the differences between the two cases can be probed for salient preemption factors. More fundamentally, *Lohr*'s acknowledgement of "[t]he ambiguity in the statute," and concomitant reliance upon "the agency's view of the statute,"<sup>21</sup> places *Riegel*'s paeon to statutory text in sharp relief.

Given its finding of statutory ambiguity in the MDA, *Lohr* ventured part way down the implied preemption path, acknowledging that the 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.'"<sup>22</sup> Considering *Lohr* and *Riegel* together provides not only an opportunity to examine how the Court has previously taken into account agency input in a medical device preemption case, but also an occasion to provide guidance on how the Court *should* use agency input, not only in express preemption cases, but perhaps even more significantly, in implied preemption cases, such as the upcoming *Wyeth* pharmaceutical case.

Section A focuses on the agency's preemption position, expressed in the form of enacted regulations or other more informal statements, ultimately concluding that although such statements are useful, the Court's focus

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<sup>19</sup> See Sharkey, *Products Liability Preemption*, *supra* note 11, at 471–72.

<sup>20</sup> 518 U.S. 470 (1996) (link).

<sup>21</sup> *Id.* at 496 ("The ambiguity in the statute . . . provide[s] a sound basis for giving substantial weight to the agency's view of the statute.") (citations omitted) (quoting *id.* at 509 (O'Connor, J., dissenting)).

<sup>22</sup> *Id.* (quoting *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941)).

should be instead on how regulations are actually administered by the agency. Section B turns to this administration, proposing that, when trying to determine whether or not state law should be preempted by federal agency action, courts should look to the regulatory record to determine whether or not an agency actually considered the risks that the state law attempts to protect against.

### A. Preemption Position

Agencies have a variety of means at their disposal to express their position on preemption, from notice-and-comment rulemaking to less formal interpretive statements, preambles to rules, and litigation briefs.<sup>23</sup>

1. *Regulations.*—The Lohr majority’s interpretation of the MDA’s express preemption provision was “substantially informed” by an FDA regulation.<sup>24</sup> The FDA had issued a regulation construing the scope of the preemption provision, which sharply cabined its preemptive force.<sup>25</sup> The FDA took the further position that the MDA “does not preempt State or local requirements of general applicability where the purpose of the requirement relates . . . to other products in addition to devices.”<sup>26</sup> The Lohr Court relied on these interpretations in finding that the FDA’s premarket notification process did not amount to device-specific preemptive requirements.<sup>27</sup>

In contrast, the majority in *Riegel* toed the textualist statutory interpretation line, concluding that “the [same FDA] regulation fails to alter our interpretation of the [statutory] text insofar as the outcome of this case is concerned.”<sup>28</sup> But, “[e]ven assuming that this regulation could play a role in defining the MDA’s pre-emptive scope,” and recognizing that “[t]he agency’s reading of its own rule is entitled to substantial deference,”<sup>29</sup> the Court nonetheless dispensed with the FDA’s interpretation of its regulation, finding its reasoning “less than compelling.”<sup>30</sup>

The most striking feature here is the *Riegel* majority’s equivocation with respect to whether courts should generally take into account the FDA’s

<sup>23</sup> For a discussion of the recent trend of agencies’ issuance of “preemption preambles” to regulations, see Catherine M. Sharkey, *Preemption by Preamble: Federal Agencies and the Federalization of Tort Law*, 56 DEPAUL L. REV. 227 (2007) [hereinafter Sharkey, *Preemption by Preamble*].

<sup>24</sup> *Lohr*, 518 U.S. at 495.

<sup>25</sup> Exemptions from Federal Preemption of State and Local Medical Device Requirements, 21 C.F.R. § 808.1(d) (2007) (restricting preemption to instances where FDA had established “specific counterpart regulations or . . . other specific requirements applicable to a particular device”).

<sup>26</sup> *Id.* § 808.1(d)(1) (listing, as examples, general electrical codes, the Uniform Commercial Code’s warranty of fitness and unfair trade practices).

<sup>27</sup> See *Lohr*, 518 U.S. at 501.

<sup>28</sup> *Riegel v. Medtronic, Inc.*, 128 S. Ct. 999, 1011 (2008) (“All in all, we think that [the FDA regulation] can add nothing to our analysis but confusion.”) (link).

<sup>29</sup> *Id.* at 1010 (citing *Auer v. Robbins*, 519 U.S. 452, 461 (1997)).

<sup>30</sup> *Id.* In the end, the Court hedges by “neither accepting nor rejecting the FDA’s” position in light of the Court’s exclusive reliance upon statutory text. *Id.* at 1011.

interpretive gloss. The Court “[n]either accept[s] nor reject[s] the proposition that this regulation can be properly consulted to determine the statute’s meaning.”<sup>31</sup> Most likely, the equivocation was necessary to carry an eight-Justice majority and masks a sharper division among the Justices on the issue, likely to rear its head once statutory text can no longer provide cover.<sup>32</sup>

2. *Informal Statements.*—Agencies also state their positions on preemption through amicus briefs, preambles to regulations, and other informal statements. In *Riegel*, although the majority does not cite the FDA’s amicus brief directly, it does make note of the brief by acknowledging the FDA’s support of the majority’s pro-preemption position.<sup>33</sup>

Court reliance upon agency amicus briefs and preambles to rules presents a challenge to notions of appropriate administrative deference. While briefs and preambles arguably lack “the force of law” necessary to warrant *Chevron* mandatory deference,<sup>34</sup> the doctrine on deference to agency preambles and amicus briefs—particularly in the realm of preemption—is far from clear. Justice Breyer has staked out the position that not only should an agency’s position on preemption be given deference in the face of an ambiguous congressional command, but also that the agency can communicate that position informally “through statements in ‘regulations, preambles, interpretive statements, and responses to comments.’”<sup>35</sup>

Justice Breyer’s strong-form deference to agencies is guided by his conviction that agencies have a “special understanding of the likely impact of both state and federal requirements, as well as an understanding of whether . . . state requirements may interfere with federal objectives.”<sup>36</sup> The thrust of my argument in this Essay is that courts should subject this

<sup>31</sup> *Id.*

<sup>32</sup> Past decisions shed some light here. Justices Scalia and Thomas (as well as then-Chief Justice Rehnquist) joined Justice O’Connor’s withering critique of the *Lohr* majority’s reliance upon FDA regulations to “inform” its statutory interpretation. *Lohr*, 518 U.S. at 512 (O’Connor, J., concurring in part and dissenting in part) (“It is not certain that an agency regulation determining the pre-emptive effect of any federal statute is entitled to deference . . .”). *Wachovia Bank, N.A. v. Watters*, 127 S. Ct. 1559 (2007), is also instructive. In that case, the majority held that state laws were preempted by the National Banking Act, thereby dodging the issue (on which the Court had granted certiorari) whether the interpretation of the Comptroller of the Currency was entitled to *Chevron* deference. *Id.* at 1572. Chief Justice Roberts and Justice Scalia joined Justice Stevens’s vigorous dissent arguing that, despite the majority’s protestations to the contrary, “this is a case about an administrative agency’s power to preempt state laws” and “[n]o case from this Court has ever applied such a deferential standard to an agency decision that could so easily disrupt the federal-state balance.” *Id.* at 1584–85 (Stevens, J., dissenting).

<sup>33</sup> See *Riegel*, 128 S. Ct. at 1009 (“In the case before us, the FDA has supported the position taken by our opinion with regard to the meaning of the statute.”).

