

# Territorial Claims in the Domain of Accidental Harm

## CONFLICTING CONCEPTIONS OF TORT PREEMPTION

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Territorial claims in the domain of accident law have a long and tortuous history. Criticism of tort as systematically failing to adequately compensate industrial injury victims led to a workers' compensation movement in the Progressive era that literally swept the tort system aside, clearing the playing field for state-by-state no-fault compensation based on legislative/administrative benefits in place of tort adjudication.<sup>1</sup> Some fifty years later, in the late 1960s, a similarly-grounded concern about inadequate compensation animated the auto no-fault movement that complemented, and in some states partially replaced tort with yet another system of legislatively-designated benefits for the victims of motor vehicle accidents.<sup>2</sup>

Then, in the mid-1970s, the tide turned. The focal point of institutional criticism of the tort system shifted dramatically from claims of under-compensation of injury victims to a perception that the system was *overly* generous (and unpredictably so).<sup>3</sup> Nonetheless, for the better part of the next twenty years, one school of tort critics leveled their attacks at the internal dynamics of the tort system, pressing for legislative limitations on punitive damages, pain and suffering awards, and other remedial measures through caps and related stratagems.<sup>4</sup> The reform efforts were incremental rather than territorial; that is, *displacement* of tort was not a priority agenda item.

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<sup>1</sup> See MORTON KELLER, REGULATING A NEW SOCIETY: PUBLIC POLICY AND SOCIAL CHANGE IN AMERICA 197-215 (1994); Lawrence M. Friedman & Jack Ladinsky, *Social Change and the Law of Industrial Accidents*, 67 COLUM. L. REV. 50 (1967).

<sup>2</sup> The movement was animated by the Keeton-O'Connell plan. See ROBERT E. KEETON & JEFFREY O'CONNELL, BASIC PROTECTION FOR THE TRAFFIC VICTIM (1965).

<sup>3</sup> An early milestone enactment was the California Medical Injury Compensation Reform Act ("MICRA") in 1975 addressing claims by the medical profession of excessive tort awards against physicians. CAL. CIV. CODE § 3333.2 (West 2009).

<sup>4</sup> For discussion of the reform initiatives, see Joseph Sanders & Craig Joyce, "*Off to the Races*": *The 1980s Tort Crisis and the Law Reform Process*, 27 Hous. L. Rev. 207 (1990).

A more foundational critique emerged initially in the academic literature, in considerable part as a rejoinder to the expanding doctrinal reach of products liability law—with particular emphasis on the complex science and technology that was often critical to determining the outcome in defective design and warning cases.<sup>5</sup> Critics posed the question of whether courts were up to the job with a negative rejoinder in mind. Juries, they asserted, could not weigh in a satisfying fashion the risk/benefit issues central to these cases, when compared to expert agencies.<sup>6</sup>

Much of the early criticism came in the guise of proposals that courts recognize a regulatory compliance defense and defer to regulatory determinations in cases of conflicting territorial claims to decisionmaking authority.<sup>7</sup> Thus, a prominent critic of the institutional competence of the tort system put his critique this way:

[J]udicial nondeference may make some sense when the administrative regulatory regime is casual or sporadic, as with consumer products. But it is wholly unpersuasive for comprehensively regulated industries. Vaccines, pesticides, aircraft, electric power plants and the like all entail potentially enormous mass-exposure hazards. Precisely because they can create public risks of this nature, these products and services are also subject to the most searching and complete state and federal safety regulation. Administrative agencies may find it politically convenient to disclaim final responsibility for the public risk choices that inhere in such licensing decisions. But the simple fact is that an agency cannot intelligently issue a license for such public-risk activities without comparing the licensee's risks to those of the competition and determining that the new offering represents some measure of progress or, at worst, no measure of regression in the risk market in question.

