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Preemption's Rise (and Bit of a Fall) as Products Liability Reform

WYETH, RIEGEL, ALTRIA, AND THE RESTATEMENT (THIRD)'S PRESCRIPTION PRODUCT DESIGN DEFECT STANDARD

Richard L. Cupp Jr.[†]

I. INTRODUCTION

On the whole, the *Restatement (Third) of Torts: Products Liability*¹ represents a fundamentally restrictive view of products liability. It both reflects and has encouraged an era of contraction in the courts following the explosive growth of products liability doctrine and litigation in the 1960s and 1970s. This Article analyzes prescription product designs as illustrative of an area in which the *Restatement (Third)* took an especially restrictive stance. The Article considers the *Restatement (Third)*'s standard for prescription products, particularly its standard for prescription product design defect claims, in light of the preemption doctrine's rising strength over the past two decades, as well as its recent limitation in 2009.

The Restatement's prescription product design standard, set forth in section 6(c), has proved to be one of the project's more controversial aspects.² In section 6(c) the Restatement took the position that, with regard to design defect claims, a prescription product manufacturer may not be liable unless no reasonable health care provider would have prescribed the product to any class of persons.³

In a 1994 article I criticized this approach as a "near-immunity standard," and I noted that it lacked foundation in case law while

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¹ RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. (1998).

² See *infra* Part II.

³ RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 6(c) (1998).

expressing doubts about whether it would serve public policy interests.⁴ Others also voiced these criticisms,⁵ but the drafters defended their position⁶ and included the standard in their 1997 final version of the Restatement.⁷

In 1999, I participated in a symposium in which I reviewed case law and scholarly commentary that had developed since my 1994 article and section 6(c)'s formal adoption in 1997. In an article written for the symposium I noted that both courts and scholars were mostly critical of the Restatement's approach; its near-immunity standard was not catching on with judges or with the academic community.⁸ It was broadly perceived as too pro-manufacturer and not sufficiently protective of consumers, in addition to being inconsistent with case law.⁹

This Article compares and contrasts the rocky (on the whole) reception section 6(c)'s restrictive prescription product design standard has received with the rise of an increasingly active judicial approach to preemption from the 1990s through the late 2000s, which may have to some extent crested (at least for now) with *Riegel v. Medtronic*¹⁰ in 2008, and which showed signs of possible contraction (again, at least for now) with *Wyeth v. Levine*¹¹ in 2009. In particular, this Article analyzes preemption's overall effect of developing a generally more restrictive approach to prescription product design defect claims, along with other prescription product design defect claims. Part II begins by setting the stage for the *Restatement (Third)*'s development as a fundamentally restrictive approach to products liability. It fleshes out section 6(c)'s standard of allowing liability for prescription product design defect only if no reasonable health care provider would prescribe it to any class of patients, and it explains why this "near-immunity" standard (which is my

⁴ Richard L. Cupp, Jr., *Rethinking Conscious Design Liability for Prescription Drugs: The Restatement (Third) Standard Versus a Negligence Approach*, 63 GEO. WASH. L. REV. 76, 99-110 (1994).

⁵ See, e.g., George W. Conk, *Is There a Design Defect in the Restatement (Third) of Torts: Products Liability?*, 109 YALE L.J. 1087, 1089 (2000) (published after the Restatement was completed but reflecting some of the criticisms voiced during the drafting process); Teresa Moran Schwartz, *Prescription Products and the Proposed Restatement (Third)*, 61 TENN. L. REV. 1357, 1363 (1994) (criticizing the Restatement's proposed prescription product design defect standard).

⁶ See, e.g., James Henderson, Jr., *Prescription Drug Design Liability under the Proposed Restatement (Third) of Torts: A Reporter's Perspective*, 48 RUTGERS L. REV. 471, 151-52 (1996).

⁷ The drafters of the *Restatement (Third)* continued participating in debate regarding this issue well after the final version of the *Restatement (Third)* was published. See, e.g., James A. Henderson, Jr. & Aaron D. Twerski, *Drug Designs Are Different*, 111 YALE L.J. 151 (2001) (defending the *Restatement (Third)*'s prescription product design defect standard).

⁸ Richard L. Cupp, Jr., *The Continuing Search for Proper Perspective: Whose Reasonableness Should Be at Issue in a Prescription Product Design Defect Analysis?*, 30 SETON HALL L. REV. 233, 244-52 (1999) (citing and discussing cases and law review articles addressing the *Restatement (Third)*'s prescription product design defect standard); see also *infra* notes 27-28 and accompanying text.

⁹ See *infra* notes 27-28 and accompanying text.

¹⁰ 128 S. Ct. 999 (2008).

¹¹ 129 S. Ct. 1187 (2009).

description, not the Reporters') is one of the most restrictive specific aspects of the generally restrictive Restatement project.

This Part also briefly addresses cases that have cited section 6. It notes that the number of cases addressing section 6 is relatively small. Further, a surprisingly large percentage of these cases addresses design defect claims, despite broad agreement that warning defect claims are much more common in cases involving prescription products. The Part addresses some potential reasons for this. It concludes by explaining that, whatever the reasons, few would likely describe the Restatement's near-immunity standard for prescription product design defect claims as a smashing success with courts and commentators.

Part III focuses on the two cases argued before the Supreme Court in 2008 addressing prescription product preemption: *Riegel* and *Wyeth* (which, though argued before the Supreme Court in 2008, was decided in 2009). It also briefly discusses a third major preemption case heard by the Supreme Court in 2008 involving a products liability-related claim, albeit one involving cigarette labeling rather than prescription products—*Altria Group, Inc. v. Good*.¹² The Part begins by providing a brief background on the rise of preemption since *Cipollone v. Liggett Group, Inc.*,¹³ which was decided in 1992 at around the time formal work on the *Restatement (Third)* was beginning. It then analyzes *Riegel*, the 2008 Supreme Court case that preempted lawsuits for defects in prescription medical devices that have been subjected to premarket FDA approval under the Medical Device Amendments Act of 1976.

Although *Riegel* is analyzed in some depth, Justice Scalia's discussion in the majority decision directed toward perceived shortcomings in the American tort system merits particular consideration. In his decision, Justice Scalia demonstrates both skepticism regarding the civil jury system and what may be a fundamental misunderstanding of aspects of products liability law. This aspect of the *Riegel* decision—which was more recently repeated by the dissenters in *Wyeth*—is especially powerful in demonstrating that even when courts are using the language of preemption doctrine, they may to some extent be seeking to reform products liability litigation.

As further evidence of broader policy concerns about litigation involving prescription products exerting influence on preemption's rise, Part III next addresses the Food and Drug Administration ("FDA")'s shift in position during the George W. Bush administration regarding whether FDA approval should create preemption. It also explores the backlash against this policy shift from FDA career officials, President Bush's political opponents, from Justice Ginsberg in her *Riegel* dissent, and from the majority in *Wyeth*.

¹² 129 S. Ct. 538, 541 (2008).

¹³ 505 U.S. 504 (1992).

Part III then analyzes *Wyeth*, the even more heralded prescription product preemption case considered by the Supreme Court in 2008 and decided in 2009.¹⁴ *Wyeth* addressed whether implied preemption should apply broadly to cases involving warnings for FDA-approved products, and concluded that preemption should be limited in this context.¹⁵ This Part considers the Vermont Supreme Court's approach to the issues, intense political wrangling related to the case prior to its being heard by the United States Supreme Court, reactions to oral arguments before the Supreme Court, and the Court's decision.

Part III concludes with a brief analysis of *Altria*, the 2008 Supreme Court case in which the Court narrowly decided to continue the approach of finding that state fraud-related cigarette labeling claims are not a requirement related to smoking and health, and thus are not preempted by federal law. *Altria*'s flirtation with extending preemption to fraud-related claims in cigarette litigation—the dissent came within only one vote of succeeding in this position—provides further evidence of pressure within the Court to expand the doctrine beyond its previous limits.

Finally, Part IV concludes by suggesting that the restrictive *tone* of section 6(c) may have to some extent caught the “mood” of courts regarding prescription product design liability, even if the specific details of the unfamiliar standard have not found much traction. Cases such as *Daubert v. Merrell Dow Pharmaceuticals*,¹⁶ decided near the time formal work on the *Restatement (Third)* began, reflect the Supreme Court's increased willingness to craft decisions that would have the effect of significantly restricting products liability law. Preemption's rise in products liability cases began in earnest just a year earlier in *Cipollone* and continued at least through *Riegel* in 2008. Whether *Wyeth* represents an end to the trend or a significant bump in its road remains to be seen.

Both *Riegel* and *Wyeth* involved prescription products, which corresponds with increasing political and judicial concern regarding whether prescription products liability is too expansive. Even though not all of the preemption cases since *Cipollone* have resulted in restrictions on products liability claims, on the whole they have narrowed the reach of products liability in prescription product design cases, as well as in other types of prescription product cases.

Indeed, some of the rationales provided for section 6(c) overlap with some of the rationales the Supreme Court employed in the 1990s and most of the 2000s to support its increasingly aggressive use of preemption analysis in prescription products cases. Thus, Part IV concludes that the currents underlying section 6(c)'s restrictive tone for prescription product design liability may have found a “back door” in

¹⁴ *Wyeth*, 129 S. Ct. 1187.

¹⁵ *Id.* at 1203-04.

¹⁶ 509 U.S. 579 (1993).

Supreme Court rulings such as *Daubert* and *Riegel*, despite most courts' and commentators' refusal to provide "front door" acceptance of the *Restatement (Third)*'s prescription product design defect standard.

II. THE *RESTATEMENT (THIRD)* ON PRESCRIPTION PRODUCTS

On the whole, defendants and their friends have been happier with the *Restatement (Third)* than have plaintiffs and their friends. The document was, and remains, a product of its time. Following years of explosive doctrinal expansion in the 1960s and 1970s,¹⁷ products liability doctrine began a gradual contraction through the 1980s. The contraction manifested itself in widespread legislative restrictions,¹⁸ in reported judicial decisions, and in jurors' reactions to products liability lawsuits.¹⁹ It also increasingly manifested itself in critical scholarly analysis.²⁰ Professors James Henderson and Aaron Twerski were prominent leaders in this scholarly trend toward questioning products liability's expansiveness.²¹ When they took up the mantle as the *Products Liability*

¹⁷ See F. Patrick Hubbard, *The Nature and Impact of the "Tort Reform" Movement*, 35 HOFSTRA L. REV. 437, 466 (2006) (describing reforms implemented during this period of "plaintiff-oriented liberalization" of U.S. tort law).

¹⁸ See *id.* at 470-80 (describing the influence of the American Tort Reform Association, whose goal was to reform tort laws to make them more favorable to defendants, on federal and state legislative tort reform processes in the 1980s).

¹⁹ See, e.g., Theodore Eisenberg & James A. Henderson, Jr., *Inside the Quiet Revolution in Products Liability*, 39 UCLA L. REV. 731, 733-35 (1992) (providing a more expansive analysis of the empirical data related to products liability cases of the late 1980s in furtherance of the conclusion that products liability jurisprudence during this time tended to favor defendants); Marc Galanter, *News From Nowhere: The Debased Debate on Civil Justice*, 71 DENVER U. L. REV. 77, 94-95 (1993) (citing and describing the results of multiple studies of tort cases in state and federal courts that "depict a sustained contraction of product liability exposure" during the late 1980s); James A. Henderson, Jr., & Theodore Eisenberg, *The Quiet Revolution in Products Liability: An Empirical Study of Legal Change*, 37 UCLA L. REV. 479, 481 (1990) (presenting an analysis of empirical data related to products liability judicial decisions from the 1960s to the 1980s, which supports the authors' theory that "changes in judicial decision making are occurring and that current trends favor defendants").