<sup>34</sup> See *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984) (link); *United States v. Mead Corp.*, 533 U.S. 218, 228 (2001) (link); see also Thomas W. Merrill, *The Mead Doctrine: Rules and Standards, Meta-Rules and Meta-Standards*, 54 ADMIN. L. REV. 807 (2002) (seeking a model through which courts may decide whether an agency action carries the “force of law”) (link).

<sup>35</sup> *Lohr*, 518 U.S. at 505–06 (Breyer, J., concurring).

<sup>36</sup> *Id.* at 506 (Breyer, J., concurring).

“wholesale” observation to scrutiny at the “retail” level of agency regulatory action. The record evidence developed by the agency, to which I turn next, should be critical in courts’ preemption decisions.

### B. Regulatory Record

Particularly when called upon to answer whether state law frustrates, or stands as an obstacle to, the federal regulatory framework, instead of relying on agency interpretation or general position on preemption—which not only might fall outside the expertise of agencies, but can also be influenced by inappropriate political considerations—courts should focus on the regulatory record of the agency.<sup>37</sup>

*Riegel* is rife with details from the FDA’s regulatory review process—though their precise legal effect, given the Court’s insistence on governing statutory text, is rather opaque. The Court drills down to the details of the FDA’s review process, repeatedly stressing the “rigorous” nature of its premarket approval (PMA) process for medical devices.<sup>38</sup> This PMA process demands considerable resources and manpower hours, culminating in the FDA’s determination of “reasonable assurance” of the medical device’s “safety and effectiveness.”<sup>39</sup>

The contrast between FDA’s PMA process (at issue in *Riegel*) and its premarket notification process (at issue in *Lohr*) is twofold. Premarket notification is a streamlined process, which is completed in an average of 20 hours (as compared to the PMA’s 1,200-hour average).<sup>40</sup> So, measured by average manpower hours, this type of regulatory review is sixty times more lax. Even more germane is the distinction the Court draws between the FDA’s premarket notification “equivalence” review, which essentially “grandfathers” devices that are equivalent to those existing on the market at

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<sup>37</sup> In this respect, I agree, at least in part, with both Richard Epstein’s and Richard Nagareda’s trenchant analyses of FDA tort preemption to the extent that each has urged an approach centered upon the agency’s regulatory action. See, e.g., Richard A. Epstein, *Why the FDA Must Preempt Tort Litigation: A Critique of Chevron Deference and a Response to Richard Nagareda*, 1 J. TORT. L. art. 5, at 20, available at <http://www.bepress.com/jtl/vol1/iss1/art5/> (2006) (“Did the agency make a considered examination of the various risks when it decided on its course of action?”) (link); Richard Nagareda, *FDA Preemption: When Tort Law Meets the Administrative State*, 1 J. TORT L. art.4, at 5, available at <http://www.bepress.com/jtl/vol1/iss1/art4/> (2006) (advocating an approach “seeking to marry a proper understanding of preemption with appropriate design of the underlying regulatory regime”) (link).

But, as usual, the devil resides in the details—namely what constitutes an agency’s “considered examination” of the precise risks at issue and what level of judicial review—of agency interpretations, actions, and inaction—should pertain? Here is where, I think, I push the ball several lengths forward.

<sup>38</sup> *Riegel*, 128 S. Ct. at 1003–04.

<sup>39</sup> *Id.* at 1004.

<sup>40</sup> *Lohr*, 518 U.S. at 478–79.



the time of the MDA's enactment,<sup>41</sup> versus the full-blown PMA "safety" review.<sup>42</sup>

In the *Riegel* Court's view, the details of the FDA's stringent safety review are relevant to the Court's interpretation of the MDA. The Court emphasizes that premarket approval *is* a safety review, and as such imposes "requirements" under the MDA.<sup>43</sup> But the significance of the FDA's level of regulatory scrutiny of medical devices to the regulatory preemption inquiry is even more far reaching and could prove influential, if not dispositive, in resolving implied conflict preemption disputes, where courts must look beyond the statutory text to decide whether or not state common law actions obfuscate or impede federal regulatory directives and goals.

While the *Riegel* opinion does not pursue this line of inquiry, several of the Justices tipped their respective hats in this direction during oral argument. Justice Kennedy proffered a concise statement of implied conflict: "The FDA is specifically charged [in the PMA process] with weighing the [potential] risks [of injury and illness] against the probable benefits [to the health of the patient]. . . . So the jury is doing the same thing that the FDA did."<sup>44</sup> Justice Scalia seemed to be of like mind, forging a distinction between *Lohr* and *Riegel* on the basis of whether the jury was engaged in the same regulatory function as the FDA: "[T]he point is that the FDA in *Lohr* had never made a determination of weighing the risks against the benefits, as they do for the issuance of PMA's. And so the jury was not replowing the same ground that the FDA had already plowed in *Lohr*."<sup>45</sup>

The Justices' queries here point in exactly the right direction—namely, when it comes to making an implied conflict preemption determination, it is critical to discern whether the FDA has weighed in on the precise risk the state tort action likewise seeks to regulate. Such a framework will focus judicial attention on the regulatory record compiled by the agency, contemporaneously with its decision whether or not to take regulatory action.

## II. JUDICIAL REVIEW

The *Riegel* majority had little to say about judicial review of agency actions or interpretations, given the primacy and determinacy of statutory

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<sup>41</sup> *Id.* at 480 (noting that the FDA's "substantial equivalence" letter to the manufacturer "emphasized . . . that this determination should not be construed as an endorsement of the pacemaker lead's safety").

<sup>42</sup> *Riegel*, 128 S. Ct. at 1004 (describing the safety review process that calls upon the FDA to "weig[h] any probable benefit to health from the use of the device against any probable risk of injury or illness from such use") (alteration in original) (internal quotation marks omitted).

<sup>43</sup> *Id.* at 1007. There is a logic to this progression of reasoning, namely: "the FDA requires a device that has received premarket approval to be made with almost no deviations from the specifications in its approval application, for the reason that the FDA has determined that the approved form provides a reasonable assurance of safety and effectiveness." *Id.*

<sup>44</sup> *Riegel* Oral Argument, *supra* note 15, at 6–7.

<sup>45</sup> *Id.* at 8. Justice Alito, too, asked questions in this same vein. *Id.* at 30–32.

text to the question at hand. But what little the Court did have to say may have resolved (at least in dicta) a simmering debate over the appropriate level of deference due to agency views on preemption:

In the case before us, the FDA has supported the position taken by our opinion with regard to the meaning of the statute. We have found it unnecessary to rely upon that agency view because we think the statute itself speaks clearly to the point at issue. If, however, we had found the statute ambiguous and had accorded the agency's current position deference, the dissent is correct that—inasmuch as mere *Skidmore* deference would seemingly be at issue—the degree of deference might be reduced by the fact that the agency's earlier position was different.<sup>46</sup>

Wrapped up in this quixotic counterfactual musing are two salient doctrinal points: first, that “mere *Skidmore*” deference—which is meted out according to the agency's “power to persuade” the court, as opposed to unconditionally<sup>47</sup>—is the appropriate level of judicial deference; and second, that agency inconsistency is a salient factor, weighing against an agency's new-found (and by hypothesis, turn-about) position. What is missing is a framework for the Court to undertake judicial review, probing the adequacy of the reasons given by the agency for taking a particular action, as well as for changing tack and taking a different course of action.