Once that determination has been made by an expert licensing agency, the courts should respect it. Regulatory agencies are equipped to make the risk comparisons on which all progressive transformation of the risk environment must be based. The courts are simply not qualified to second-guess such decisions; when they choose to do so they routinely make regressive risk choices. Requiring—or at least strongly encouraging—the courts to respect the comparative risk choices made by competent, expert agencies would inject a first, small measure of rationality into a judicial regulatory system that currently runs quite wild.<sup>8</sup>

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<sup>5</sup> See, e.g., Peter Huber, *Safety and the Second Best: The Hazards of Public Risk Management in the Courts*, 85 COLUM. L. REV. 277 (1985). For Huber's mass-audience versions of the critique, see PETER HUBER, *LIABILITY: THE LEGAL REVOLUTION AND ITS CONSEQUENCES* (1990); PETER HUBER, *GALILEO'S REVENGE: JUNK SCIENCE IN THE COURTROOM* (1993); see also RICHARD A. EPSTEIN, *MODERN PRODUCTS LIABILITY LAW* (1980).

<sup>6</sup> For a recent version of the critique, see Peter Schuck, *FDA Preemption of State Tort Law in Drug Regulation: Finding the Sweet Spot*, 13 ROGER WILLIAMS U. L. REV. 73 (2008).

<sup>7</sup> See AM. LAW INST., *REPORTER'S STUDY, 2 ENTERPRISE RESPONSIBILITY FOR PERSONAL INJURY* 83-110 (1991); Richard B. Stewart, *Regulatory Compliance Preclusion of Tort Liability: Limiting the Dual-Track System*, 88 GEO. L.J. 2167 (2000).

<sup>8</sup> Huber, *supra* note 5, at 334-35.

For a variety of reasons, the regulatory compliance defense never gained a firm foothold in the state courts.<sup>9</sup> Only one state, Michigan, affords it full recognition (by way of legislation); a handful of other states treat it as a bar to punitive damages.<sup>10</sup> Both the *Products Liability Restatement* and the *Restatement of the Law Third Torts: Liability for Physical and Emotional Harm*, give it only non-determinative “some evidence” status, reflecting the view of most states courts.<sup>11</sup>

Meanwhile, however, a far more formidable challenge to the territorial claims of tort has arisen. Beginning in 1992, with the landmark decision in *Cipollone v. Liggett Group, Inc.*,<sup>12</sup> the U.S. Supreme Court has decided a burgeoning number of preemption cases, squarely challenging the continuing vitality of tort in many domains of accident law.<sup>13</sup> As I will indicate, *Cipollone* addressed the preemption question in an atypical context. The case did not involve competing claims to territorial authority between a regulatory regime and state tort law; rather, *Cipollone* involved a challenge to the continuing viability of tort in the face of *statutory* directives mandating explicit industry conduct.<sup>14</sup>

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<sup>9</sup> For discussion of the reasons, see Robert L. Rabin, *Reassessing Regulatory Compliance*, 88 GEO. L.J. 2049 (2000).

<sup>10</sup> MICH. COMP. LAWS ANN. § 600.2946 (2000) (codifying the regulatory compliance defense). For a recent review of the status of the regulatory compliance defense in state law, see Carl Tobias, *FDA Regulatory Compliance Reconsidered*, 93 CORNELL L. REV. 1003, 1026-27 nn. 158-61 (2008).

<sup>11</sup> RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 4 (1998) (“In connection with liability for defective design or inadequate instructions or warnings: . . . (b) a product’s compliance with an applicable product safety statute or administrative regulation is properly considered in determining whether the product is defective with respect to the risks sought to be reduced by the statute or regulation, but such compliance does not preclude as a matter of law a finding of product defect.”); RESTATEMENT (THIRD) OF TORTS: LIAB. FOR PHYSICAL & EMOTIONAL HARM § 13 cmt. b (Proposed Final Draft No. 1, 2005) (“[I]n products liability cases, despite the quasi-contractual relationship between the consumer and the manufacturer, the latter’s compliance with custom in designing its product is only some evidence of the adequacy of the product’s design.”).

<sup>12</sup> 505 U.S. 504 (1992).