²⁰ For example, when the New Jersey Supreme Court in *Beshada v. Johns-Manville Products Corp.*, 447 A.2d 539, 546 (N.J. 1982) imputed knowledge of a risk in a warnings case without requiring evidence that the risk was known or should have been known, within two years six law review articles were published criticizing the case as an inappropriate expansion of liability. See Robert D. Casale, Comment, *Beshada v. Johns Manville Products Corp.: Adding Uncertainty to Injury*, 35 RUTGERS L. REV. 982, 984 (1983); William R. Murray, Jr., Comment, *Requiring Omniscience: The Duty to Warn of Scientifically Undiscoverable Product Defects*, 71 GEO. L. REV. 1635, 1637 (1983); Joseph A. Page, *Generic Product Risk: The Case Against Comment k and for Strict Tort Liability*, 58 N.Y.U. L. REV. 853, 855-56 (1983); Victor Schwartz, *The Post-Sale Duty to Warn: Two Unfortunate Forks in the Road to a Reasonable Doctrine*, 58 N.Y.U. L. REV. 892, 893 & n.9 (1983); Robert D. Towey, Note, *Products Liability—Strict Liability in Tort-State-of-the-Art Defense Inapplicable in Design Defect Cases—Beshada v. Johns-Manville Products Corp.*, 13 SETON HALL L. REV. 625, 635 (1983); John W. Wade, *On the Effect in Product Liability of Knowledge Unavailable Prior to Marketing*, 58 N.Y.U. L. REV. 734, 738 (1983). These articles were cited in 1984 by the New Jersey Supreme Court in *Feldman v. Lederle Laboratories*, a case criticizing aspects of *Beshada* and limiting its expansive imputed knowledge holding to asbestos cases. *Feldman v. Lederle Labs.*, 479 A.2d 374, 387-88 (N.J. 1984).

²¹ See, e.g., James A. Henderson, Jr. & Aaron D. Twerski, *Closing the American Products Liability Frontier: The Rejection of Liability Without Defect*, 66 N.Y.U. L. REV. 1263,

Restatement's Reporters in the early 1990s, few could be surprised that their concerns about expansive liability were reflected in their work on the project.

The Restatement's position on prescription product design liability is one of the most restrictive sections of the project. Found in section 6(c), the standard allows liability for drug and prescription device designs only if no reasonable prescription health care provider knowing the therapeutic risks and benefits would prescribe them to any class of patients.²² Specifically:

A prescription drug or medical device is not reasonably safe due to defective design if the foreseeable risks of harm posed by the drug or medical device are sufficiently great in relation to its foreseeable therapeutic benefits that reasonable health-care providers, knowing of such foreseeable risks and therapeutic benefits, would not prescribe the drug or medical device for any class of patients.²³

The Reporters understood that their approach was quite restrictive. Only in rare circumstances would a prescription product design be so bad that it would be unreasonable for a health care provider to prescribe it to *any* class of patients. Comment f to section 6(c) calls it a "very demanding" standard and says that under this rule "liability is likely to be imposed only under unusual circumstances."²⁴

In addition to addressing design defect claims, section 6 also sets forth liability standards for prescription products warnings defect claims²⁵ and manufacturing defect claims.²⁶ Manufacturing defect claims

1267 (1991) (arguing against ruling for the plaintiff in a products liability case if the product is not defective); James A. Henderson, Jr., *Judicial Review of Manufacturers' Conscious Design Choices: The Limits of Adjudication*, 73 COLUM. L. REV. 1531, 1531 (1973) (maintaining that judicial bodies are ill-equipped to develop appropriate product design standards to determine reasonableness standards in products liability cases, at the expense of providing a fair trial for defendant product manufacturers); James A. Henderson, Jr., *Manufacturers' Liability for Defective Product Design: A Proposed Statutory Reform*, 56 N.C. L. REV. 625, 626 (1978) (decrying the practice of using a reasonableness standard in design defect product liability cases); Aaron D. Twerski, *A Moderate and Restrained Federal Product Liability Bill: Targeting the Crisis Areas for Resolution*, 18 U. MICH. J.L. REFORM 575, 580 (1985) (arguing for the creation of uniform nationwide legal standards to ensure that defendant manufacturers are not subject to unfair products liability litigation).

²² RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 6(c) (1998).

²³ *Id.*

²⁴ *Id.* § 6(c) cmt. f.

²⁵ *Id.* § 6(d). The Restatement's standard for prescription product warning defect cases is as follows:

A prescription drug or medical device is not reasonably safe due to inadequate instructions or warnings if reasonable instructions or warnings regarding foreseeable risks of harm are not provided to:

- (1) prescribing and other health-care providers who are in a position to reduce the risks of harm in accordance with the instructions or warnings; or
- (2) the patient when the manufacturer knows or has reason to know that health-care providers will not be in a position to reduce the risks of harm in accordance with the instructions or warnings.

Id.

comprise only a small percentage of cases involving prescription products, and the Restatement's liability standard for such claims has been uncontroversial. The largest category of product liability claims relating to prescription products involves alleged warnings defects; however, as with manufacturing defect claims, the Restatement's approach to prescription product warning defect claims has been fairly uncontroversial.

The Restatement's prescription product design defect standard has been by far the most disputed aspect of its approach to prescription drugs and medical devices. Numerous law review articles, many of them critical, have focused on this design standard.²⁷ The Restatement's approach to prescription product designs may be described as a near-immunity standard, because manufacturers would rarely produce a drug or prescription device that would not provide a net benefit to at least *some* patients, even if its overall harm is far greater than its overall benefits for patients as a whole.²⁸ Some support for a near-immunity interpretation of section 6(c) may be found in Professors Henderson and Twerski's pre-Restatement scholarship. In 1992 they published an article outlining what they would like to see in a *Products Liability Restatement* before the project began.²⁹ In the article they argued that prescription

²⁶ *Id.* § 6(b)(1) (incorporating the general manufacturing defect set forth in section 2(a)).

²⁷ See, e.g., Andrew Barrett, Note, *The Past and Future of Comment k: Section 4(b)(4) of the Tentative Draft Restatement (Third) of Torts—Is It the Beginning of a New Era for Prescription Drugs?*, 45 SYRACUSE L. REV. 1291, 1324 (1994); Kelley E. Cash, Note, *The New Restatement (Third) of Torts: Is It the Cure for the AIDS Vaccine Ailment?*, 16 REV. LITIG. 413, 428-37 (1997); George W. Conk, *The True Test: Alternative Safer Designs for Drugs and Medical Devices in a Patent-Constrained Market*, 49 UCLA L. REV. 737, 738-39 (2002); Richard L. Cupp Jr., *Rethinking Conscious Design Liability for Prescription Drugs: The Restatement (Third) Standard Versus a Negligence Approach*, 63 GEO. WASH. L. REV. 76, 80 (1994); Dustin R. Marlowe, Note, *A Dose of Reality for Section 6(c) of the Restatement (Third) of Torts: Products Liability*, 39 GA. L. REV. 1445, 1446 (2005); Jerry J. Phillips, *The Unreasonably Unsafe Product and Strict Liability*, 72 CHI.-KENT L. REV. 129, 130 (1996); Angela C. Rushton, Comment, *Design Defects Under the Restatement (Third) of Torts: A Reassessment of Strict Liability and the Goals of a Functional Approach*, 45 EMORY L.J. 389, 419, 435-36 (1996); Teresa Moran Schwartz, *Prescription-Products and the Proposed Restatement (Third)*, 61 TENN. L. REV. 1357, 1382 (1994); Mark D. Shifton, Note, *The Restatement (Third) of Torts: Products Liability—The ALI's Cure for Prescription Drug Design Liability*, 29 FORDHAM URB. L.J. 2343, 2344 (2002); David S. Torborg, Comment, *Design Defect Liability and Prescription Drugs: Who's in Charge?*, 59 OHIO ST. L.J. 633, 644 (1998); Dolly M. Trompeter, Comment, *Sex, Drugs, and the Restatement (Third) of Torts, Section 6(c): Why Comment e is the Answer to the Woman Question*, 48 AM U. L. REV. 1139, 1141-42 (1999); Frank J. Vandall, *Constructing a Roof Before the Foundation Is Prepared: The Restatement (Third) of Torts: Products Liability Section 2(b) Design Defect*, 30 U. MICH. J.L. REFORM 261, 270 (1997); Michael J. Wagner & Laura L. Peterson, *The New Restatement (Third) of Torts—Shelter from the Product Liability Storm for Pharmaceutical Companies and Medical Device Manufacturers?*, 53 FOOD & DRUG L.J. 225, 225 (1998); Jeffrey D. Winchester, Note, *Section 8(c) of the Proposed Restatement (Third) of Torts: Is It Really What the Doctor Ordered?*, 82 CORNELL L. REV. 644, 647-48 (1997).

²⁸ Cupp, *supra* note 4, at 99 (criticizing the Restatement's approach as a “[n]ear-[i]mmunity standard”).

²⁹ James A. Henderson, Jr., & Aaron Twerski, *A Proposed Revision of Section 402A of the Restatement (Second) of Torts*, 77 CORNELL L. REV. 1512 (1992).

product designs should have *complete* immunity from tort liability.³⁰ Although the reasonable physician approach they eventually developed in section 6(c) does not provide absolute immunity for prescription product designs, it is not far off from the Reporters' original ideal of simply disallowing all liability in such cases.

In comment d to section 6(c) the Reporters note that design claims involving prescription products “[have] been the subject of appellate review in relatively few cases.”³¹ Although asserting that prescription product warning defect cases outnumber prescription product design cases is hardly controversial, since the Restatement's adoption, a surprising percentage of the cases addressing section 6 have focused on design defect claims—not just warnings. Most of these design defect claims have involved prescription medical devices rather than drugs.

Specifically, by the end of 2007, the Restatement's case citations list reported thirty-six decisions citing section 6.³² Fifteen of those thirty-six cases—approximately forty-two percent—are cited as involving design defect claims.³³ Further, of the fifteen cases cited as involving design defect claims, ten of the cases—two-thirds of the total—involved prescription medical devices rather than prescription drugs.³⁴ One might

³⁰ *Id.* at 1536. For a summary of Professors Henderson's and Twerski's argument and an alternative approach they suggested, see Cupp, *supra* note 4, at 96 n.126.

³¹ RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 6(c) cmt. d, Reporters' Notes (1998).

³² RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB., CASE CITATIONS TO THE RESTATEMENT OF THE LAW (Supp. 2008) (citing cases from July 1984 through November 2007). Although the Restatement's citation search technically goes back to 1984, the earliest case it cites addressing section 6 is from 1994, when the Restatement was a work in progress. *Tansy v. Dacomed Corp.*, 890 P.2d 881, 892-94 (Okla. 1994).