#### A. Applying *Skidmore* Deference

*Skidmore* deference trains the court's review of an agency's interpretation on “all those factors which give it power to persuade, if lacking power to control,” such as “the thoroughness evident in its consideration, the validity of its reasoning, [and] its consistency with earlier and later pronouncements.”<sup>48</sup> Perhaps the sole point of agreement between the majority and dissent in *Riegel* was that if *Skidmore* deference were to apply, then the court should consider whether the FDA's position on preemption merited less deference on account of its inconstancy.

Twelve years before *Riegel*, under the Clinton administration, the FDA publicly endorsed an anti-preemption position vis-à-vis the MDA's regulation of medical devices. Before the Court in *Lohr*, the FDA put forward a narrow view of its preemptive power, emphasizing the manufacturer's ulti-

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<sup>46</sup> *Riegel*, 128 S. Ct. at 1009 (citation omitted); see also *id.* at 1015-16 & n.18 (noting that the FDA had reversed its “long held view” against preemption and that the “FDA's new position is entitled to little weight”) (Ginsburg, J., dissenting).

<sup>47</sup> *Skidmore v. Swift & Co.*, 323 U.S. 134, 140 (1944) (link).

<sup>48</sup> *Id.* See Kristen E. Hickman & Matthew D. Kreuger, *In Search of the Modern Skidmore Standard*, 107 COLUM. L. REV. 1235, 1281-91 (2007) (demonstrating, based upon a review of more than one hundred recent federal appellate cases applying *Skidmore* deference, that courts tend to apply *Skidmore* as a sliding scale based upon five key factors: (1) the thoroughness of the agency's consideration, (2) the formality of the agency's procedure in staking out its interpretation, (3) the validity of the agency's reasoning, (4) the consistency of the agency's interpretations, and (5) the relevance of agency expertise) (link).

mate responsibility for its design of medical devices.<sup>49</sup> And the year following *Lohr*, in an amicus brief urging the Court to grant certiorari in another medical devices case (where the catheter device at issue had gone through the full PMA process), the FDA took the position that the MDA's preemption provision is *not* preemptive.<sup>50</sup>

Fast forward to the Bush II administration. The FDA did a seeming 180-degree turn-about and first articulated its new pro-preemption position for PMA devices in 2004 in an amicus brief in *Horn v. Thoratec*,<sup>51</sup> a case before the Third Circuit Court of Appeals. The FDA argued that the PMA process creates specific federal requirements because, following approval, the manufacturer cannot alter the design or labeling of the device without FDA approval.<sup>52</sup>

Sweeping *Chevron* deference to agencies on preemption questions raises the troubling specter of enabling or encouraging cycles of agency political flip-flop,<sup>53</sup> and, more generally, of foregoing a key judicial check by relieving the agency of responsibility to supply an adequate record to substantiate its position regarding the preemptive effect of federal statutes and regulations. *Riegel* could in fact be hypothetical "exhibit A." The FDA's change in position did not escape notice in *Riegel*. Justice Stevens drew attention to it during oral argument.<sup>54</sup> And Justice Ginsburg hammered the point home that the FDA's previous position "was 180 degrees different."<sup>55</sup> Stipulation of the weaker *Skidmore* deference standard still leaves much to be decided. Namely, how should a court determine whether the agency's change in position has been reasonably explained?

### B. Demanding Reasonable Explanations

In the *Riegel* opinion below, the Second Circuit was little troubled by the FDA's change of heart; the court explained: "It is certainly true that the FDA previously took a different view, but as the Third Circuit noted in *Horn*, 'an agency may change its course so long as it can justify its change

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<sup>49</sup> Brief for the United States as Amicus Curiae Supporting Respondents/Cross Petitioners at 20, *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996) (Nos. 95-754, 95-886), 1996 WL 118035, at \*20.

<sup>50</sup> Brief for the United States as Amicus Curiae at 13, *Smith Indus. Med. Sys., Inc. v. Kernats*, 522 U.S. 1044 (1997) (No. 96-1405), 1997 WL 33561767, at \*13.

<sup>51</sup> 376 F.3d 163 (3d Cir. 2004).

<sup>52</sup> Letter-Brief for the United States as Amicus Curiae at 16–17, *Horn v. Thoratec*, 376 F.3d 163 (3d Cir. 2004) (No. 02-4597), 2004 WL 1143720, at \*16–17 [hereinafter *Horn* Letter-Brief for the United States as Amicus Curiae].

<sup>53</sup> See, e.g., Epstein, *supra* note 37, at 15 ("[A]ny court wedded to *Chevron* deference has to abide by [agency decisions regarding preemption] . . . so that the preemption question could oscillate to and fro with a change in personnel and administrations.").

<sup>54</sup> *Riegel* Oral Argument, *supra* note 15, at 39.

<sup>55</sup> *Id.* at 45; see also *Riegel v. Medtronic, Inc.*, 128 S. Ct. 999, 1015–16 & n.8 (2008) (Ginsburg, J., dissenting) (link).

with “reasoned analysis,” a standard satisfied here.”<sup>56</sup> But the FDA provided little more than an ipse dixit justification of its change in position in *Horn*, based upon its “further analysis of the relevant legal and policy issues” as well as recent contrary court decisions.<sup>57</sup>

In its amicus brief filed at the petition stage at the Supreme Court, the Solicitor General added only that “[t]he government’s [previous anti-preemption] position . . . is also inconsistent with the risk-management principles that the FDA currently follows.”<sup>58</sup> The government seemed to rely heavily on the notion that its position is entitled to substantial deference and that its explanation of “risk-management principles” and “the need to prevent over-warning” should suffice to demonstrate the incompatibility of state tort law with the FDA regulatory standards.

The government’s proffers based solely on its “judgment” or new policy preferences—of the sorts offered in *Horn* and *Riegel*—should not pass judicial muster in implied conflict preemption cases. Instead, courts should apply searching review and require direct, hard evidence from the agency’s regulatory record of how state common law conflicts with the federal regulatory scheme and, where applicable, the basis for any change in agency position.<sup>59</sup> Justice Alito made a gesture in this direction, when he asked during the *Riegel* oral argument whether the PMA regulatory record would reflect whether the precise design defect complained of by petitioner was

<sup>56</sup> *Riegel v. Medtronic, Inc.*, 451 F.3d 104, 125 (2d Cir. 2006) (citing *Motor Vehicle Mfrs. Ass’n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 42 (1983)).

<sup>57</sup> *Horn* Letter-Brief for the United States as Amicus Curiae, *supra* note 52, at 3.

<sup>58</sup> Brief for the United States as Amicus Curiae, On Petition for Writ of Certiorari, at 17, *Riegel v. Medtronic*, 128 S. Ct. 999 (2008) (No. 06-179), 2007 WL 1511526. The SG expanded upon this rationale only a tad in its amicus brief at the merits stage: “[T]he United States’ earlier position was based in part on proposed regulations that FDA has since withdrawn, and its prior position is inconsistent with FDA’s current understanding and application of the risk-management principles discussed above (e.g., the need to prevent over-warning). Neither FDA’s reasoned change in position, nor the absence of a formal agency regulation addressing the specific question presented here, negates deference.” Brief for the United States as Amicus Curiae Supporting Respondent at 24, *Riegel v. Medtronic, Inc.*, 128 S. Ct. 999 (2008) 2007 WL 3231418, at \*24 [hereinafter *Riegel* Brief for the United States as Amicus Curiae] (citing *Auer v. Robbins*, 519 U.S. 452, 461–62 (1997)).