<sup>13</sup> The principal Supreme Court decisions addressing preclusion in tort after *Cipollone* are *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996), discussed *infra* Part II, *Geier v. American Honda Motor Co., Inc.*, 529 U.S. 861 (2000), discussed *infra* Part II, *Buckman Co. v. Plaintiffs’ Legal Comm.*, 531 U.S. 341 (2001) (preempting a stand-alone claim of fraud on the FDA in the approval process of a manufacturer’s orthopedic bone screws under the Medical Device Amendments), *Spietsma v. Mercury Marine*, 537 U.S. 51 (2002) (holding that neither the Federal Boat Safety Act nor the Coast Guard’s decision not to promulgate specific regulations preempted plaintiff’s state common law claim that her boat motor was unreasonably dangerous), *Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 449 (2005) (refusing to preempt a claim of inadequate warning under the Federal Insecticide, Fungicide and Rodenticide Act after finding no inconsistency with the agency-approved warning), *Riegel v. Medtronic, Inc.*, 128 S. Ct. 999 (2008), discussed *infra* notes 43-45, *Altria Group, Inc. v. Good*, 129 S. Ct. 538 (2008), discussed *infra* Part III.B, and *Wyeth v. Levine*, 129 S. Ct. 1187 (2009), discussed *infra* Part III.

<sup>14</sup> The 1969 version of the cigarette labeling act, reviewed in *Cipollone*, required four explicit warnings to be used on a rotating basis: (1) “Surgeon General’s Warning: Smoking Causes Lung Cancer, Heart Disease, Emphysema, And May Complicate Pregnancy”; (2) “Surgeon General’s Warning: Quitting Smoking Now Greatly Reduces Serious Risks to Your Health”; (3) “Surgeon General’s Warning: Smoking By Pregnant Women May Result in Fetal Injury, Premature Birth, and Low Birth Weight”; (4) “Surgeon General’s Warning: Cigarette Smoke Contains Carbon Monoxide.” Public Health Cigarette Smoking Act of 1969, Pub. L. No. 91-222, § 2, 84 Stat. 87 (current version at 15 U.S.C. § 1333 (2000)).

As one moves beyond *Cipollone* to the far more common situations in which it is *agency* regulatory directives, rather than statutory warning language that arguably preempt tort law, it is critical to keep the institutional competence question in proper constitutional perspective. Preemption cases do *not* raise a question for free-standing judicial determination of whether agencies are better constituted to impose optimal standards of industry conduct than courts. That is a question of common law deference raised by the regulatory compliance defense; it is *not* the question posed by a claim of preemption. In preemption cases, whatever the frustration engendered by the difficulties in discerning legislative intent, the question under the Supremacy Clause is inescapably whether *Congress* intended to displace tort law.<sup>15</sup>

In Part I of this article, I will revisit *Cipollone* to reassess what it has to offer as a foundation for setting the boundaries of regulatory containment of the tort system. Then, in Part II, I will discuss three leading cases from the series of efforts by the Supreme Court to grapple with express preemption clauses in a variety of regulatory schemes.<sup>16</sup> Against this backdrop, in Part III, I will discuss the circumstances under which it might be justified to imply preemption despite the absence of an express provision.<sup>17</sup> A concluding note will tie the strands together.

## I. CIPOLLONE REVISITED

Forty years of tobacco litigation came to a crossroads in *Cipollone*. The tobacco industry defendants, looking for a knockout punch to eliminate a continuing barrage of claims by smoking victims of failure to adequately warn, argued successfully for preemption of these tort suits based on language in the cigarette package warning label legislation.<sup>18</sup> The amended version of that legislation contained a preemption provision, which read: “No *requirement* or prohibition based on smoking and health shall be imposed under State law with respect to the advertising or promotion of any cigarettes the packages of which are labeled in conformity with the provisions of this Act.”<sup>19</sup>

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<sup>15</sup> U.S. CONST. art. VI, cl. 2 (The Supremacy Clause provides that the laws of the United States “shall be the supreme law of the Land; . . . any Thing in the Constitution or Laws of any state to the Contrary notwithstanding.”). For a recent reassertion of this point, see *Altria*, 129 S. Ct. at 543 (“Our inquiry into the scope of a statute’s pre-emptive effect is guided by the rule that ‘[t]he purpose of Congress is the ultimate touchstone’ in every pre-emption case.”).