³³ The cases cited as involving design defect claims include: *Anderson v. Siemens Corp.*, 335 F.3d 466, 468, 470, 471 (5th Cir. 2003) (prescription device design defect claim); *Transue v. Aesthetech Corp.*, 341 F.3d 911, 919 (9th Cir. 2002) (prescription device design defect claim citing section 6(c)); *Madsen v. Am. Home Prod. Corp.*, 477 F. Supp. 2d 1025, 1034, 1037 (E.D. Mo. 2007) (prescription drug design defect claim and warning defect claim citing section 6(c) and (d)); *Gerber v. Hoffman-La Roche, Inc.*, 392 F. Supp. 2d 907, 922 (S.D. Tex. 2005) (prescription drug design defect claim citing section 6(c)); *Parkinson v. Guidant Corp.*, 315 F. Supp. 2d 741, 747-48 (W.D. Pa. 2004) (prescription device design, warning, and manufacturing defect claims); *Sita v. Danek Med., Inc.*, 43 F. Supp. 2d 245, 256, 258 (E.D.N.Y. 1999) (prescription device design defect claim citing section 6(c)); *Wheat v. Sofamor, S.N.C.*, 46 F. Supp. 2d 1351, 1362 (N.D. Ga. 1999) (prescription device design defect claim; section 6(c) cited); *Gebhardt v. Mentor Corp.*, 191 F.R.D. 180, 185 (D. Ariz. 1999), *aff'd*, 15 F. App'x. 540 (9th Cir. 2001) (prescription device design defect claim citing section 6(c)); *Bryant v. Hoffman-La Roche, Inc.*, 585 S.E.2d 723, 727-28, 731, 733-34 (Ga. Ct. App. 2003) (prescription drug design defect claim; citing section 6(c)); *Hansen v. Baxter Healthcare Corp.*, 764 N.E.2d 35, 46 (Ill. 2002) (prescription device design defect claim); *Mele v. Howmedia, Inc.*, 808 N.E.2d 1026, 1038-39 (Ill. App. Ct. 2004) (prescription device design defect claim citing section 6(c)); *Freeman v. Hoffman-La Roche, Inc.*, 618 N.W.2d 827, 835, 837-40 (Neb. 2000) (warning, design, and manufacturing defect claims and misrepresentation claim; citing section 6(c)); *Parker v. St. Vincent Hosp.*, 919 P.2d 1104, 1111 (N.M. Ct. App. 1996) (prescription device design defect claim); *Militrano v. Lederle Labs.*, 769 N.Y.S.2d 839, 851 (N.Y. Sup. Ct. 2003), *aff'd*, 810 N.Y.S.2d 506 (N.Y. App. Div. 2006) (prescription drug design defect claim citing section 6(c)); *Tansy*, 890 P.2d at 892-94 (prescription device design defect claim).

³⁴ The decisions involving prescription medical devices rather than prescription drugs are all of the cases cited above in note 33 except for *Freeman*, 618 N.W.2d 827 (acne medication),

suspect that a possible explanation for these surprising statistics might be found in the common practice of warning and design claims being pleaded concurrently. If such were the case, the cases might have remained largely focused on warnings issues even though design defect claims were also technically pleaded. However, many of the cases may not bear out this possibility. Of the fifteen cited cases involving design defect claims, only three are cited by the Restatement as specifically addressing warning defect claims in addition to design defect claims.³⁵ Another factor to consider relates to the more solid grounding of the Restatement's warning defect standard in existing case law than is the case with its design defect standard. Given that the Restatement's warning standard is not particularly controversial or groundbreaking, courts may have less reason or inclination to cite or discuss it compared to the new and controversial design defect standard.

The prevalence of design cases involving prescription *devices* rather than prescription drugs is particularly interesting. I have argued previously that prescription device cases are different from prescription drug cases, and that arguments for design defect liability are stronger for devices than for drugs.³⁶ In 1994, when the Restatement project was still in progress, I noted that prescription devices "generally offer the same universe of design options as do nonmedical devices"³⁷ and that "[t]he argument that FDA approval eliminates the need for design liability is especially faulty as applied to medical devices."³⁸ In a 1999 article I wrote that "[p]roviding prescription medical devices the same near-immunity given to drugs under the reasonable physician standard is an especially troubling aspect of the *Restatement (Third)*'s approach."³⁹

The reasons for this concern remain relevant with the passage of time. My strongest concern about applying a near-immunity standard to prescription devices was, and remains, that, unlike many drugs, they often provide "a broad universe of design alternatives."⁴⁰ In some ways prescription medical devices are more like nonmedical devices than they are like prescription drugs and vaccines. A lot of design alternatives are available to manufacturers of all-terrain vehicles, just as a lot of design alternatives are available to manufacturers of pacemakers. In contrast, although drug manufacturers sometimes make what may be accurately described as design decisions, often their choices are limited. Because more conscious choices are involved in producing devices than in

Madsen, 477 F. Supp. 2d 1025 (diet drugs), *Gerber*, 392 F. Supp. 2d 907 (acne medication), *Bryant*, 585 S.E.2d 723 (heart medication), and *Militrano*, 769 N.Y.S.2d 839 (vaccine).

³⁵ Those three cases are *Freeman*, 618 N.W.2d at 835, 837-40, *Madsen*, 477 F. Supp. 2d at 1034, 1037, and *Parkinson*, 315 F. Supp. 2d at 747-48.

³⁶ Cupp, *supra* note 8, at 256.

³⁷ Cupp, *supra* note 4, at 94.

³⁸ *Id.* at 105.

³⁹ Cupp, *supra* note 8, at 256 (alteration to original).

⁴⁰ *Id.*

producing many drugs, design liability will be a genuine issue in more device cases than drug cases.

Further, the scrutiny applied by the FDA to prescription devices is different from the FDA scrutiny applied to prescription drugs; in many cases the FDA scrutiny of prescription devices is less stringent.⁴¹ Also, prescription medical devices are proliferating,⁴² and, as demonstrated by the 2008 Supreme Court decision in *Riegel v. Medtronic*,⁴³ design defect liability claims involving prescription medical devices have become an increasingly important part of the products liability landscape.

Whatever the reasons, few would likely describe the Restatement's near-immunity standard for prescription drugs and devices as a smashing success with courts and commentators. Although the approach has some supporters, most of the law review articles that have addressed the standard are critical.⁴⁴ Courts have often bypassed the standard, frequently continuing to cite the *Restatement (Second)*'s section 402A while ignoring the *Restatement (Third)*'s approach to prescription products.⁴⁵ The strongest support for section 6(c)'s anti-liability impulse, if not its explicit standard, would be indirect, and would come from the Supreme Court's application of the trump card of constitutional law in the form of preemption doctrine.

III. PREEMPTION'S RISE IN DRUG LITIGATION: *RIEGEL* AND *WYETH*

As noted recently by Professor Catherine Sharkey, “[p]reemption is the fiercest battle in products liability litigation today.”⁴⁶ As fate would have it, the Supreme Court provided its “watershed” case that thrust preemption into the foreground of products liability in 1992 at about the same time that the *Products Liability Restatement* was getting underway.⁴⁷ In that year the Court decided *Cipollone v. Liggett Group, Inc.*, a case that analyzed whether the Public Health Cigarette Smoking Act of 1969 expressly preempted failure to warn tort claims.⁴⁸ The Act's language that formed the basis of the Court's express preemption analysis was that “[n]o requirement or prohibition . . . shall be imposed

⁴¹ See Schwartz, *supra* note 27, at 1391-95.

⁴² *The Bleeding Edge*, THE ECONOMIST, Mar. 1, 2008, at 74 (discussing how technological advances and an aging population encourage increased innovation in the medical device technology industry and create heightened public demand for new devices).

⁴³ 128 S. Ct. 999 (2008). For a discussion of *Riegel*, see *infra* Part III.A.

⁴⁴ See *supra* note 27 and accompanying text.

⁴⁵ According to prominent plaintiffs' lawyer Paul D. Rheingold, between 2003 and 2008 some 200 cases discuss section 402A, while only “a handful” discuss section 6. Paul D. Rheingold, Remarks at the Brooklyn Law Review Symposium: The Products Liability Restatement (Nov. 13, 2008) (transcript on file with author).

⁴⁶ Catherine M. Sharkey, *Products Liability Preemption: An Institutional Approach*, 76 GEO. WASH. L. REV. 449, 450 (2008).

⁴⁷ *Id.* at 459 (describing *Cipollone v. Liggett Group Inc.*, 505 U.S. 504 (1992), as “a watershed case in products liability preemption jurisprudence”).

⁴⁸ *Cipollone*, 505 U.S. at 508.

under State law with respect to the advertising or promotion of any cigarettes.⁴⁹ The Court ruled fairly broadly, holding that this preemption language applies to common law tort warning defect claims as well as to state statutes and regulations.⁵⁰

Despite the significance of the *Cipollone* decision and other cases to tobacco litigation and to other areas of products liability litigation where some federal regulation existed, the American Law Institute more or less punted on addressing preemption in the *Products Liability Restatement*. In comment a to section 6, the Reporters assumed the issue under the rug as follows:

The rules imposing liability on a manufacturer for inadequate warning or defective design of prescription drugs and medical devices assume that the federal regulatory standard has not preempted the imposition of tort liability under state law. When such preemption is found, liability cannot attach if the manufacturer has complied with the applicable federal standard. See §4, Comment e.⁵¹

The Court provided another major products liability preemption decision in 1996, shortly before the *Products Liability Restatement* was completed. In *Medtronic Inc., v. Lohr*, the Court addressed express preemption in the context of the Medical Device Act.⁵² In *Lohr*, the plaintiff claimed that a pacemaker made by defendant had both design and manufacturing defects that injured the plaintiff.⁵³ The Court split on the question of whether the plaintiff's claims were preempted by the FDA, and the plurality decision authored by Justice Stevens seemed to retreat from *Cipollone*'s stance that express preemption language addressing "requirements" applies equally to common law tort claims as well as it does to state statutes and regulations.⁵⁴

Following *Lohr*, the Court continued analyzing preemption in products liability cases on a fairly regular basis. For example, in 2000 the Court held that an airbag defect claim was impliedly preempted by the

⁴⁹ *Id.* at 515 (citing 15 U.S.C. § 1334(b)).

⁵⁰ *Id.* at 524-31; *see also* Sharkey, *supra* note 46, at 460.

⁵¹ RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 6 cmt. b (1998). The comment went on to briefly note:

The doctrine of preemption based on the supremacy of federal law should be distinguished from the proposition that compliance with statutory and regulatory standards satisfies the state's requirements for product safety. Subsections (c) and (d) recognize common-law causes of action for defective drug design and for failure to provide reasonable instructions or warnings, even though the manufacturer complied with governmental standards. For the rules governing compliance with governmental standards generally, see § 4(b).

Id.

⁵² 518 U.S. 470, 474 (1996).

⁵³ *Id.* at 481; *see also* Mary J. Davis, *The Battle Over Implied Preemption: Products Liability and the FDA*, 48 B.C. L. REV. 1089, 1121 (2007).

⁵⁴ *Medtronic*, 518 U.S. at 501-02; *see also* Davis, *supra* note 53, at 1121; Sharkey, *supra* note 46, at 466.

National Traffic and Motor Vehicle Safety Act of 1966.⁵⁵ In 2001 the Court used implied preemption to negate a lawsuit against a device manufacturer's regulatory consultant.⁵⁶ In 2002 the Court declined to find express or implied preemption by the Federal Boat Safety Act of 1971 for tort claims against a boat manufacturer for failing to equip the boat with propeller guards.⁵⁷ And in 2005, the Court declined to apply preemption under the Federal Insecticide, Fungicide, and Rodenticide Act to farmers' claims that a pesticide manufactured by defendant damaged their crops.⁵⁸ However, despite the importance of these decisions, early 2008 through early 2009 may be remembered as the most significant period thus far for products liability preemption analysis. In that twelve month span the Court decided no fewer than three major preemption cases involving products liability.

A. *Riegel v. Medtronic—Cutting Back on Liability for Prescription Medical Devices*

Although preemption is presently the fiercest battle in products liability generally, two of the three products liability preemption cases that the Supreme Court decided between early 2008 and early 2009 made the issue particularly heated in prescription product litigation. The first of these cases, *Riegel v. Medtronic*,⁵⁹ was a prescription product preemption case that generated broad interest among lawyers, products liability scholars, and the media.