<sup>59</sup> Brian Galle and Mark Seidenfeld have likewise called for something akin to *Skidmore* deference, coupled with a type of “hard look” review, which would allow agencies the flexibility to change their position when necessary, offering agencies incentive to show that they reached their decision through “good and open deliberation.” Brian D. Galle & Mark Seidenfeld, *Administrative Law’s Federalism: Preemption, Delegation, and Agencies at the Edge of Federal Power*, 57 DUKE L.J. (forthcoming 2008), available at <http://ssrn.com/abstract=1101141>. See also *Motor Vehicle Mfrs. Ass’n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 42–43 (1983) (“[A]n agency changing its course by rescinding a rule is obligated to provide a reasoned analysis for the change . . . . [T]he agency must examine the relevant data and articulate a satisfactory explanation for its action.”). I have in mind something like “*State Farm* with teeth,” keeping in mind that the Second Circuit gave the green light to the FDA’s changed position pursuant to what I would characterize as a “lax *State Farm*” standard, see *supra* notes 56–57 and accompanying text.

considered by the FDA.<sup>60</sup> The informational demands of such an approach are significant, which perhaps explains why it has been resisted by the FDA.<sup>61</sup>

The *Riegel* Court did not have to squarely face these issues of appropriate deference to the FDA, or judicial review of the bases for its preemption position, given the Court's exaltation of statutory text. The Court, moreover, declined to venture down the implied conflict preemption path, where it might have taken account of, and accorded *Skidmore* deference to, the FDA's preemption position, the basis for which it would then subject to some level of judicial scrutiny. These issues are sure to rear their head in future challenges before the Court.

### III. FUTURE CHALLENGES: PHARMACEUTICALS

In the wake of *Riegel*, what will the state law products liability landscape look like? *Riegel* certainly narrows the scope of state law claims of allegedly defective FDA-approved medical devices that can withstand a federal preemption challenge. That said, claims of tort litigation's demise in the arena of medical devices, let alone all of products liability, have been overstated.<sup>62</sup>

Four caveats to the Court's opinion suggest categories of surviving claims. First, manufacturing defect (as distinct from design defect and fail-

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<sup>60</sup> *Riegel* Oral Argument, *supra* note 15, at 31–32 (“If you look at the file of a PMA proceeding after it is concluded, can you tell exactly which design features and which risks the FDA has considered?”).

<sup>61</sup> In response to Justice Alito's question, Wyeth's attorney answered: “No, I don't think you can . . . The FDA will have examined, and presumably done its job, with respect to every aspect of the design, manufacture, and labeling of the device. . . .” *Id.* at 32 (Mr. Olson). The government likewise resisted the suggestion:

We don't think that a preemption test can really realistically turn on that. That would require extensive and intrusive inquiry into what FDA had done. We think that the best way to look at this is what the end product was . . . You look at what was put before the agency and what was approved, not what might have gone into—into consideration.

*Id.* at 50 (Mr. Kneedler).

<sup>62</sup> In the wake of *Riegel*, some news media headlines pronounced the death of claims by those injured by medical devices. See, e.g., Robert Barnes, *Supreme Court Shields Medical Device Makers; Decision Rules Out State Lawsuits Over Products That Meet FDA's Highest Standards*, WASH. POST, Feb. 21, 2008, at D1, available at <http://www.washingtonpost.com/wp-dyn/content/article/2008/02/20/AR2008022001140.html> (“Yesterday's decision seemed in step with the court's recent rulings favoring business and expressing skepticism about the role of civil lawsuits in disciplining corporations.”) (link); Janet McConaughy, *A 'Get Out of Jail Free Card' for Manufacturers; If Regulatory Agency OK'd Product, Jury Can't Second Guess*, PITTSBURGH POST-GAZETTE, Mar. 31, 2008, at A4; see also Editorial, *No Recourse for the Injured*, NY TIMES, Mar. 22, 2008, at 22, available at [http://www.nytimes.com/2008/02/22/opinion/22fri1.html?\\_r=1&oref=slogin](http://www.nytimes.com/2008/02/22/opinion/22fri1.html?_r=1&oref=slogin) (reading *Riegel* to “mean[] that any consumer harmed by a fault device . . . will have no chance of fair compensation and the manufacturer will have a dangerous sense of impunity”) (link).

ure to warn) claims are allowed to proceed.<sup>63</sup> Second, keeping in mind the distinction between *Riegel*, which addressed itself to devices that were approved via the FDA's PMA process, and *Lohr*, which pertained to devices that had secured approval via the FDA's "substantial equivalence" premarket notification process, only manufacturers of medical devices that enter the market via PMA (at present, roughly ten percent of relevant devices) can use the shield of *Riegel* to stave off state tort claims using a preemption defense. A third important caveat involves negligence per se actions—state tort law actions based upon the violation of a federal regulatory standard. The *Riegel* majority is explicit that "the state duties in such a case 'parallel,' rather than add to, federal requirements" and are thus not preempted.<sup>64</sup> Finally, there may be an additional opening for situations where new product risks come to light after the FDA's initial approval.<sup>65</sup> What *Riegel* portends for the future may, nonetheless, lie more in the questions left unanswered, or at least not fully answered.

Pharmaceutical litigation involving FDA-approved drugs lies just over the Court's horizon. Indeed, when the Court heard argument in *Riegel*, the specter of the upcoming FDA pharmaceutical preemption case, *Wyeth v. Levine*, loomed large in the background.<sup>66</sup> During the *Riegel* oral argument, Justice Scalia turned from devices to drugs, asking (seemingly rhetorically): "Then the States can issue regulations that go beyond—beyond what the FDA says in drug matters? I would be surprised if that's the case."<sup>67</sup>

When the Court ruled 8-1 in favor of preemption in *Riegel*, some preemption enthusiasts seemed poised to celebrate an FDA preemption "hat-trick" at the Supreme Court—with impending victories in the two

<sup>63</sup> See *Riegel v. Medtronic, Inc.*, 128 S. Ct. 999, 1006 (2008). Not surprisingly, a proliferation of such claims is anticipated. Drug and Device Law Blog, <http://druganddevicelaw.blogspot.com/search?q=July+17%2C+2008> (July 17, 2008, 12:27 EST) ("Watch out for disguised 'manufacturing' claims. . . . We'll need to watch carefully for plaintiffs trying to pass off what are really *Riegel*-preempted design defect claims . . . as so-called 'manufacturing' claims.") (link).

<sup>64</sup> *Riegel*, 128 S. Ct. at 1011.

<sup>65</sup> See *id.* at 1013 n.1 (Ginsburg, J., dissenting) ("The Court's holding does not reach an important issue outside the bounds of this case: . . . where evidence of a medical device's defect comes to light only *after* the device receives premarket approval."). The majority opinion is silent here—although several of the Justices took an interest in this issue during oral argument, see *Riegel* Oral Argument, *supra* note 15, at 26–27 (Roberts, C.J.); *id.* at 27–28 (Kennedy, J.); *id.* at 28 (Stevens, J.); *id.* at 29 (Souter, J.)—so perhaps the most that can be said is that this is an open (and sure to be heavily litigated) issue. The approach I have advocated—with due attention to the agency's regulatory record as to the precise risk regulated—is consistent with Justice Ginsburg's position here.

<sup>66</sup> See *Riegel*, 128 S. Ct. at 1018–19 & n.16 (Ginsburg, J., dissenting).