<sup>16</sup> The three leading cases I will discuss are *Lohr*, *Riegel*, and *Geier*, cited *supra* note 13.

<sup>17</sup> In particular, I will discuss the recently decided *Wyeth v. Levine*, 129 S. Ct. 1187 (2009), addressing preemption in the context of prescription drug regulation.

<sup>18</sup> The Court was sharply split: Justice Stevens wrote for a four-justice plurality, holding that the 1969 Act preempted failure to warn claims but not claims based on fraudulent concealment of material facts (or express warranties); Justice Blackmun wrote for three justices who rejected the displacement of common law tort claims; Justices Scalia and Thomas would have preempted categorically.

<sup>19</sup> Public Health Cigarette Smoking Act of 1969, Pub. L. No. 91-222, 84 Stat. 87 (codified as amended at 15 U.S.C. §§ 1331-40 (2000)) (emphasis added).

*Cipollone* has been taken to be the foundational case on express preemption and in particular on the preclusion of common law tort through the reading of tort duties as “requirements.”<sup>20</sup> In fact, *Cipollone* provided a questionable foundation for any broad equation of tort duties with “requirements.” As recently as *Riegel v. Medtronic, Inc.*,<sup>21</sup> decided in the 2007-08 Term of the Court, Justice Ginsburg argued in dissent, in a case involving the preemption provision in the Medical Devices Amendments, that Congress could have meant “requirements” as precluding only state *regulatory* schemes imposing requirements beyond federal standards.<sup>22</sup>

The key to this continuing skepticism is straightforward. Tort duties do not “require” anything other than the payment of damages. If tort liability does lead a defendant to a private assessment in favor of greater future precautionary measures, then tort, of course, has had a regulatory effect.<sup>23</sup> But tort itself dictates no particular change in a losing defendant’s conduct.<sup>24</sup> Indeed, under a strict liability regime, tort imposes liability with total indifference to whether a defendant might reasonably have decided against investing in additional safety. High priority is given to compensating injury victims and/or risk-spreading.<sup>25</sup>

But the *Cipollone* plurality did not meet the challenge head-on. Rather, the plurality’s pivotal point was statutory construction of the cigarette labeling act: that the changed wording in the 1969 preemption provision—statutory language that prohibited conflicting “requirements”

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<sup>20</sup> *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 521-22 (1992).

<sup>21</sup> 128 S. Ct. 999 (2008).

<sup>22</sup> *Id.* at 1013-14 (Ginsburg, J., dissenting); see also *Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 443 (2005) (“An occurrence that merely motivates an optional decision does not qualify as a requirement. The Court of Appeals was therefore quite wrong when it assumed that any event, such as a jury verdict, that might ‘induce’ a pesticide manufacturer to change its label should be viewed as a requirement.”); *Sprietsma v. Mercury Marine*, 537 U.S. 51, 63 (2002) (“The contrast between [the savings clause’s] general reference to ‘liability at common law’ and the more specific and detailed description of what is pre-empted by [the express preemption clause] indicates that [the preemption clause] was drafted to preempt performance standards and equipment requirements imposed by statute or regulation.”).

<sup>23</sup> Tort as a regulatory regime has come to great prominence in the academic literature. For general discussion, see John C.P. Goldberg, *Twentieth-Century Tort Theory*, 91 GEO. L.J. 513, 513-17 (2003). For advocacy of viewing tort from a regulatory perspective in the context of preemption, see Richard A. Epstein, *Why the FDA Must Preempt Tort Litigation: A Critique of Chevron Deference and a Response to Richard Nagareda*, 1 J. TORT L. art. 5 (2006); Schuck, *supra* note 6.

<sup>24</sup> Justice Blackmun, concurring in part and dissenting in part, made this point forcefully in *Cipollone*, 505 U.S. at 535-39. In fact, the same is often true of regulatory requirements: a violator who is willing to pay the penalty can ignore compliance. In general, however, the normative implications are quite different.