Riegel addressed whether the Medical Device Amendments Act of 1976 ("MDA") preempts products liability lawsuits for defects in prescription devices covered under the Act.⁶⁰ Increasingly "complex [medical] devices proliferated" in the 1960s and 1970s,⁶¹ a trend that has continued to the present and that seems likely only to become stronger in the future as medical science progresses. The enactment of the MDA in 1976 was propelled by "[a] series of high-profile medical device failures that caused extensive injuries and loss of life."⁶² The best known of these failures involved the Dalkon Shield intrauterine device, which was designed to provide birth control.⁶³ Between 1970 and 1974, over two million women in the United States used the Dalkon Shield.⁶⁴ By the middle of 1975 numerous deaths and miscarriages had been attributed to

⁵⁵ *Geier v. Am. Honda Motor Co.*, 529 U.S. 861, 884-86 (2000).

⁵⁶ *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 353 (2001).

⁵⁷ *Sprietsma v. Mercury Marine*, 537 U.S. 51, 68-70 (2002).

⁵⁸ *Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 434-36, 444 (2005).

⁵⁹ 128 S. Ct. 999 (2008).

⁶⁰ *Id.* at 1002.

⁶¹ *Id.* at 1003.

⁶² *Id.* at 1014 (Ginsburg, J., dissenting).

⁶³ *Id.* at 1014-15.

⁶⁴ *Id.* at 1014-15.

the device, and “by early 1976 [over] 500 lawsuits . . . had been filed.”⁶⁵ The lawsuits sought more than \$400 million in compensatory and punitive damages.⁶⁶ Eventually the “manufacturer . . . settled or litigated approximately 7,700 Dalkon Shield cases.”⁶⁷

In response to public concern generated by situations such as the Dalkon Shield fiasco, the MDA created differing levels of oversight for medical devices based on the devices’ risks.⁶⁸ “Class III” devices receive the greatest degree of scrutiny, requiring premarket approval unless they are “substantially equivalent” to existing devices.⁶⁹ Premarket approval is a “rigorous” process.⁷⁰ Currently, it is only required for a small percentage of devices placed on the market because most devices are considered substantially equivalent to existing devices. For example, in 2005 only about one percent—thirty-two out of 3,148 devices—entering the market had been subjected to the premarket approval process.⁷¹

In *Riegel*, the plaintiff Charles Riegel suffered from a “diseased and heavily calcified coronary artery.”⁷² The plaintiff’s doctor surgically implanted an Evergreen Balloon Catheter manufactured by Medtronic into the plaintiff’s artery to dilate it even though the device’s label warned against using it for calcified stenoses.⁷³ The doctor also inflated the catheter more than the instructions allowed.⁷⁴ The fifth time the doctor inflated the catheter it ruptured.⁷⁵ The plaintiff then “developed a heart block,” requiring emergency surgery.⁷⁶ The plaintiff sued in the Northern District of New York, alleging design, warning, and manufacturing defects under negligence, strict liability in tort, and implied warranty of merchantability theories.⁷⁷

Medtronic asserted that the plaintiff’s design, warning, and manufacturing claims were preempted by the MDA, and the district court agreed, dismissing the claims.⁷⁸ The United States Court of Appeals for the Second Circuit affirmed, holding that the plaintiff’s claims “would, if

⁶⁵ *Id.* at 1015 (citing H.R. Rep. No. 94-853, at 8 (1976)) (quotation marks omitted).

⁶⁶ *Id.*

⁶⁷ *Id.* at 1015 n.6 (citing R. SOBOL, *BENDING THE LAW: THE STORY OF THE DALKON SHIELD BANKRUPTCY* 23 (1991)).

⁶⁸ *Id.* at 1003.

⁶⁹ *Id.* at 1004 (citing 21 U.S.C. § 360c(f)(1)(A) (2006)).

⁷⁰ *Id.*

⁷¹ *Id.*

⁷² *Id.* at 1005. By the time the Supreme Court addressed the case Charles Riegel had died, and his widow Donna Riegel was petitioner “on her own behalf and as administrator of her husband’s estate.” *Id.* at 1006 n.3.

⁷³ *Id.* at 1005.

⁷⁴ *Id.*

⁷⁵ *Id.*

⁷⁶ *Id.*

⁷⁷ *Id.* at 1005-06.

⁷⁸ *Id.* The district court held that the MDA did not preempt claims based on violation of federal law. *Id.* at 1006. The district court also found the MDA preempted the loss of consortium claim brought by Donna Riegel, Charles’ widow, “to the extent it was derivative of the pre-empted claims.” *Id.*

successful, impose state requirements that differed from, or added to” the requirements of the MDA.⁷⁹

The Supreme Court also affirmed in an 8-1 decision authored by Justice Scalia. Justice Stevens joined the decision except for Parts III-A and III-B, and Justice Ginsburg dissented. Justice Scalia noted that the MDA includes an express preemption clause at 21 U.S.C. § 360k(a).⁸⁰ It states that:

Except as provided in subsection (b) of this section, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—

(1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and

(2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.⁸¹

Justice Scalia portrayed the case as presenting two questions. The first was “whether the Federal Government ha[d] established requirements applicable to Medtronic’s catheter.”⁸² In addressing this question Justice Scalia contrasted *Riegel*’s facts with the facts of *Lohr*,⁸³ the previously mentioned 1996 Supreme Court case that addressed whether federal manufacturing and labeling requirements applicable to medical devices generally preempted common law claims of negligence and strict liability.⁸⁴ In *Lohr*, the Court rejected finding preemption based on broad federal labeling requirements applicable to medical devices that reflected “entirely generic concerns about device regulation generally.”⁸⁵

Justice Scalia emphasized that *Riegel*, unlike *Lohr*, involved a federal requirement that is “specific to individual devices.”⁸⁶ Under *Riegel*’s facts, each and every medical device that is not substantially equivalent to existing devices must undergo the federal premarket approval process. The MDA, rather than exempting federal safety review, “is federal safety review.”⁸⁷ Thus, Justice Scalia concluded that the federal government has established requirements applicable to Medtronic’s catheter.⁸⁸

Justice Scalia presented the second question in *Riegel* as whether the plaintiff’s claims rely on any “requirement” of New York law that is

⁷⁹ *Riegel v. Medtronic, Inc.*, 451 F.3d 104, 121, 127 (2d Cir. 2006).

⁸⁰ *Riegel*, 128 S. Ct. at 1003.

⁸¹ 21 U.S.C. § 360k(a) (2006).

⁸² *Riegel*, 128 S. Ct. at 1006.

⁸³ 518 U.S. 470 (1996).

⁸⁴ *Riegel*, 128 S. Ct. at 1006; *see supra* text accompanying notes 52-54.

⁸⁵ *Lohr*, 518 U.S. at 501.

⁸⁶ *Riegel*, 128 S. Ct. at 1007.

⁸⁷ *Id.*

⁸⁸ *See id.*

different from or in addition to federal requirements.⁸⁹ He again cited *Lohr* for guidance, noting that in that case five Justices held that state negligence and strict liability causes of action constitute “‘requirement[s]’ and would be preempted by federal requirements specific to a medical device.”⁹⁰ Justice Scalia asserted that under normal circumstances “‘requirements’ include [state] common-law duties.”⁹¹ Further, under *Riegel*’s facts, “there is nothing to contradict this normal meaning.”⁹² This is because “[s]tate tort law that requires a manufacturer’s catheters to be safer, but hence less effective, than the model the FDA has approved disrupts the federal scheme no less than state regulatory law to the same effect.”⁹³

The tone of Justice Scalia’s analysis suggests that skepticism regarding American tort law may be an important factor in preemption’s rise. Indeed, the decision is surprisingly derisive regarding the tort system in products liability cases. Perhaps even more surprisingly, the majority opinion may reflect a fundamental misunderstanding of important aspects of products liability law.

Justice Scalia’s majority opinion argues that tort liability under negligence or strict liability is “less deserving of preservation” in the presence of federal regulation than are state statutes or state regulations.⁹⁴ He views state statutes or regulations related to prescription products as at least similar to FDA regulations, in that they can “be expected to apply cost-benefit analysis similar to that applied by the experts at the FDA.”⁹⁵ In Justice Scalia’s view, this cost-benefit analysis by state regulators and FDA regulators asks: “How many more lives will be saved by a device which, along with its greater effectiveness, brings a greater risk of harm?”⁹⁶

Juries in torts cases, Justice Scalia seemingly asserts, are simply not to be trusted to balance these interests. In what appears to represent a significant misunderstanding of design defect analysis, he insists that “[a] jury . . . sees only the cost of a more dangerous design, and is not concerned with its benefits; the patients who reaped those benefits are not represented in court.”⁹⁷

Apparently Justice Scalia is not familiar with the *Restatement (Third)*’s design defect standard nor the numerous decisions by state courts setting forth a risk/utility test for liability.⁹⁸ Under this dominant

⁸⁹ *Id.* (citing 21 U.S.C. § 360k(a) (2006)).

⁹⁰ *Id.*

⁹¹ *Id.* at 1008.

⁹² *Id.*

⁹³ *Id.*

⁹⁴ *See id.*

⁹⁵ *Id.*

⁹⁶ *Id.*

⁹⁷ *Id.*

⁹⁸ According to the *Restatement (Third)*, a product

approach to design defects, jurors are of course instructed to consider a design's benefits as well as its risks.⁹⁹ True, the patients who reaped a design's benefits are not themselves represented in court, but the defendant-seller most certainly is, and it will communicate as much as possible to the jury about these patients' reaping benefits (at least in general terms). In addition to minimizing the design's risks (often in comparison to what the plaintiff asserts is a reasonable alternative design),¹⁰⁰ the defendant manufacturer or other seller of course focuses on evidence highlighting the design's benefits and, at least in general terms, its ability to achieve good results for other patients.

Even if a court rejects the risk/utility approach in favor of its most common alternative, the reasonable consumer expectations test,¹⁰¹ the product's benefits as well as its risks are relevant to a jury's analysis of reasonable expectations.¹⁰² Consumers might expect that

is defective in design when the foreseeable risks of harm posed by the product could have been reduced or avoided by the adoption of a reasonable alternative design by the seller or other distributor, or a predecessor in the commercial chain of distribution, and the omission of the alternative design renders the product not reasonably safe.

RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 2(b) (1998). For example, Arizona has adopted a risk-utility test, rather than a consumer expectations test, for its design defect cases, since "consumers will very often not know what to expect of a complex or unfamiliar design." *Id.* at cmt. d, Reporters' Notes, at 66 (citing *Dart v. Wiebe Mfg.*, 709 P.2d 876, 878 (Ariz. 1985)). A risk-utility test is also used in Maine design defect cases—according to the Maine Supreme Court, "To determine whether a product is defectively dangerous, we balance the danger presented by the product against its utility." *Id.* at 70. (citing *Guiggey v. Bombardier*, 615 A.2d 1169, 1172 (Me. 1992)). In addition, both New Hampshire, as outlined in *Thibault v. Sears Roebuck & Co.*, 395 A.2d 843 (N.H. 1978), and New Mexico, as indicated in *Brooks v. Beech Aircraft Corp.*, 902 P.2d 54 (N.M. 1995), use a risk-utility analysis to determine design defect. *Id.*

⁹⁹ The *Restatement (Third)* notes that some form of risk-utility balancing typically requiring evidence of a reasonable alternative design in design defect cases is followed by "the overwhelming majority of American jurisdictions." RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 2(b), cmt. d Reporters' Note (1998). For example, South Carolina's risk-utility balancing test includes the following factors: "[T]he usefulness and desirability of the product, the cost involved for added safety, the likelihood and potential seriousness of injury, and the obviousness of danger." *Claytor v. Gen. Motors Corp.*, 286 S.E.2d 129, 132 (S.C. 1982)).