<sup>67</sup> *Riegel* Oral Argument, *supra* note 15, at 11. Justice Scalia's view of *Riegel* seemed to go the farthest, pushing beyond implied conflict preemption to the broader realm of implied field preemption. *Id.* at 12 ("It is field preemption, isn't it?"). This more expansive view was taken up by the government, arguing as *amicus curiae* in support of the respondent device manufacturer. See *id.* at 42 ("[M]aybe in this context it is best to conceptualize it as field preemption, of the things that are included within the application that is submitted to the FDA and the labeling.").

pharmaceutical preemption cases to come, *Kent v. Warner-Lambert*,<sup>68</sup> a fraud-on-the-agency case also decided last Term, and *Wyeth*.<sup>69</sup> The eight-person majority, after all, rose against Justice Ginsburg's lone dissenting voice to clarify that "[i]t has not been established (as the dissent assumes) that no tort lawsuits are pre-empted by drug or additive approval under the FDCA."<sup>70</sup> But selective parsing of Court opinions has its perils. For, far from intimating that its decision in *Riegel* would preordain the same result in the pharmaceutical context, the Court emphasized a key statutory distinction between the realms of medical devices and drugs: a preemption clause applies to the former, but not the latter.<sup>71</sup> The whole game, then, switches from express preemption in *Riegel* to implied conflict preemption in *Wyeth*.<sup>72</sup> Moving the battleground from express preemption (in medical devices context) to implied preemption (in pharmaceutical context) is likely to divide the ranks, as was the case in *Kent*, where the Court handed down its 4-4 split decision (with Justice Roberts' having recused himself).<sup>73</sup>

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<sup>68</sup> *Warner-Lambert Co. v. Kent*, 128 S. Ct. 1168 (2008) (per curiam) (link).

<sup>69</sup> See Posting of Ted Frank to PointofLaw.com, <http://www.pointoflaw.com/archives/2008/02/riegel-v-medtronic.php> (Feb. 20, 2008, 24:38 EST) (calling *Riegel* "[a] phenomenally good . . . decision [that] . . . bodes well for the cause of federal preemption in the pending [*Kent*] and [*Wyeth*] cases") (link); Drug and Device Law Blog (Feb. 20, 2008), <http://druganddevicelaw.blogspot.com/2008/02/more-on-riegel.html> (Feb. 20, 2008, 08:13 EST) ("[W]e have to say that we feel better about [*Wyeth*] after reading [*Riegel*].") (link); see also Posting of Amanda to Poptort.com (Feb. 21, 2008), <http://www.thepoptort.com/2008/02/in-love-us-supr.html> (Feb. 21, 2008, 11:46 EST) (lamenting that *Riegel* "was clearly a Valentine gift (a few days belated) to drug companies—and there's more to come!") (link).

In a telling exchange during the *Kent* oral argument, Justice Breyer certainly telegraphed his leanings as well. See Transcript of Oral Argument at 30, *Warner-Lambert Co.*, 128 S. Ct. 1168 (No. 06-1498) ("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 role who see before them only the people whom the drug hurt and don't see those who need the drug to cure them?").

<sup>70</sup> *Riegel*, 128 S. Ct. at 1009.

<sup>71</sup> *Id.* ("[I]f . . . Congress wanted the two regimes [medical devices and drugs] to be alike; Congress could have applied the pre-emption clause to the entire FDCA. It did not do so, but instead wrote a pre-emption clause that applies only to medical devices.").

<sup>72</sup> Not only are the FDCA drug provisions bereft of any preemption provision, but they also contain a qualified savings clause: "Nothing in the amendments . . . shall be construed as invalidating any provision of State law which would be valid in the absence of such amendments unless there is a direct and positive conflict between such amendments and such provision of State law." Drug Amendments of 1962, § 202, 76 Stat. 780, 793 (1962) (codified as 21 U.S.C. § 321 (2007)) (link); see also Sharkey, *Products Liability Preemption*, *supra* note 11, at 503-04 (arguing that "direct and positive conflict" language embraces implied conflict preemption of both the impossibility and obstacle/frustration of purposes varieties).

<sup>73</sup> 128 S. Ct. 1168 (2008) (mem). This "non-decision" let stand the Second Circuit opinion below, which held that common law tort claims were not impliedly preempted in a case applying a statutory fraud exception to a drug liability immunity provision. *Id.* For a discussion of the wider implications of the issues raised in *Kent*, see Catherine M. Sharkey, *The Fraud Caveat to Agency Preemption*, 102 NW. U. L. REV. 841 (2008) [hereinafter Sharkey, *The Fraud Caveat to Agency Preemption*].

Certainly with statutory text unable to take up the gauntlet to resolve the preemption question, issues that lurked in the background of *Riegel* come decidedly to the fore. The presumption against preemption may once again rear its head (although quiescent in *Riegel*) and policy preferences could reveal themselves in the guise of pronouncements on the compatibility of ex ante FDA regulation of drugs with ex post juror resolution of state tort claims. But all eyes should be trained on the Court's treatment of the FDA's involvement.

#### A. FDA Input

Recall that *Riegel* can be distinguished from *Lohr* on the basis of the rigor of the PMA process at issue in the former as compared to the premarket notification process in the latter. The *Riegel* dissent carries this line of analysis into pharmaceuticals, making the point that "the process for approving new drugs is at least as rigorous as the [PMA] process for medical devices."<sup>74</sup> Justice Ginsburg means for this to be a strike against reliance upon the rigor of FDA regulatory review, staking her argument on the claim that courts have not found that FDA approval of drugs preempts state tort lawsuits. The *Riegel* majority instead takes the rigor of the device approval process to support its pro-preemption interpretation of the MDA.

As I suggested above, the significance is even greater in the realm of implied conflict preemption analysis, where the question whether allowance of state tort law claims enables a jury to "redo" the very same cost-benefit analysis conducted by the agency is relevant to a court's consideration of whether state tort law impedes the federal regulatory process. With this in mind, the details of the FDA drug approval process provided by Justice Ginsburg take on an added significance.<sup>75</sup> As summed up by the Solicitor General in *Riegel*, "FDA's risk-benefit balancing for devices is parallel to the risk-benefit balancing it undertakes . . . as part of the pre-market approval process for drugs."<sup>76</sup>

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<sup>74</sup> *Riegel*, 128 S. Ct. at 1018 (Ginsburg, J., dissenting); see also *Riegel* Oral Argument, *supra* note 15, at 25 (Ginsburg, J.) ("I would think that if everything that [counsel for device manufacturer] said about new devices would apply in bold letters to new drugs, because the testing procedures are much longer, are they not?").

<sup>75</sup> See *Riegel*, 128 S. Ct. at 1018–19 n.15 (Ginsburg, J., dissenting) (citations omitted) (recounting the details of the FDA's process for approving a new drug).

<sup>76</sup> *Riegel* Brief for the United States as Amicus Curiae, *supra* note 58, at 11; see also Brief of the United States as Amicus Curiae Supporting Petitioner at 13–15, *Wyeth v. Levine*, 128 S. Ct. 1118 (2008) (No. 06-1249), 2008 WL 2308908, at \*13–15 [hereinafter *Wyeth* Brief of the United States as Amicus Curiae Supporting Petitioner] ("FDA's 'rigorous evaluation process' . . . scrutinizes everything about the drug—from the design of clinical trials to the severity of side effects to the conditions under which the drug is manufactured. [A]n FDA review team—medical doctors, chemists, statisticians, microbiologists, pharmacologists, and other experts—evaluates whether the studies the sponsor submitted show that the drug is safe and effective for its proper use.") (alterations in original) (quoting FDA, *The FDA's Drug Review Process: Ensuring Drugs Are Safe and Effective (Review Process)* (visited June 2, 2008), <http://www.fda.gov/fdac/special/testtubetopatient/drugreview.html>).