<sup>25</sup> In this regard, see Justice Traynor’s landmark concurrence in *Escola v. Coca Cola Bottling Co. of Fresno*, 150 P.2d 436, 440-41 (Cal. 1944) (“Those who suffer injury from defective products are unprepared to meet its consequences. The cost of an injury and the loss of time or health may be an overwhelming misfortune to the person injured, and a needless one, for the risk of injury can be insured by the manufacturer and distributed among the public as a cost of doing business.”). For articulation of this position in the context of rejecting a regulatory compliance defense claim, see *Ferebee v. Chevron Chemical Company*, 736 F.2d 1529 (D.C. Cir. 1984).

rather than just “statements” (the 1965 statutory terminology)—suggested a more expansive intent than the earlier limitation to conflicting state regulatory measures.<sup>26</sup> Even so, the *Cipollone* plurality did not proscribe all tort litigation. Instead, it read the preemption provision narrowly to leave open the prospect of claims for fraud and misrepresentation against the tobacco companies.<sup>27</sup> Indeed, in a nice bit of irony, tort claimants began to realize a measure of success for the first time immediately after *Cipollone*, as plaintiffs relied on the nearly contemporaneous discovery of tobacco industry documents revealing a pattern of deceptive practices by the industry as a foundation for non-preempted tort claims.<sup>28</sup>

What can be taken from *Cipollone* that might be useful in providing broader guidance when *regulatory agency* directives are satisfied but injury victims nonetheless argue for liability in tort? It seems sensible to think that when Congress enacted, and then subsequently refined, specific cautionary language required on cigarette package labels, it did not mean to have that very process and outcome reopened in another forum through tort claims of failure to adequately warn. This is the core meaning of so-called “conflict” preemption, and it seems questionable—in the absence of an explicit savings clause—to read Congress as desiring, in effect, penalties on compliance, even in the guise of compensation.<sup>29</sup>

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<sup>26</sup> The 1965 statute’s preemption clause stated: “(a) No *statement* relating to smoking and health, other than the statement required by section 4 of this Act, shall be required on any cigarette package; (b) No *statement* relating to smoking and health shall be required in the advertising of any cigarettes the packages of which are labeled in conformity with the provisions of this Act.” Federal Cigarette Labeling and Advertising Act of 1965, Pub. L. No. 89-92, § 5 (1965) (current version at 15 U.S.C. § 1334 (2000)) (emphasis added).

<sup>27</sup> This issue resurfaced before the Supreme Court in *Altria Group, Inc. v. Good*, 129 S.Ct. 538 (2008), when the defendant tobacco company sought to interpose a preemption defense to plaintiff’s claim of economic harm from purchasing “light” cigarettes under the supposition that there would be less nicotine and tar intake. Defendant argued that this was a health and safety claim barred by the proscription of requirements exceeding the statutorily-prescribed warning label. A majority of the Court (5-4) disagreed, holding that the claim was one of fraud in violation of the state consumer protection law, rather than one based on health and safety. *Altria* is discussed further in Part III.B.

<sup>28</sup> See Robert L. Rabin, *The Third Wave of Tobacco Tort Litigation*, in REGULATING TOBACCO ch. 7 (Robert L. Rabin & Stephen D. Sugarman eds., 2001).

<sup>29</sup> This is a closer question than most proponents of preemption acknowledge, precisely because the well-established tradition of strict liability in tort poses a federalism challenge to conflict preemption—short of expressly-stated preclusion of tort. Thus, Professor Stephen Sugarman points out that compensation is a dominant concern reflected in state tort law and that there is no reason to think that federal regulatory legislation is indifferent to that concern—i.e., would be designed to extinguish it via preemption—unless there is explicit indication of that intent in the regulatory legislation. Moreover, the uniformity interest, offered as one justification for conflict preemption, does not override that concern because tort does not compromise uniformity; tort requires nothing beyond the payment of damages. E-mail from Stephen Sugarman to Robert Rabin (Sept. 29, 2008) (on file with author); E-mail from Stephen Sugarman to Robert Rabin (Sept. 30, 2008) (on file with author); E-mail from Stephen Sugarman to Robert Rabin (Jan. 8, 2009) (on file with author).