¹⁰⁰ See, e.g., *Green v. Denney*, 742 P.2d 639, 640-41 (Or. Ct. App. 1987) (Defendant car manufacturer, in response to plaintiff's claim of defective car roof design and suggestion of a superior alternative design, downplayed the true risk of the type of injury that occurred in this case, in which a passenger was killed when the car struck a horse, causing the horse to land on the roof and the roof to crush the victim.).

¹⁰¹ The states' use of these two tests has evolved significantly since the *Restatement (Second)*'s product liability standards were created. Richard W. Wright, *The Principles of Product Liability*, 26 REV. LITIG. 1067, 1079 (2007). Although most states initially adopted the consumer expectations test, which was outlined in comment i of the *Restatement (Second)* section 402A, certain problems arose as courts attempted to use this test exclusively. *Id.* Accordingly, some courts followed the lead of the California Supreme Court in *Barker v. Lull Engineering Company, Inc.*, 573 P.2d 443 (Cal. 1978), establishing a two-prong test for defective product design: consumer expectations and risk-utility. *Wright, supra*, at 1079-80. Note, however, that many courts continue to employ a consumer expectations test alone. *Id.* at 1080.

¹⁰² Douglas A. Kysar, *The Expectations of Consumers*, 103 COLUM. L. REV. 1700, 1781 (2003) ("The expectations of consumers are most helpful in product design litigation when they capture lay values that do not appear in the comparatively narrow risk-utility test. Technical analysis of product risks and benefits remains necessary, however, to ensure that product manufacturers face

manufacturers would market a product that features high risk if the product also offers correspondingly high benefits, thus making the dangerous product arguably non-defective under a consumer expectations analysis. Arguing, as did Justice Scalia, that a jury is “not concerned with [a design’s] benefits” is only tenable if one assumes that juries completely disregard the defendant’s evidence and arguments.¹⁰³ Judging from manufacturers’ frequent success in products liability litigation, this is simply not accurate.¹⁰⁴ Jurors in products liability cases as a matter of course consider designs’ benefits, and very frequently they find that because of those benefits an injured plaintiff must lose.¹⁰⁵

Another potential signal that perhaps drug regulation and tort law were not considered carefully enough is found in Justice Scalia’s somewhat dramatic pronouncement that the cost-benefit analysis used by FDA and by state drug regulators focuses on “how many more lives will be saved by a device which . . . brings a greater risk of harm.”¹⁰⁶ In reality, many Class III medical devices have nothing to do with saving lives. Class III medical devices, subject to MDA regulation, entail a wide range of utilities and purposes. Breast implants, to pick an easy example, are Class III medical devices but are rarely thought of as saving lives.¹⁰⁷ Some Class III medical devices save lives, but many or perhaps most have an honorable but less compelling use. Stating the cost-benefit analysis as one of “saving lives” is at best loose language and seems to equate Class III regulation with life or death matters across the board, thus making potential interference by the tort system seem to risk life or death across the board. Tort law that regulates a matter of life or death seems more grave than tort law that plays a role in regulation that is

appropriate safety incentives whenever consumer expectations, for whatever reason, are lower than the level of safety that a risk-utility test would deem reasonable.”)

¹⁰³ *Riegel v. Medtronic, Inc.*, 128 S. Ct. 999, 1008 (2008).

¹⁰⁴ According to the Department of Justice, “[n]on-asbestos product liability trials declined by about two-thirds from 1990 to 2003.” OFFICE OF JUSTICE PROGRAMS, DEP’T OF JUSTICE, NUMBER OF FEDERAL TORT TRIALS FELL BY ALMOST 80 PERCENT FROM 1985 THROUGH 2003 (2005), available at <http://www.ojp.usdoj.gov/bjs/pub/press/fitv03pr.htm>. During the fiscal year 2002-2003, the Justice Department found that (1) juries heard just over 70% of the products liability cases decided in federal court, and (2) there was a judgment for the plaintiff in just one-third of all federal products liability cases. *Id.* The Justice Department has also recently studied civil trial statistics in state courts. In state court civil trials during 2005, plaintiffs won a very low percentage (20%) of product liability trials that did not involve asbestos, despite winning more than half (56%) of the total number of state court civil cases, and more than half (52%) of the total number of tort cases, during this time period. BUREAU OF JUSTICE STATISTICS, DEP’T OF JUSTICE, SPECIAL REPORT: CIVIL BENCH AND JURY TRIALS IN STATE COURTS 4 (2008), available at <http://www.ojp.usdoj.gov/bjs/pub/pdf/cbjtsc05.pdf>. Over 92% of the non-asbestos products liability cases heard in state courts during this time were decided by a jury. *Id.* at 2.

¹⁰⁵ See *supra* note 104.

¹⁰⁶ *Riegel*, 128 S. Ct. at 1008.

¹⁰⁷ Even though breast implants are not considered to save lives, they fall under the Class III devices category because they present a “potential unreasonable risk of illness or injury.” Mark C. Levy & Gregory J. Wartman, *Amicus Curiae Efforts to Reform Product Liability at the Food and Drug Administration: FDA’s Influence on Federal Preemption of Class III Medical Devices and Pharmaceuticals*, 60 FOOD & DRUG L.J. 495, 498 (2005) (quoting 21 U.S.C. § 360(a)(1)(C)).

sometimes a matter of life or death, sometimes a matter of cosmetics, and probably most often somewhere between those two extremes.

The *Riegel* majority concluded that state tort lawsuits are only preempted “to the extent that they are different from, or in addition to” federal requirements.¹⁰⁸ Under this reading, the court, again citing *Lohr*, held that damages remedies are not preempted if they run “parallel” to federal requirements rather than adding to them.¹⁰⁹ A claim would parallel the MDA regulations if the defendant’s medical product ran afoul of both the MDA and state tort law.

Justice Stevens concurred in part and concurred with the judgment. He disagreed with the majority’s assertion that Congress decided when enacting the MDA that costs of injuries caused by medical devices falling within the Act’s scope would be outweighed by concern that some medical devices would not be available if juries were permitted to apply the tort law of all fifty states.¹¹⁰ To the contrary, Justice Stevens asserted that “[t]here is nothing in the preenactment history of the MDA suggesting that Congress thought state tort remedies had impeded the development of medical devices.”¹¹¹ He agreed with Justice Ginsburg’s dissent that “the overriding purpose of the legislation was to provide additional protection to consumers, not to withdraw existing protections.”¹¹² However, despite his disagreement over Congress’ intent in enacting the MDA, Justice Stevens agreed with the majority that the plaintiff’s tort claims must be preempted. Regardless of Congress’ intent when the MDA became law, Justice Stevens believed that allowing plaintiffs’ tort claims would “constitute requirements with respect to the device at issue that differ from federal requirements relating to safety and effectiveness.”¹¹³

Justice Ginsburg provided the sole dissent. In doing so she focused heavily on the history and background of the MDA. She described the majority’s position as a “radical curtailment” of tort claims that was not intended by Congress when it enacted the MDA.¹¹⁴ In Justice Ginsburg view, the reason Congress enacted the MDA “is evident.”¹¹⁵ As addressed above, prior to 1976 the federal government did not regulate medical devices before they entered the market.¹¹⁶ However, the Dalkon Shield tragedy and other problems with prescription devices created political pressure for some form of regulation.¹¹⁷ Several “states acted to

¹⁰⁸ *Riegel*, 128 S. Ct. at 1011.

¹⁰⁹ *Id.*

¹¹⁰ *Id.* at 1012 (Stevens, J., concurring in part and concurring in the judgment).

¹¹¹ *Id.*

¹¹² *Id.*

¹¹³ *Id.* at 1012-13.

¹¹⁴ *Id.* at 1013 (Ginsburg, J., dissenting).

¹¹⁵ *Id.*

¹¹⁶ *Id.*; see *supra* notes 60-68 and accompanying text.

¹¹⁷ *Riegel*, 128 S. Ct. at 1014-15.

fill the void by adopting their own regulatory systems for medical devices.”¹¹⁸ By the time of the MDA’s enactment in 1976, thirteen states had already created statutes governing medical devices.¹¹⁹ Needing to comply with these states’ explicit regulations as well as the federal government’s new regulations in 1976 was considered overly burdensome to prescription product manufacturers. Thus, Justice Ginsburg explained, the MDA’s preemption clause was drafted to eliminate these state regulatory systems rather than to preempt state tort claims.¹²⁰ Since Congress’ intent is the “ultimate touchstone” of preemption analysis, Justice Ginsburg could not agree with the majority’s decision.¹²¹

Justice Ginsburg’s dissent briefly noted a point widely discussed among scholars and in the media: that during the litigation, the FDA announced a new position favoring preemption in premarket approval MDA claims.¹²² Justice Ginsburg emphasized that previously, under the Clinton administration, the FDA had taken the position that “FDA product approval and state tort liability usually operate independently, each providing a significant, yet distinct, layer of consumer protection.”¹²³ She asserted that inconsistency in an agency’s position regarding whether preemption should apply is a factor to consider in deciding how much weight the agency’s position is due and summarily rejected the FDA’s new pro-preemption position as “entitled to little weight.”¹²⁴

In late 2008, after *Riegel* had been decided and shortly before the Supreme Court heard oral arguments in the later preemption case of *Levine v. Wyeth*, controversy related to the FDA’s shift in position made headlines. On October 29th, United States House of Representatives member Henry Waxman released documents detailing a rift in the FDA’s management between top staff regulators and Bush administration political appointees regarding whether to shift the FDA’s position on preemption.¹²⁵

During his administration, President George W. Bush expressed concerns regarding tort liability for prescription products.¹²⁶ Perhaps not

¹¹⁸ *Id.* at 1013.

¹¹⁹ *Id.* at 1003 (majority opinion) (citing Robert B. Leflar & Robert S. Adler, *The Preemption Pentad: Federal Preemption of Products Liability Claims After Medtronic*, 64 TENN. L. REV. 691, 703 (1997)).

¹²⁰ *Id.* at 1018 (Ginsburg, J., dissenting).

¹²¹ *Id.* at 1013.

¹²² *Id.* at 1016 n.8.

¹²³ *Id.* at 1015 (quoting Margaret Jane Porter, *The Lohr Decision: FDA Perspective and Position*, 52 FOOD & DRUG L.J. 7, 11 (1997)).

¹²⁴ *Id.* at 1016 n.8.

¹²⁵ See David G. Savage, *Memos Shed Light on Drug Lawsuit Dispute*, L.A. TIMES, Oct. 30, 2008, at A18.

¹²⁶ For example, President Bush backed a 2005 medical malpractice bill that shielded pharmaceutical companies from liability for punitive damages, as long as their drugs meet the Food and Drug Administration’s (“FDA”) approval standards. Jim VandeHei, *Malpractice Bill Shields*

surprisingly, he appointed officials who favored expanding preemption to limit tort liability for prescription products.¹²⁷ According to the documents released by Representative Waxman, the struggle between the Bush administration and senior FDA staff members developed early in the Bush administration.¹²⁸ Critics of the FDA's shift in position to support preemption hailed the Waxman report as evidence that the Bush administration was playing politics with the FDA rather than acting in the best interests of consumers. One consumer activist described the documents as showing "that the nonpolitical people—the actual experts in the drug-approval process—didn't agree with the approach of deferring to the companies."¹²⁹

Another interesting sidebar to Justice Ginsburg's dissent is her emphasis that the majority decision does not address an "important issue" whether the MDA's express preemption language preempts tort lawsuits "where evidence of a medical device's defect comes to light only *after* the device receives premarket approval."¹³⁰ Assuming that a defect for which the manufacturer is responsible exists, finding no preemption in such cases may be consistent with the reasoning of *Riegel*'s majority opinion; in such cases the FDA has not made a fully informed decision that a product's benefits as marketed outweigh its costs.