Further questions must be asked, however, in the context of drugs, which is governed by implied conflict preemption analysis: Does FDA regulation (including rigorous approval processes ensuring the safety and efficacy of drugs) constitute a minimal safety “floor” or an optimal level of protection, and thus a regulatory “ceiling” as well? Even if the latter, which precise risks (costs) has the FDA considered and weighed in on in the course of its risk-benefit balancing? Only then can we know whether allowing state tort claims to proceed when FDA-approved drugs cause harm will obstruct the federal regulatory process.

Chief Judge Reiber, the dissenting judge in the *Wyeth* lower court opinion, perceived such a conflict. To him, the issue was fairly clear-cut: “FDA concluded that the drug—with its approved methods of administration and as labeled—was both safe and effective,” whereas the “jury concluded that the same drug—with its approved methods of administration and as labeled—was ‘unreasonably dangerous.’”<sup>77</sup> But the *Wyeth* majority embraced the view that the FDA standards were minimal ones, rife for enhancement by state tort law. The majority’s interpretation is buttressed by the literal language of an FDA regulation, known as the “changes being effected” (CBE) regulation, that seems to permit drug manufacturers to add or strengthen FDA-approved warnings, at least in certain circumstances.<sup>78</sup> In 1979, moreover, the FDA said that its regulations did not prohibit labeling changes made to add or strengthen warnings without prior FDA approval.<sup>79</sup>

Today, the FDA takes the interpretive position that the CBE should be read to apply only to “newly discovered risks”—although those words do not appear in the regulation.<sup>80</sup> The FDA relies upon its policy not to take enforcement action against a manufacturer that modifies a label absent FDA approval in light of newly discovered risk information.<sup>81</sup> Recently, the FDA has proposed a rule to codify what it says is the “agency’s longstanding view.”<sup>82</sup> The FDA argues that any broader interpretation, which would al-

<sup>77</sup> *Levine v. Wyeth*, 944 A.2d 179, 197 (Vt. 2006) (Reiber, C.J., dissenting).

<sup>78</sup> The CBE regulation permits a drug manufacturer which has filed a supplemental new drug application to the FDA to implement a labeling change before the FDA has acted on the application either “[t]o add or strengthen a contraindication, warning, precaution, or adverse reaction” or “[t]o add or strengthen an instruction about dosage and administration that is intended to increase the safe use of the drug product.” 21 C.F.R. § 314.70(c)(6)(iii)(A),(C) (2007).

<sup>79</sup> Labeling and Prescription Drug Advertising, 44 Fed. Reg. 37,434, 37,447 (June 26, 1979).

<sup>80</sup> Brief for Petitioner at 10, *Wyeth v. Levine*, 128 S. Ct. 1118 (2008) (No. 06-1249), 2008 WL 2273067 [hereinafter *Wyeth* Brief for Petitioner]. According to *Wyeth*, “[t]hat reading is supported by the history of the regulation and its relationship to the purposes of the FDCA as a whole; it is also the interpretation that FDA has reasonably advanced.” *Id.* at 27.

<sup>81</sup> In addition, “as a practical matter, FDA encourages sponsors to consult with FDA prior to adding safety-related information to the labeling for an approved product even when such a change is submitted in a CBE supplement, and sponsors typically do so.” Supplemental Applications Proposing Labeling Changes for Approved Drugs, Biologics, and Medical Devices, 73 Fed. Reg. 2848, 2849 (proposed Jan. 16, 2008) (to be codified at 21 C.F.R. pts. 314, 601, 814).

<sup>82</sup> *Id.* at 2849.

low manufacturers unilaterally to add new warnings to drugs would “undermine the FDA approval process required by Congress.”<sup>83</sup> The FDA thus wants to circumscribe the domain of unilateral manufacturer labeling activity to what it defines as “newly discovered risks.”<sup>84</sup> The Solicitor General has pressed this view before the Supreme Court in *Wyeth*.<sup>85</sup>

The FDA’s new proposed rule is of a piece with its earlier 2006 “preemption preamble” to a rule on the content and format of drug labels, which sets forth the FDA’s belief that “FDA approval of labeling under the act . . . preempts conflicting or contrary State law.”<sup>86</sup> In the preamble, the FDA asserts that “product liability lawsuits have directly threatened the agency’s ability to regulate manufacturer dissemination of risk information for prescription drugs in accordance with the [FDCA].”<sup>87</sup> In both the earlier preemption preamble and the recent proposed CBE regulation, the agency squarely takes the position that the new drug approval process, culminating in the FDA’s finding that a drug is “safe and effective” under the conditions as stated in its labeling constitutes optimal, or ceiling, safety standards, as opposed to minimal, or floor, ones. According to the FDA, “[t]he centerpiece of risk management for prescription drugs generally is the labeling which reflects thorough FDA review of the pertinent scientific evidence.”<sup>88</sup>

### B. Judicial Review

The potential clash between federal regulation and state tort law is premised upon the FDA’s claim—as put forward in its preemption preamble, the proposed CBE regulation, and in the Solicitor General’s amicus brief in *Wyeth*—that the agency is engaged in setting optimal, as opposed to minimal, standards. As I have emphasized, input from the relevant agency on the question of interference with federal regulatory schemes is critical for courts to make implied conflict preemption decisions. But, equally important, courts must scrutinize the bases for agency’s claims and determinations.

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<sup>83</sup> *Id.* (explaining that unilateral decisions by the manufacturer “would disrupt FDA’s careful balancing of how the risks and benefits of the product should be communicated”).

<sup>84</sup> *Id.* at 2850 (defining “newly acquired information” on safety as “data, analyses, or other information not previously submitted to the agency, or submitted within a reasonable time period prior to the CBE supplement, that provides novel information about the product, such as a risk that is different in type or severity than previously known risks about the product”).

<sup>85</sup> See *Wyeth* Brief of the United States as Amicus Curiae Supporting Petitioner, *supra* note 76, at 22 (arguing that a manufacturer can unilaterally change a drug label only “to correct concerns about newly discovered risks from use of the drug”) (quoting 47 Fed. Reg. 46,622, 46,623 (Oct. 19, 1982)) (emphasis added in original); see also *id.* at 15 (noting that manufacturers typically consult with the FDA before making any changes to the drug’s labeling).

<sup>86</sup> Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. 3922, 3934 (Jan. 24, 2006).

<sup>87</sup> *Id.*

<sup>88</sup> *Id.*

The FDA's main concern with allowing state tort claims on top of FDA regulation of drug labels is the risk that overwarning can harm patients and interfere with regulatory goals.<sup>89</sup> In its preemption preamble, the FDA claimed that "additional requirements for the disclosure of risk information are not necessarily more protective of patients" and cautioned that an overabundance of warnings "can erode and disrupt the careful and truthful representation of benefits and risks that prescribers need to make appropriate judgments about drug use."<sup>90</sup> The nefarious effects of overwarning induced by state tort liability are (at least) two-fold. First, there is the risk of warning dilution, namely, "labeling that includes theoretical hazards not well-grounded in scientific evidence can cause meaningful risk information to lose its significance."<sup>91</sup> Second, "[e]xaggeration of risk, or inclusion of speculative or hypothetical risks, could discourage appropriate use of a beneficial drug."<sup>92</sup> In sum, according to the FDA, "where warnings are concerned, more is not always better."<sup>93</sup>

The FDA preemption preamble suffers from serious procedural irregularities, including the fact that in the original notice of proposed rulemaking, the FDA stated that its proposed rule would *not* preempt state tort law; only at the end of the process, after the comment period had closed, did the FDA switch its position and insert the contrary position into the preamble of the final rule.<sup>94</sup> The process failure bespeaks lack of engaged debate on the matter and certainly raises the bar with respect to the kind of evidence the FDA would have to provide to substantiate preemption. While the preamble seems a fairly egregious process failure, more generally, agencies are notorious for flouting the congressional and executive commands that they conduct federalism impact statements and carefully assess any alleged conflict between their regulations and state tort law. I have previously suggested that courts should condition deference to agencies' regulations on their undertaking these basic responsibilities.<sup>95</sup>

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<sup>89</sup> Here, I put to one side the arguably separate and important interest in uniformity. Brief for the United States as Amicus Curiae at 5, *In re Paxil Litig.*, No. CV 01-07937 MRP, 2002 WL 31375497, at \*5 (C.D. Cal. Sept. 5, 2002) ("[T]he public undoubtedly would receive inconsistent information from region to region.").