In response, Professor Peter Schuck argues

One simply cannot separate the compensation and regulatory issues without affecting drug manufacturer incentives in ways that are difficult to predict and that involve the

In the final analysis, there are competing considerations in resolving these preemption claims. On the one hand, it is beyond argument that Congress could limit preemption to conventional legislative and regulatory guidelines: Congress might recognize that tort plays a distinctive role in providing compensation to victims who suffer harm despite regulatory compliance. A regulatory regime like the Food and Drug Administration (“FDA”) provides no remedy to those who are injured despite compliance with regulatory directives. Correlatively, there is no inexorable principle that productivity gains from uniform national health and safety standards—a frequently invoked rationale for preemption—should be borne by injury victims in cases of residual harm. Moreover, once again, it is critical to underscore the dynamics of tort. Liability does not entail enforced departure from regulatory standards; it only compels payment of damage awards.<sup>30</sup>

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highest social stakes. The prospect of having to pay compensation under a strict liability rule, especially one not subject to a state-of-the-art defense, would surely increase the already large uncertainty that surrounds manufacturers’ large long-term investments that are necessary in order to develop socially valuable pharmaceutical products. It might also cause risk-averse manufacturers to include more in their labeling than would be optimal for consumers.

Schuck, *supra* note 6, at 101 n.114.

But this argument does not seem entirely responsive. For one thing, it is detached from reading preemption with congressional intent as the focal point. Congress knows how to create statutory immunity from tort law when it is concerned about the welfare of an industry. *See e.g.*, Protection of Lawful Commerce in Arms Act, Pub. L. No. 109-92 (2005) (eliminating liability of gun manufacturers and sellers when guns are used in criminal or illegal activities to harm third persons). And for another, it rests entirely on empirical assumptions about consequential effects on industry investment decisions that are not well-documented. Indeed, Schuck rests his argument in this regard on a single citation to a newspaper article, Stephanie Saul, *Bristol-Myers to Eliminate 4,800 Jobs*, N.Y. TIMES Dec. 6, 2007, at C1, discussing the decline in approvals of new drug formulations between 2006-07. *See* Schuck, *supra* note 6 at 78 n.21. The Saul article makes no mention of tort liability as an explanation for job elimination. To the contrary, it references “[g]eneric competition, a dearth of new drugs and a more safety-conscious posture by the [FDA]” as factors explaining industry-wide layoffs. The article goes on to note that Bristol-Myers “is facing the same problem as many of the other drug-makers: the looming loss of patent protection for an important drug.” Saul, *supra*. For further skepticism about the empirical assumptions, see Michelle M. Mello & Troyen A. Brennan, *Legal Concerns and the Influenza Vaccine Shortage*, 294 JAMA 1817 (2005) (addressing the contraction of the vaccine suppliers’ market).

In the final analysis, one must discern congressional intent without clear guidance. But as I develop in the text, *infra*, the often-ignored compensation goal of tort, which has been prominent in the background when Congress has enacted regulatory legislation, provides a compelling basis for reading conflict preemption narrowly. *See* David A. Kessler & David C. Vladeck, *A Critical Examination of the FDA’s Efforts to Preempt Failure-to-Warn Claims*, 96 GEO. L.J. 461 (2008).

<sup>30</sup> In addition, Kessler and Vladeck emphasize the distinctive, searching nature of the tort discovery process even when compared to the new drug approval protocol: “The information-gathering tools lawyers have in litigation are, by any measure, more extensive than the FDA’s. Indeed, the FDCA does not give the FDA the most important tool trial lawyers have—the right to subpoena relevant information from any source.” Kessler & Vladeck, *supra* note 29, at 491. But of course, there is a trade-off between the regulatory process that brings disciplined expertise to its review process, incorporating risk/risk analysis, and the determination by a lay jury in an adversarial process focused on the particulars of a plaintiff’s injury.