Justice Ginsburg's dissent addresses at least two additional matters of interest. First, she noted that the FDA's premarket approval of Medtronic's medical device would remain relevant even under her position.¹³¹ Although she would have rejected express preemption under section 360k(a), implied conflict preemption would still remain a possibility in appropriate cases. Thus, "a medical device manufacturer

Drugmakers, WASH. POST, Jan. 5, 2005, at A3. The Bush administration also supported pharmaceutical companies that seek to avoid liability in products defect lawsuits by claiming that federal law preempts state tort law. See Jerry Markon, *High Court Case Looms Large for Drugmakers*, WASH. POST, Nov. 4, 2008, at D1. The Bush administration supported the drug-maker involved in the latest Supreme Court case in which the defendants argued federal preemption, *Wyeth v. Levine*, after "[h]aving failed to persuade Congress or the states to limit" suits against prescription drug-makers. David G. Savage, *Drug Makers Seek Shield From Suits*, L.A. TIMES, Sept. 7, 2008, at A16.

¹²⁷ See Stephen Labaton, 'Silent Tort Reform' is Overriding States' Powers, N.Y. TIMES, Mar. 10, 2006, at C5; Savage, *supra* note 125.

¹²⁸ According to Congressman Waxman's report, "[i]nternal FDA documents indicate that in at least 138 cases involving drugs or biological products" between 2000 and 2005, the "FDA failed to take enforcement actions recommended by the agency's own field inspectors." SPECIAL INVESTIGATIONS DIV., H. COMM. ON GOV'T REFORM, PRESCRIPTION FOR HARM: THE DECLINE IN FDA ENFORCEMENT ACTIVITY 10 (2006), available at http://oversight.house.gov/documents/2006_0627101434-98349.pdf. According to the report, "[i]n many of the cases, FDA officials in Washington undermined the efforts of field officials through extended delays in acting on the enforcement recommendations." *Id.* at 11. These actions were far from harmless: "[i]n multiple cases, enforcement recommendations were rejected where actual harm, including death, resulted from the violations." *Id.* at 12.

¹²⁹ Savage, *supra* note 125.

¹³⁰ *Riegel v. Medtronic, Inc.*, 128 S. Ct. 999, 1013 n.1 (2008) (Ginsburg, J., dissenting).

¹³¹ See *id.* at 1019-20.

may have a dispositive defense if it can identify an actual conflict between the plaintiff's theory of the case and the FDA's premarket approval of the device in question."¹³² Justice Ginsburg noted that Medtronic did not argue implied conflict preemption in this case.¹³³

Second, Justice Ginsburg pointed out that medical device manufacturers also can make regulatory compliance defenses based on the FDA's premarket approval of their product.¹³⁴ Although in most states the fact that a manufacturer has complied with regulations does not automatically clear him or her of liability, it is nevertheless "regarded as one factor to be considered by the jury."¹³⁵

Near the end of her dissent, Justice Ginsburg indicated that she found Medtronic's preemption argument wanting on policy grounds in addition to grounds of conflicting with congressional intent. Although Medtronic's product underwent a premarket approval process, "the process for approving new drugs is at least as rigorous as the premarket approval process for medical devices."¹³⁶ However, "[c]ourts that have considered the question have overwhelmingly held that FDA approval of a new drug application does not preempt state tort law suits."¹³⁷ If rigorous premarket approval for prescription drugs does not preempt tort claims, Justice Ginsburg reasoned, on policy grounds neither should premarket approval for prescription medical devices.¹³⁸ She noted: "This court will soon address the issue in *Levine v. Wyeth*."¹³⁹

B. Levine v. Wyeth—Seeking to Extend Preemption to Drug Failure to Warn Claims

The second prescription product case considered by the Supreme Court in 2008—and decided in 2009—featured even higher stakes for the future of tort liability for prescription products. In *Levine v. Wyeth*, plaintiff Diana Levine sued over harm related to defendant Wyeth's drug Phenageran.¹⁴⁰ In April 2000, Levine went to the Northeast Washington County Community Health, Inc. in Vermont complaining of nausea related to a migraine headache.¹⁴¹ To treat the nausea she was given two injections of Phenageran.¹⁴² The first injection was given intramuscularly.¹⁴³ However, because the nausea continued, later in the

¹³² *Id.*

¹³³ *Id.* at 1020.

¹³⁴ *Id.*

¹³⁵ *Id.*

¹³⁶ *Id.* at 1018.

¹³⁷ *Id.* at 1018-19.

¹³⁸ *Id.*

¹³⁹ *Id.* at 1019 n.16.

¹⁴⁰ 944 A.2d 179, 182 (Vt. 2006), *aff'd*, 129 S. Ct. 1187 (2009).

¹⁴¹ *Id.*

¹⁴² *Id.*

¹⁴³ *Id.*

day she was given another injection by an intravenous injection directly into her arm.¹⁴⁴ The intravenous injection was performed through a procedure called “IV push,”¹⁴⁵ during which the Phenageran was accidentally injected into one of Levine’s arteries.¹⁴⁶ This caused severe damage to the artery, leading to gangrene and eventually to amputation of Levine’s hand and forearm.¹⁴⁷ Levine sued Wyeth for failure to provide adequate warnings related to accidental intra-arterial injections with Phenageran.¹⁴⁸ Levine’s attorneys argued that Wyeth should have warned against ever injecting the drug.¹⁴⁹

Wyeth’s label for Phenageran did provide warnings for health care providers about the dangers of inadvertent intra-arterial injection.¹⁵⁰ The warnings stated that “extreme care should be exercised to avoid perivascular extravasation or inadvertent intra-arterial injection.”¹⁵¹ The label also stated that “[w]hen administering any irritant drug intravenously it is usually preferable to inject it through the tubing of an intravenous infusion set that is known to be functioning satisfactorily.”¹⁵²

The FDA had approved this warning used by Wyeth.¹⁵³ Levine argued that “the label should not have allowed IV push as a means of administration, as it was safer to use other available options, such as intramuscular injection or administration through the tubing of a hanging IV bag.”¹⁵⁴ The trial court instructed jurors that they could consider the label’s compliance with FDA requirements, but that regulatory compliance was not dispositive as a defense.¹⁵⁵ The jury found for Levine, awarding her \$7.4 million in compensatory damages.¹⁵⁶ The Vermont Supreme Court affirmed the jury verdict,¹⁵⁷ and Wyeth appealed to the United States Supreme Court, which granted certiorari.

1. *Wyeth* in the Vermont Supreme Court

The Vermont Supreme Court’s decision in *Wyeth* set forth many of the issues to be considered by the United States Supreme Court.

¹⁴⁴ *Id.*

¹⁴⁵ *Id.*

¹⁴⁶ *Id.*

¹⁴⁷ *Id.*

¹⁴⁸ *Id.*

¹⁴⁹ *Id.*; see also David G. Savage, *High Court Looks Split on Suits Against Drug Makers*, L.A. TIMES, Nov. 4, 2008, at A5.

¹⁵⁰ *Wyeth*, 944 A.2d at 183 n.1.

¹⁵¹ *Id.*

¹⁵² *Id.*

¹⁵³ *Id.* at 182.

¹⁵⁴ *Id.*

¹⁵⁵ *Id.*

¹⁵⁶ *Id.* at 184.

¹⁵⁷ The award affirmed by the Vermont Supreme Court was actually for \$6,744,000, the reduction accounting for prejudgment interest and “plaintiff’s recovery in a settlement of a separate action she had filed against the Health Center.” *Id.*

Wyeth argued to the Vermont Supreme Court that “any state common law duty to provide a stronger warning about the dangers of administering Phenergan by IV push conflicts with the FDA’s approval of the drug’s label.”¹⁵⁸ Thus, Wyeth argued, preemption should disallow Levine’s tort claims. Wyeth conceded that Congress did not expressly preempt claims such as Levine’s in the Food, Drug and Cosmetics Act, and instead asserted implied preemption.¹⁵⁹ According to Wyeth, it was impossible to comply both with federal requirements and the regulation of Vermont tort law.¹⁶⁰ Wyeth alternatively argued that Levine’s tort claim presented an obstacle to compliance with federal regulations by penalizing drug companies for compliance with FDA standards.¹⁶¹

In rejecting these arguments, the Vermont Supreme Court summarized its position with the familiar refrain that the FDA’s requirements create “a floor, not a ceiling, for state regulation.”¹⁶² The court focused its analysis on the existence of “[a] key FDA regulation” that permits drug manufacturers to alter their labeling without prior approval by the FDA when necessary.¹⁶³ The regulation, found at 21 C.F.R. § 314.70(c), allows manufacturers, among other things, “[t]o add or strengthen a contraindication, warning, precaution, or adverse reaction” and to “add or strengthen an instruction about dosage and administration that is intended to increase the safe use of the drug product.”¹⁶⁴ The court held that this regulation not only permits, but also “arguably encourages” manufacturers to add warnings when the FDA warnings are not enough to provide adequate safety.¹⁶⁵ Tort lawsuits “simply give these manufacturers a concrete incentive to take this action as quickly as possible.”¹⁶⁶

2. *Wyeth* in the United States Supreme Court

After being granted certiorari by the United States Supreme Court, *Wyeth* garnered significant media attention.¹⁶⁷ It was perceived as potentially becoming an extremely important case, in that it offered the possibility of a broad preemption ruling that could virtually destroy prescription product warning litigation. In analyzing the case before oral arguments were heard by the Supreme Court, Professors Anthony Sebok

¹⁵⁸ *Id.*

¹⁵⁹ *Id.*

¹⁶⁰ *Id.* at 185.

¹⁶¹ *Id.*

¹⁶² *Id.* at 188.

¹⁶³ *Id.* at 186.

¹⁶⁴ 21 C.F.R. § 314.70(c) (1999).

¹⁶⁵ *Wyeth*, 944 A.2d at 186.

¹⁶⁶ *Id.*

¹⁶⁷ See, e.g., Robert Barnes, *Justices to Hear Cigarette, Drug Cases*, WASH. POST, Jan. 19, 2008, at A2; Adam Liptak, *Drug Label, Maimed Patient, and Crucial Test for Justices*, N.Y. TIMES, Sept. 19, 2008, at A1; Savage, *supra* note 126.

and Benjamin Zipursky opined that “it is no exaggeration to say that the case presents the Roberts Court with the opportunity to eliminate most of pharmaceutical liability under state tort law in one fell swoop, if it so chooses.”¹⁶⁸

Both consumer groups and drug industry supporters seemed to agree, as numerous amicus briefs were filed on both sides of the issue.¹⁶⁹ In July 2008, the *New England Journal of Medicine* published an editorial warning that drug companies “could effectively be immunized” from tort lawsuits involving warnings approved by the FDA if the court ruled for the manufacturer.¹⁷⁰ Praising the impact of products liability litigation on drug safety, the editorial argued that “[p]reemption will thus result in drugs and devices that are less safe and will thereby undermine a national effort to improve patient safety.”¹⁷¹ The editorial urged Congress to legislatively reverse *Riegel* and to consider doing the same with *Wyeth* if the Court chose to apply preemption to that case.¹⁷² Numerous other editorials and op-ed articles appeared in other publications both supporting and opposing the possibility of a broad preemption ruling in *Wyeth*.¹⁷³ As noted above, Representative Waxman’s report on the conflict between the Bush administration and FDA staff members regarding preemption made headlines shortly before the Court heard oral arguments.¹⁷⁴ By the time the Court heard oral arguments, *Wyeth* had become “the highest profile business case of the

¹⁶⁸ Anthony J. Sebok & Benjamin C. Zipursky, *The Upcoming Supreme Court Case of Wyeth v. Levine and the Preemption Temptation*, FINDLAW.COM, Sept. 23, 2008, <http://writ.news.findlaw.com/sebok/20080923.html>. Professors Sebok and Zipursky urged the court not to undertake this sweeping change, but rather to rule “quite narrowly” in the case. *Id.*

¹⁶⁹ In total, thirty-three amicus briefs were filed with the Supreme Court in connection with the case before oral arguments took place on November 3, 2008. *Levine v. Wyeth*, 129 S. Ct. 1187 (2009).