<sup>90</sup> 71 Fed. Reg. at 3935.

<sup>91</sup> 73 Fed. Reg. at 2851

<sup>92</sup> *Id.*; see also 71 Fed. Reg. at 3935.

<sup>93</sup> Brief of the United States as Amicus Curiae in Support of Defendants-Appellees at 16, *Colacicco v. Apotex Inc.*, 521 F.3d 253 (3d Cir. 2008) (No. 06-3107), 2006 WL 5691532, at \*16.

<sup>94</sup> Sharkey, *Preemption by Preamble*, *supra* note 23, at 254 (noting that the FDA's decision to insert preemptive language in the preamble "provoked charges that it had flouted its obligation to consult with State and local authorities and circumvented the proper notice-and-comment process").

<sup>95</sup> *Id.* at 256-57 ("Consistent with Executive Order 13,132, courts might condition deference to agency interpretations of the preemptive scope of regulations on compliance with various congressional and executive measures designed to increase the public participation of states, the legislature, and outside political groups: consultation mandates, 'federalism impact statements,' or even notice-and-comment periods could be required for all preemption statements.").

In terms of accountability, it is heartening that the FDA is proceeding with revisions to the CBE regulation via public notice-and-comment rule-making—albeit against the backdrop of the *Wyeth* litigation—and not replicating the mistakes of the procedurally flawed process that led to promulgation of the preemption preamble.<sup>96</sup>

But the FDA is still trying to accomplish too much at the wholesale level by “legal interpretation” and too little at the retail level by way of “regulatory record.” Applying the framework I have set out above to the *Wyeth* case, the agency’s regulatory record should have to supply direct, hard evidence on the precise risks considered by the FDA and provide some record evidence to substantiate the danger of overwarning.

*Wyeth* argues that the FDA did in fact conduct a cost-benefit analysis with regard to the precise risk at issue, but provides little in the way of record evidence to substantiate this claim.<sup>97</sup> The Solicitor General more circumspectly argues that the FDA was “fully aware” of the precise risk.<sup>98</sup> Some ground exists between the SG’s position that awareness of the risk suffices and the plaintiff-respondent’s position that nothing short of the FDA’s specific rejection of the warning proposed by plaintiff will do.<sup>99</sup> The difference between awareness of a risk and conducting a thorough risk-risk analysis in approving the drug label without requiring further warnings is really a matter of the FDA’s supplying the requisite record evidence to show that it thoroughly considered the issue.

A key problem in this case, however, is that the Vermont Supreme Court gave short shrift to the agency and its actions, so there is an incomplete regulatory record before the U.S. Supreme Court.<sup>100</sup> And plaintiff’s counsel certainly seemed to have free rein to denigrate the FDA’s role, exhorting the jury to take on the FDA’s role: “Thank God we don’t rely on the

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<sup>96</sup> See 73 Fed. Reg. at 2850 (“FDA invites comments regarding the circumstances when information regarding a safety issue associated with a drug . . . should be considered newly acquired and thus appropriate to be included in a CBE supplement.”); see also *id.* at 2853 (“FDA invites comments from State and local officials.”).

<sup>97</sup> *Wyeth* Brief for Petitioner, *supra* note 80, at 28 (referring to FDA’s “determination that, with appropriate warnings and instructions . . . the benefits of IV administration . . . outweigh the well-known risk of harm”).

<sup>98</sup> *Wyeth* Brief of the United States as Amicus Curiae Supporting Petitioner, *supra* note 76, at 4 (“FDA was thus fully aware of the risk of an inadvertent intra-arterial injection, and the labeling or revised labeling it approved uniformly contained warnings to address that risk.”).

<sup>99</sup> Here, I agree with the Solicitor General that “[t]he agency could not reasonably be expected to expressly reject every possible variant of approved labeling as part of its decisional process.” *Id.* at 25.

<sup>100</sup> I have criticized the Vermont Supreme Court’s *Wyeth* decision as an example of the “presumption against preemption” run amok. Sharkey, *Products Liability Preemption*, *supra* note 11, at 507 (“In the hands of the [*Wyeth*] Court, the presumption does most of the necessary work to resolve the case. It is as if the presumption casts a wide protective shadow against implied preemption; regardless of the precise risk regulated by the FDA or specific agency actions taken, the FDA is taken to impose minimum safety standards, ripe for supplementation by state tort law.”).

FDA to rely on this drug and make the safe decision. You will make the decision.”<sup>101</sup>

The Vermont Supreme Court did not solicit the views of the FDA (nor did the FDA intervene in the case on its own). The agency record evidence before the Court consists of letters between Wyeth and the FDA concerning the labeling of the anti-nausea drug Phenergan over a span of nearly fifty years. The letters establish that FDA was made aware of the risk posed by inadvertent intra-arterial injection of Phenergan.<sup>102</sup> What is missing are the FDA’s reasoned explanations of its action in approving the label, notwithstanding its understanding of the relevant risks, for example, because they are outweighed by greater risks inherent in overwarning.<sup>103</sup>

With respect to the danger of overwarning, the FDA continues its practice (also evident in the preemption preamble) of speaking in broad generalities. The FDA is thus vulnerable to criticisms that it has supplied “abstract concerns and dire predictions” as opposed to hard “evidence of interference.”<sup>104</sup> Some of the *Wyeth* amici have tried to come to the FDA’s aid by supplying concrete examples of overwarning.<sup>105</sup> But, of course, this cannot fill the void with respect to the FDA’s particular consideration of the inherent risks in the case at hand. Moreover, with its proposed CBE regulation, the FDA makes a wholesale pitch for deference based upon its general overwarning argument. In a comment to the proposed rule, Senator Kennedy (along with six colleagues) asked point blank for the FDA to substantiate its overwarning claim. In response to his query asking the FDA to provide specific examples where a manufacturer had used the CBE procedure to add a warning that had proved detrimental to public health, the FDA provided a

<sup>101</sup> Joint Appendix at 211, *Wyeth v. Levine*, 128 S. Ct. 1118 (2008) (No. 06-1249), 2008 WL 2309484 [hereinafter *Wyeth* Joint Appendix].

<sup>102</sup> See *id.* at 266–385 (letters between the FDA and Wyeth).

<sup>103</sup> My read of the scant agency record is that the evidence implies that FDA was not only aware of, but had actively considered, the competing risks. The Vermont Supreme Court, by contrast, was convinced that “[t]he FDA could have rejected the new warning for any number of reasons, including clarity or technical accuracy, without implicitly prohibiting a stronger warning.” *Levine v. Wyeth*, 944 A.2d 179, 189 (Vt. 2006). Disputed inferences, however, should not lie at the heart of a sound implied conflict preemption analysis. My approach seeks to put the analysis on sounder evidentiary footing.