These strong, federalism-grounded arguments for taking a cautionary approach to displacing tort have, at times, led the Supreme Court to refer to a “presumption against preemption.” For the most recent example, see the majority opinion in *Wyeth*, 129 S. Ct. 1187, 1195 n.3 (2009). But as Professor Sharkey has argued, the Court has shown no consistency in invoking the

On the other hand, it is similarly clear that Congress *can* preclude recourse to tort if it chooses to do so. Immunity from liability for accidental harm is not an unknown proposition, and in addition to the benefits from nationally uniform health and safety standards, there is the institutional competence argument for making regulatory standards determinative: in the recent context of *Riegel v. Medtronic*, that the FDA has far greater expertise than juries in deciding optimal design and warning standards for medical devices.<sup>31</sup>

If *Cipollone* is a good starting point in highlighting these cross-cutting considerations, a more focused exploration of the parameters of preemption requires discussion of the Supreme Court's subsequent efforts to forge a sensible pathway through the conflicting territorial claims of *federal regulatory agencies* and state tort law.

## II. BEYOND *CIPOLLONE*: THREE LEADING CASES

Nearly two decades have passed since the *Cipollone* venture into the domain of tort. In the ensuing years, the Supreme Court has had numerous occasions to demarcate the boundaries of preemption with greater precision.<sup>32</sup> Since every such effort has entailed a contextualized exercise in discerning Congressional intent, it is perhaps not surprising that commentators find little guidance in the Court's performance.<sup>33</sup> In my view, however, by focusing on a limited number of recent decisions, it is possible to point the way to a sensible working principle for resolving the tension between regulation and tort generated by preemption claims.

I begin with the Medical Devices Amendments to the Food, Drug and Cosmetic Act (MDA), which authorized FDA approval of new medical devices prior to marketing.<sup>34</sup> In establishing the regulatory regime, Congress enacted an express preemption provision that has provided the Supreme Court with two opportunities—roughly a decade apart—to weigh in on the preclusive effect of the statute on tort claims.<sup>35</sup>

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presumption. See Catherine M. Sharkey, *Products Liability Preemption: An Institutional Approach*, 76 GEO. WASH. L. REV. 449, 455-59 (2008). In my view, invoking the presumption (or ignoring it) is of no operational consequence.

<sup>31</sup> See *Riegel v. Medtronic, Inc.*, 128 S. Ct. 999 (2008); see also discussion of *Riegel v. Medtronic, Inc.*, *infra* notes 43-45 and accompanying text.

<sup>32</sup> See cases cited *supra* note 13.

<sup>33</sup> See, e.g., Sharkey, *supra* note 30, at 459-71 (“The Supreme Court’s preemption jurisprudence reflects an incoherent, and at times internally inconsistent, conception of the tort-regulation pas-à-deux. . . . The Court has oscillated between competing conceptions of tort as either primarily regulatory or compensatory, with the regulatory view justifying preemptive results and the compensatory view compelling the opposite.”).

<sup>34</sup> Medical Device Amendments of 1976, 21 U.S.C. § 360(e) (2006).

<sup>35</sup> The Medical Devices Act preemption provision, reads as follows:

[N]o State . . . may establish or continue in effect with respect to a device intended for human use any requirement—

In *Medtronic, Inc. v. Lohr*,<sup>36</sup> the Court interpreted the MDA in a fashion that left tort claims undisturbed.<sup>37</sup> Ruling to the contrary in *Riegel v. Medtronic, Inc.*,<sup>38</sup> the Court rejected a tort suit under the same preemption provision.<sup>39</sup> Despite these contrasting holdings, the *Lohr/Riegel* tandem offers a useful perspective on what should be the critical factor in determining conflict preemption, as I see it: *an analysis of whether the agency directive was grounded in the same evidence-based risk/benefit inquiry as the tort process would entail.*