¹⁷⁰ Gregory D. Curfman, Stephen Morrissey, & Jeffrey M. Drazen, *Why Doctors Should Worry About Preemption*, 359 NEW ENG. J. MED. 1 (2008).

¹⁷¹ *Id.* at 2.

¹⁷² *Id.* at 3.

¹⁷³ For examples of arguments in favor of preemption, see Steve Huntley, Editorial, *Firms That Follow Rules Deserve Protection*, CHI. SUN-TIMES, Sept. 23, 2008, at 21 (“Preemption would not prevent suits for shoddy drug production or other wrongdoing. . . . Finding new drugs is expensive enough—and consumers end up paying those costs—without pharmaceutical companies facing the prospect of using dry scientific data to counter the raw emotional appeals of the injured to juries.”); Editorial, *Wyeth Should Win: Otherwise, a Bad Case Will Make Bad Law*, SAN DIEGO UNION TRIB., Nov. 17, 2008, at B6 (arguing in favor of preemption: “Why have the Food and Drug Administration? To have uniform, scientific, nationwide standards to prevent unsafe drugs. . . . Allowing lawsuits based on inconsistent mandates will cause the confusion and vulnerability the FDA exists to prevent.”). For examples of arguments against preemption, see Editorial, *No Haven for Dangerous Drugs*, BOSTON GLOBE, Sept. 27, 2008, at A14 (arguing against preemption: “The Supreme Court has no business depriving patients of their recourse to courts.”); Editorial, *The Court Confronts a Grievous Injury*, N.Y. TIMES, Nov. 7, 2008, at A26 (arguing against preemption: “For the court to broadly endorse the concept of ‘implied pre-emption’ in this case would show disrespect for the considered decisions of Congress and could foreclose injury suits involving not only drugs, but also motor vehicles, household products and other things. The ultimate effect would be to undermine consumer safety.”).

¹⁷⁴ See *supra* notes 125-129 and accompanying text.

year¹⁷⁵ and one of the most intensely debated cases related to products liability in many years. The National Chamber of Commerce described it, perhaps a bit too breathlessly, as “the business case of the century.”¹⁷⁶

Reactions to oral arguments on November 3, 2008, were mixed, although the Justices’ questions and comments seemed to lower many observers’ expectations regarding a potentially sweeping decision that might virtually eliminate prescription product warnings defect litigation. The *Los Angeles Times* reported that “the justices appeared to be closely split” on whether to follow the Bush administration’s approach to preemption.¹⁷⁷ The *Houston Chronicle* was less equivocal, with the headline of its article covering the oral argument reading in part: “Justices appear poised to side with drugmakers.”¹⁷⁸ The *New York Times* reported that what “was supposed to be the term’s blockbuster business case . . . quickly turned into a search for limiting principles.”¹⁷⁹ Although several of the Justices asked questions or made comments that may have reflected openness to some form of preemption in warning cases involving FDA approval, several of them also may have hinted at an interest in restricting preemption in some cases involving FDA-approved labels; for example, cases in which drug companies learn of new risks after the FDA has approved their labeling.¹⁸⁰ Many of the Justices’ questions, particularly those directed at the plaintiff’s counsel, seemed to focus on when a risk is “new,” and on which party might have the burden of persuasion that a risk was discovered after FDA approval.¹⁸¹

When the Supreme Court delivered its decision in *Wyeth* in March 2009, many were surprised. In a six-to-three decision the court held that Levine’s claims against Wyeth were not preempted by the FDA’s approval of Phenergan’s warning label. The *New York Times* described this ruling as “a major setback for business groups that had hoped to build a barrier against injury lawsuits seeking billions of dollars.”¹⁸²

¹⁷⁵ Michael Doyle, *Justices Appear Poised to Side with Drugmakers: Pleas for Lawsuit Protection Come as Amputee Argues State Law, Not FDA Warning, Prevails*, HOUSTON CHRON., Nov. 4, 2008, at A7.

¹⁷⁶ Alicia Mundy & Shirley S. Wang, *In Drug Case, Justices to Weigh Right to Sue*, WALL ST. J., Oct. 27, 2008, at B1. Depending on how it is decided, *Wyeth* could indeed be one of the most important business cases of the 21st century thus far, but we have ninety-two years remaining in the century.

¹⁷⁷ Savage, *supra* note 149.

¹⁷⁸ Doyle, *supra* note 175.

¹⁷⁹ Adam Liptak, *Justices Weigh Effect of F.D.A. Approval of Drug Labels on Suits in State Courts*, N.Y. TIMES, Nov. 3, 2008, at A20.

¹⁸⁰ *Id.* For a complete transcript of the oral argument, see Transcript of Oral Argument, *Levine v. Wyeth*, No. 06-1249 (U.S. argued Nov. 3, 2008), available at http://www.supremecourtus.gov/oral_arguments/argument_transcripts/06-1249.pdf [hereinafter Oral Argument Transcript].

¹⁸¹ See generally Oral Argument Transcript, *supra* note 180.

¹⁸² Adam Liptak, *No Legal Shield in Drug Labeling, Justices Rule*, N.Y. TIMES, Mar. 5, 2009, at A1.

In its decision, the Court rejected *Wyeth's* impossibility defense and its argument that failing to find preemption would obstruct the purposes and objectives of FDA regulations. Regarding impossibility, the Court held that FDA regulations allow manufacturers to add to or strengthen warnings based on “newly acquired information,” and that newly acquired information may include new analyses of previously submitted data.¹⁸³ In this case, the Court held that the plaintiff had provided evidence “of at least 20 incidents prior to her injury in which a Phenergan injection resulted in gangrene and an amputation,”¹⁸⁴ and that on the basis of this information *Wyeth* could have added a stronger warning regarding use of the IV-push method.¹⁸⁵ Noting that “impossibility pre-emption is a demanding defense,” the Court found *Wyeth's* argument for it lacking.¹⁸⁶

Regarding *Wyeth's* argument that allowing liability would obstruct the FDA regulatory scheme's purposes and objectives, the Court agreed with the Vermont Supreme Court that FDA requirements provide merely a floor for drug regulation, rather than “both a floor and a ceiling” as contended by *Wyeth*.¹⁸⁷ State tort lawsuits, the Court held, are an important aspect of drug regulation that builds up from the floor of FDA requirements.¹⁸⁸ The Court emphasized that the FDA has only limited resources to monitor the thousands of drugs on the market, and that the tort system may be especially helpful in regulating new risks that may emerge in drugs' postmarketing phase.¹⁸⁹ The Court also found it significant that Congress had never chosen to insert an express preemption provision into the Federal Drug and Cosmetic Act in its seventy-year history; if Congress thought state tort claims interfered with its objectives, the Court reasoned that Congress would have at some point enacted an express preemption provision.¹⁹⁰

Significantly, the Court found that the FDA's 2006 preamble supporting preemption “does not merit deference.”¹⁹¹ In language that may reflect consciousness of the political controversy surrounding the FDA's new pro-preemption stance under the George W. Bush administration, the Court described the FDA's 2006 preamble as “inherently suspect.”¹⁹² This is because the FDA articulated a new “sweeping position” in the preamble without offering states or other

¹⁸³ *Wyeth v. Levine*, 129 S. Ct. 1187, 1196-97(2009).

¹⁸⁴ *Id.* at 1197.

¹⁸⁵ *Id.*

¹⁸⁶ *Id.* at 1199.

¹⁸⁷ *Id.*

¹⁸⁸ *Id.* at 1202.

¹⁸⁹ *Id.*

¹⁹⁰ *Id.* at 1200.

¹⁹¹ *Id.* at 1190.

¹⁹² *Id.*

interested parties notice or opportunity to comment.¹⁹³ Further, the Court found the preamble “at odds” with other evidence of Congress’ purposes, criticizing it for failing to provide any discussion of how state tort law has interfered with Congress’ purposes.¹⁹⁴ The Court also found the George W. Bush administration’s amicus brief “similarly undeserving of deference,” because its “explanation of federal drug regulation departs markedly from the FDA’s understanding at all times relevant to this case.”¹⁹⁵

Justice Breyer wrote a separate concurring opinion seeking to emphasize that state tort law sometimes is an obstacle to the FDA’s objectives, and thus may be in some instances preempted, but that preemption is not applicable to this case.¹⁹⁶ Justice Thomas also wrote a separate concurring opinion to express that he has become “increasingly skeptical” of the Court’s “‘purposes and objectives’ preemption jurisprudence,” and that he cannot join the majority’s “implicit endorsement of far-reaching implied preemption doctrines.”¹⁹⁷

Justice Alito, joined by Justice Scalia and Chief Justice Roberts, dissented. The dissent argued that the majority’s decision was inconsistent with prior preemption decisions, and that in its decision the majority effectively allows state tort juries to countermand considered decisions by the FDA.¹⁹⁸ The dissent expressed concern that this “has potentially far-reaching consequences.”¹⁹⁹

An especially interesting aspect of the dissent is its repetition of Justice Scalia’s attack on the civil jury system in drug cases set forth in *Riegel*.²⁰⁰ Justice Alito argued that “[b]y their very nature, juries are ill-equipped to perform the FDA’s cost-benefit-balancing function.” This is because, according to the dissenters, juries only see the injured plaintiff and do not see the patients who reaped the benefits of a drug. As noted above, this criticism seems to reflect misunderstanding of what information juries consider in prescription drug litigation.²⁰¹ Further, drug cases are not unique with respect to jurors only seeing the injured party and not seeing those who benefited from a products design or warning. Rather, this would be typical in all forms of product liability litigation based on design or warning defect claims where the defendant manufacturer argues that other consumers were benefited by the design or warning chosen. Only the injured plaintiff is before the jury’s eyes, and the defendant is permitted to present evidence to the jury of the

¹⁹³ *Id.*

¹⁹⁴ *Id.*

¹⁹⁵ *Id.* at 1203 n.13.

¹⁹⁶ *Id.* at 1204 (Breyer, J., concurring).

¹⁹⁷ *Id.* at 1205 (Thomas, J., concurring).

¹⁹⁸ *Id.* at 1217-18 (Alito, J., dissenting).

¹⁹⁹ *Id.* at 1229.

²⁰⁰ See *supra* notes 94-105 and accompanying text.

²⁰¹ See *supra* notes 94-105 and accompanying text.

design or warning's benefits to other consumers even though those consumers are not present in the courtroom. Casting out prescription product litigation on this basis as being ill-suited to determination by juries would seemingly implicate most other types of design or warning litigation.