<sup>104</sup> *Regulatory Preemption: Are Federal Agencies Usurping Congressional and State Authority?: Hearing Before the S. Comm. on the Judiciary* 110th Cong. (1997) (statement of David C. Vladeck, Professor of Law, Georgetown University Law Center), available at [http://www.law.georgetown.edu/oneillinstitute/documents/vladeck\\_testimony.pdf](http://www.law.georgetown.edu/oneillinstitute/documents/vladeck_testimony.pdf) (last visited July 2, 2008) (link).

<sup>105</sup> Brief of Washington Legal Foundation & American College of Emergency Physicians as Amici Curiae in Support of Petitioner at 13–26, *Wyeth v. Levine*, 128 S. Ct. 1118 (No. 06-1249) (June 3, 2008), 2008 WL 2355771, at \*13–26 (describing recent scientific and medical studies demonstrating adverse public health consequences of overwarning); Brief of John E. Calfee et al. at 11, *Wyeth*, 128 S. Ct. 1118 (No. 06-1294) (June 3, 2008), 2008 WL 2322237, at \*11 (discussing risks of overwarning and “clutter”: the presence of so much information that physicians would find it hard to distinguish important information from relatively unimportant information and might not even bother to peruse all the information”).

mere four examples—three of which were examples where the FDA had in fact required a *stronger* warning, and the remaining one involved a label that was approved after the manufacturer submitted some additional data.<sup>106</sup>

Perhaps the wisest course for the U.S. Supreme Court, then, would be to reverse and remand *Wyeth*, directing the Vermont Supreme Court to put into practice something akin to the “agency reference model” with searching judicial review. Such a framework would, as an initial matter, require the court to solicit input from the FDA and to accord deference to FDA findings of implied conflict to the extent that they are supported by substantial evidence in the agency record.

To be sure, judicial scrutiny of the agency record is potentially burdensome.<sup>107</sup> The Solicitor General raises the specter of intrusive, second-guessing of the agency’s decisionmaking via costly litigation.<sup>108</sup> But there are also corresponding long-term gains, not only in terms of ensuring that the agency has actually carefully considered the risks at issue,<sup>109</sup> but also in terms of fueling more comprehensive and transparent agency decisionmaking.<sup>110</sup>

<sup>106</sup> Letter from Stephen R. Mason, Acting Assistant Commissioner for Legislation, FDA to The Honorable Edward M. Kennedy, Chairman, Committee on Health, Education, Labor, and Pensions 3 (Mar. 7, 2008), *available at* <http://www.regulations.gov/fdmspublic/component/main?main=DocketDetail&d=FDA-2008-N-0032> (follow the “Page 2” link at the bottom of the page, then follow the “FDA-2008-N-0032-0023.4”) (link).

<sup>107</sup> See, e.g., Ronald J. Krotoszynski, Jr., “*History Belongs to the Winners*”: *The Bazelon-Leventhal Debate and the Continuing Relevance of the Process/Substance Dichotomy in Judicial Review of Agency Action*, 58 ADMIN. L. REV. 995, 1002 (2006) (discussing various challenges facing “hard look review” of the substance of agency decisionmaking).

<sup>108</sup> *Wyeth* Brief of the United States as Amicus Curiae Supporting Petitioner, *supra* note 76 (“With the passage of time, however, it would be increasingly difficult to reconstruct the agency’s decisionmaking process . . . preemption analysis would devolve into an intrusive, and potentially inconclusive, second-guessing of the agency’s decisional process.”).

<sup>109</sup> If the agency regulatory record before the Court is incomplete in *Wyeth*, where there was a fifty-year history of correspondence between the manufacturer and the FDA over various risks, imagine the dearth of record evidence that might emerge in other cases. Moreover, without a developed agency record courts will have great difficulty in determining whether evidence of new risks has come to light since FDA approval. The plaintiff in *Wyeth* apparently did not make any such allegation. See Brief for Petitioner at 27, *Wyeth v. Levine*, 128 S. Ct. 1118 (2008) (No. 06-1249), 2008 WL 2273067, at \*27 (“[R]espondent has never suggested that Wyeth had any new information about the risks of IV administration of Phenergan that would have warranted a change without FDA approval.”) (Amended Complaint); *Wyeth* Joint Appendix, *supra* note 101, at 16 (alleging that Wyeth had “known for more than 25 years of the grave risks associated with inadvertent arterial injection or extravasation of Phenergan, including irreversible gangrene and amputation”). But, again, this is likely to be a highly controversial issue in future cases down the road and one that should not be left to inferences drawn from partial agency records.

<sup>110</sup> See, e.g., Mark Seidenfeld, *Cognitive Loafing, Social Conformity and Judicial Review of Agency Rulemaking*, 87 CORNELL L. REV. 486, 523–26 (2002) (discussing the beneficial effects that the knowledge of impending judicial review of an agency record can have of the quality of agency decisionmaking processes) (link); Mark Seidenfeld, *The Psychology of Accountability and Political Review of Agency Rules*, 51 DUKE L.J. 1059, 1064 (2002) (arguing that “hard look” judicial review encourages an

## CONCLUSION

We began the preemption inquiry in *Riegel* with the text of the statute, which is where Justice Scalia's majority opinion claims we may also end. But in cases where Congress has either not been clear or (quite commonly) has sent contradictory signals in the statutory language, courts must go further down an implied conflict preemption path. This is just what the *Riegel* majority did, even while disclaiming the need to look beyond the text. Where are courts to turn next? We made a brief stopover to consider the presumption against preemption statutory canon of construction; but we did not stay long. Nowhere in the *Riegel* majority is this once-esteemed canon mentioned; if anything, *Riegel* signals its potential demise, or at least its waning influence over the Justices. We moved on to consider policy preferences. As a positive matter, it is difficult not to characterize some portions of the Court's opinion—both the embrace of the regulatory role of state tort law and, further, the perception of the jury as ill-equipped to handle cost-benefit decisionmaking—as reflecting policy preferences. But this raises troubling normative implications. The Justices' anxiety here manifests itself in the Court's repeated efforts to ascribe such policy choices to Congress. But the evidence mustered—the text of the statute—is in fact rather oblique on these points.

So we come finally to a more comfortable resting place, and consider the role of federal agencies in assisting courts with their preemption decisionmaking and the concomitant level of judicial scrutiny over agency findings. The Justices' queries during oral argument in *Riegel*—with *Wyeth* looming in the distance—point in the direction of a new framework for implied conflict preemption decisions: The key is discerning whether the FDA has weighed in on the precise risk that the state tort action likewise seeks to regulate. Questions of implied conflict preemption—whether or not state common law actions are irreconcilable with, or would stand as an obstacle to, frustrate or impede, the command of federal regulatory directives and goals—should turn, first and foremost, upon a particularized understanding of the regulatory review and action taken by the relevant agency. Input from the relevant agency constitutes one pillar of the framework; the second is searching judicial review of the record evidence amassed by the agency in support of any preemptive position.

To whom much is given, much is required. Under the proposed agency reference model, the FDA would be given an enhanced role, partnering so to speak with the courts in making preemption determinations; for this reason, courts must ensure that the actions and positions taken by the FDA merit deference. Redirecting the preemption inquiry in these directions would go a long way towards helping courts make implied conflict preemptive

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increased sense of accountability in agencies, leading them to "take greater care and avoid [decision-making] biases," and to engage in information seeking behavior).

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tion decisions in products liability cases, where statutory text provides scant guidance.