C. *Altria Group, Inc. v. Good—If at First You Don't Preempt, Try, Try Again*

A third products liability preemption case analyzed by the Supreme Court between early 2008 and early 2009 was *Altria Group, Inc. v. Good*.²⁰² Although *Altria* did not involve prescription products, it merits a brief discussion in this analysis. *Altria* involved an assertion by a cigarette manufacturer that the Federal Cigarette Labeling and Advertising Act preempted a lawsuit based on state unfair practices statute.²⁰³ The lawsuit centered on allegations that the defendant engaged in fraud (which allegedly violated the Maine Unfair Trade Practices Act) by conveying the message that its "light" cigarettes "deliver less tar and nicotine to consumers."²⁰⁴ In reality, the lawsuit alleged, the cigarette company knew that "[b]y covering filter ventilation holes with their lips or fingers, taking larger or more frequent puffs, and holding the smoke in their lungs for a longer period of time, smokers of 'light' cigarettes unknowingly inhale as much tar and nicotine as do smokers of regular cigarettes."²⁰⁵

The Federal Cigarette Labeling and Advertising Act "establish[ed] a comprehensive federal program to deal with cigarette labeling and advertising with respect to any relationship between smoking and health."²⁰⁶ A narrow five-to-four majority held that the state law claim was not expressly preempted because a state-imposed duty not to engage in fraud "has nothing to do with smoking and health."²⁰⁷ Rather, it has to do with not engaging in fraud.

The majority relied heavily on *Cipollone*, the 1992 cigarette warning case that arguably started the Court's evolution toward increased preemption in products liability claims.²⁰⁸ As noted above, *Cipollone* held that the Public Health Cigarette Smoking Act of 1969 expressly preempted failure to warn tort claims.²⁰⁹ However, a plurality in *Cipollone* declined to preempt fraud claims under the Act, holding that

²⁰² 129 S. Ct. 538 (2008).

²⁰³ *Id.* at 541.

²⁰⁴ *Id.*

²⁰⁵ *Id.*

²⁰⁶ *Id.* at 544 (quoting 15 U.S.C. § 1331 (2006)).

²⁰⁷ *Id.* at 545.

²⁰⁸ The majority also relied upon *Lorillard Tobacco Co. v. Reilly*, 533 U.S. 525 (2001), another cigarette-related preemption case. *Altria*, 129 S. Ct. at 542.

²⁰⁹ See *supra* notes 48-50 and accompanying text.

fraud claims “rely only on a single, uniform standard: falsity.”²¹⁰ Such fraud claims, the *Cipollone* plurality held, are not “based on” smoking and health.²¹¹ The majority in *Altria* agreed with this holding in addressing the fraud-related claim before it.

Perhaps the most interesting aspect of *Altria* for our purposes is how close it came to cutting off many fraud-related claims against cigarette manufacturers. Four Justices—Justice Alito, Chief Justice Roberts, Justice Scalia, and Justice Thomas (the dissent’s author) —dissented from the majority’s holding, and would have preempted the fraud-related claim. Expressly disagreeing with the plurality in *Cipollone*, the dissenters argued that the majority’s decision in *Altria* “will thus result in a ‘requirement’ that petitioners represent the effects of smoking on health in a particular way in their advertising and promotion of light cigarettes.”²¹² This position, which would have provided yet another significant expansion of preemption’s scope in cigarette litigation, came within one vote of prevailing.

IV. CONCLUSION: HEARING THE TUNE IF NOT THE WORDS: THE RESTATEMENT (THIRD)’S PRESCRIPTION PRODUCT STANDARD AND COURTS’ TREND TOWARD RESTRICTIVENESS

As noted above in Part II, the *Restatement (Third)*’s prescription product design standard set forth in section 6(c)—the no-reasonable-health-care-provider-would-prescribe-to-any-class-of-patients test—has not experienced great success on its own terms. The standard did not have strong support in case law when it was adopted,²¹³ and relatively few appellate courts have expressly applied the standard in the years that have followed the *Restatement (Third)*’s completion.²¹⁴ Further, much, although not all, of the scholarly commentary addressing the standard has been critical.²¹⁵

However, if one looks from a wider angle at the *tone* of section 6(c) and its comments and Reporters’ notes, more grounds for optimism arise in assessing its general consistency with judicial trends. Section 6(c)’s restrictive tone may have to some extent caught the broad *mood* of courts in assessing prescription product design liability, even if the specific details of the unfamiliar standard have not found much traction.

From this broad perspective, section 6(c)’s near-immunity standard is one of the most dramatic examples of the *Restatement (Third)*’s generally conservative approach to products liability, and courts have on the whole become increasingly conservative regarding

²¹⁰ *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 529 (1992).

²¹¹ *Id.* at 530.

²¹² *Altria*, 129 S. Ct. at 552 (Thomas, J., dissenting).

²¹³ See *supra* text accompanying notes 44–45.

²¹⁴ See *supra* note 32 and accompanying text.

²¹⁵ See *supra* note 27 and accompanying text.

products liability in general, and specifically regarding liability for prescription products. The Supreme Court's decision in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*²¹⁶ in 1993, and, even more importantly, the enthusiasm with which many state and federal courts embraced *Daubert's* restrictive tone, provides a helpful illustration. *Daubert* was a products liability case; it involved expert testimony regarding Bendectin.²¹⁷ As I noted in an earlier article, "[w]ithout products liability, there would have been no *Daubert*, and there may have been relatively little perceived need for a decision like *Daubert*."²¹⁸ The *Daubert* decision, one of the most influential evidence cases of the twentieth century, was neither pro-plaintiff nor pro-defendant in its specific holding. However, the concerns with "junk science" that spawned the case were widely perceived as primarily problems with plaintiffs' experts, and many products liability cases such as Bendectin litigation are particularly reliant upon experts. Thus, not surprisingly, *Daubert's* application in federal and state courts is generally viewed as pro-defendant and anti-liability.

Indeed, in practice *Daubert's* evidentiary restrictions, when viewed broadly, may be thought of as a form of judicial tort reform.²¹⁹ Most courts' and commentators' general perception from at least the 1990s to the present has seemed to be, on the whole, that torts and products liability needed to be reigned in, as is reflected in the *Restatement (Third)'s* leanings. By significantly increasing the cost of expert testimony to meet its reliability standards, *Daubert* and its progeny (particularly its progeny) made thousands of products liability cases much more expensive to litigate, thus rendering many medium-value claims²²⁰ financially unviable for plaintiffs and their attorneys.²²¹

Preemption's rise also reflects a judicial outlook that may be, on the whole, increasingly attracted to limiting products liability. *Riegel v. Medtronic, Inc.*,²²² addressed at some length above,²²³ provides an illustration with prescription medical device design. Through its expansive preemption holding, the Supreme Court moved us closer to the *Restatement (Third)'s* goal of being quite restrictive in this area.

²¹⁶ 509 U.S. 579 (1993).

²¹⁷ *Id.* at 582.

²¹⁸ Richard L. Cupp, Jr., *Believing in Products Liability: Reflections on Daubert, Doctrinal Evolution, and David Owen's Products Liability Law*, 40 U.C. DAVIS L. REV. 511, 516 (2006).

²¹⁹ *Id.* at 528.

²²⁰ Because of the expense of litigation, small products liability claims requiring expert testimony were, of course, already rare even before *Daubert*.

²²¹ Cupp, *supra* note 218, at 528-29. Because of the expense of litigation, small products liability claims requiring expert testimony were, of course, already rare even before *Daubert*.

²²² 128 S. Ct. 999 (2008).

²²³ *See supra* Part III.A.

Riegel specifically focused on prescription medical devices that have undergone premarket FDA approval.²²⁴ Although most new Class III devices do not undergo the premarket approval process (according to *Riegel*, only thirty-two out of 3,148 in 2005),²²⁵ the ruling eliminates lawsuits for a category of new medical devices that might most likely be the subject of litigation—since they are entirely new rather than “substantially equivalent” to already existing devices. Thus, *Riegel* will have a substantial restrictive effect on prescription product design defect claims. Particularly when one considers Justice Scalia’s derisive tone in addressing the jury system in prescription product claims (“A jury . . . sees only the cost of a more dangerous design, and is not concerned with its benefits; the patients who reaped those benefits are not represented in court”),²²⁶ it does not seem a stretch to speculate that the case’s expansive preemption ruling may have been influenced in part by a more general concern that products liability claims for prescription products need to be restricted as a matter of general public policy. Although it focuses on preemption rather than doctrinal limitations, *Riegel* presents a *tone* of restrictiveness consistent with the *Restatement (Third)*’s tone.

Further, some of section 6(c)’s reasons for being restrictive overlap with some of the arguments for preemption in drug design cases. For example, in supporting the Restatement’s restrictive standard for prescription drug design, comment b notes that “[c]ourts have also recognized that the regulatory system governing prescription drugs is a legitimate mechanism for setting the standards for drug design.”²²⁷ The comment notes that this deference results in part from concerns over increased cost and decreased availability related to liability, and in part from assumptions that health care providers can ensure that “the right drugs and medical devices reach the right patients.”²²⁸ However, the comment also notes that the deference is based in part on an assumption “that governmental regulatory agencies adequately review new prescription drugs and devices, keeping unreasonably dangerous designs off the market.”²²⁹ Additionally, comment f asserts that section 6(c) “shows appropriate deference to the regulated market.”²³⁰

The full impact of the *Wyeth* decision in 2009 will only be known over time. Professor Catherine Sharkey is probably correct in asserting that now, in light of *Wyeth*, “there is certainly a thumb on the scale against the more aggressive arguments for implied preemption.”²³¹ This seems especially true in light of Barak Obama’s election as

²²⁴ *Riegel*, 128 S. Ct. at 1002.

²²⁵ *Id.* at 1004.

²²⁶ *Id.* at 1008; *see supra* notes 94-107 and accompanying text.

²²⁷ RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 6(c) cmt. b (1998).

²²⁸ *Id.*

²²⁹ *Id.*

²³⁰ *Id.* § 6(c) cmt. f (1998).

²³¹ Liptak, *supra* note 167.

President in late 2008. President Obama seems unlikely to appoint Supreme Court justices that would empower the *Wyeth* dissenters (Justices Alito, Roberts, and Scalia) to effectively reverse the decision in the coming several years. Also important, President Obama seems unlikely to staff the FDA with officials who would equal the George W. Bush administration's appointees in disdain for tort law involving prescription product warnings.

Although *Wyeth* provides some boundaries for preemption's growth, it is a case involving prescription product warning claims, not prescription product design claims. *Riegel*, decided only a short time before *Wyeth*, addressed prescription design claims in the context of prescription medical devices and applied preemption fairly aggressively.²³²

Thus, perhaps, when viewed broadly, the *Riegel* and *Wyeth* preemption decisions may to some extent parallel the *Restatement (Third)*'s disdain for prescription product design liability but acceptance of prescription product warning liability. Maybe section 6(c) missed the song's words but heard its tune when developing a standard with a tone of deference to federal regulation in prescription product design defect claims that is in line with courts' evolution, even though the section's explicit standard is not. Section 6(c) has increasingly seemed to capture courts' general pulse on prescription design defects despite failing to attain traction with its doctrinal analysis.

²³² In the aftermath of *Wyeth*, congressional critics of *Riegel*'s preemption holding indicated that they would present a bill seeking to legislatively overrule *Riegel*. Barry Meier & Natasha Singer, *Drug Ruling Puts Devices in Spotlight*, N.Y. TIMES, Mar. 5, 2009, at B1. An expert speculated that the *Wyeth* decision "might have energized members of Congress who were already eager to nullify last year's device ruling." *Id.*