In *Lohr*, the plaintiff's defective design claim was based on injury from the malfunctioning of a pacemaker inserted to correct a cardiac irregularity.<sup>40</sup> The FDA had approved the device under the "substantial equivalence" provisions of the Amendments, a fast-track system under which new devices that appeared to be substantially similar to medical devices already on the market could be certified without independent testing of the product.<sup>41</sup> There was, in other words, no evidence-based risk/benefit inquiry by the FDA, focused on the precise design of the defendant's pacemaker; hence, there was no basis for a claim that the tort suit would be going over the same ground as the regulatory process. As a consequence, a comparative institutional competence claim for displacing a tort suit seemed unwarranted.<sup>42</sup>

*Riegel* provides a counterpoint to *Lohr* that brings home the essential point. Plaintiff's design defect claim in *Riegel* was based on the rupturing of a balloon catheter, manufactured by defendant, during an angioplasty procedure.<sup>43</sup> The device had been cleared for marketing in the FDA's product-specific pre-market approval process, *not* via the fast-

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(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.

*Id.* at 360k(a).

<sup>36</sup> 518 U.S. 470 (1996).

<sup>37</sup> *Id.* at 503.

<sup>38</sup> 128 S. Ct. 999 (2008).

<sup>39</sup> *Id.* at 1006, 1011.

<sup>40</sup> *Lohr*, 518 U.S. at 480-81. In both *Lohr* and *Riegel*, the Court characterizes the claims as design defects, rather than manufacturing defects (that is, departures from the intended design). *Id.* at 483. See generally *Riegel*, 128 S. Ct. 999 (discussing design requirements to which medical devices are subjected in the approval process). See RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB., §§ 2(a), 2(b) (1998). There is general agreement that tort claims based on injuries from manufacturing defects, which are departures from the approved product, are not preempted.

<sup>41</sup> 21 U.S.C. § 360(c)(f)(1) (2006).

<sup>42</sup> But might not the "substantial equivalence" determination be grounded in full-scale premarket approval of the earlier product? This remote possibility that the new product tracks the old in all material particulars, and that nothing substantial has occurred in the risk universe in the intervening time, is further put to rest in U.S. GOVERNMENT ACCOUNTABILITY OFFICE, GAO-09-190, MEDICAL DEVICES: FDA SHOULD TAKE STEPS TO ENSURE THAT HIGH-RISK DEVICE TYPES ARE APPROVED THROUGH THE MOST STRINGENT PREMARKET REVIEW PROCESS (2009), a highly critical review of the "substantial equivalence" process. See also Gardiner Harris, *In F.D.A. Files, Claims of Rush to Approve Devices*, N.Y. TIMES, Jan 13, 2009, at A14.

<sup>43</sup> *Riegel*, 128 S. Ct. at 1005 (majority opinion).

track “substantial equivalence” process relied on in *Lohr*.<sup>44</sup> Contra to *Lohr*, the Court preempted state tort claims, emphasizing that “premarket approval is specific to individual devices,” and referring to the substantial equivalence process in *Lohr* as an exemption rather than full-scale safety review.<sup>45</sup>

A third leading case, *Geier v. American Honda Motor Co.*<sup>46</sup> offered a refinement that contributed to identifying the pathway for future territorial limitations on the tort domain. *Geier*, which involved interposition of a preemption defense under the National Traffic and Motor Vehicle Safety Act,<sup>47</sup> posed a not uncommon obstacle to conventional preemption analysis: the Act on its face appeared to equivocate on the displacement of state tort law (if not rejecting displacement entirely) by providing a “saving” clause—to the effect that “[c]ompliance with [a federal safety standard] does not exempt any person from any liability under common law.”<sup>48</sup> At the same time, the Act contained an express preemption provision for regulatory safety standards.<sup>49</sup>

Plaintiff sued in tort on a design defect theory, arguing that his injuries were enhanced by the absence of a driver’s side airbag; defendant responded by asserting a preemption defense based on a safety standard adopted by the DOT that allowed for the phasing in of air bags over time.<sup>50</sup> At trial, defendant introduced testimony on technical feasibility, cost considerations, and consumer acceptance concerns that led the agency to opt for a graduated approach to the mandating of air bags.<sup>51</sup>

But how was the Court to reconcile the seeming ambiguity created by both preemption and saving clauses appearing in the same

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<sup>44</sup> *Id.* at 1006.

<sup>45</sup> *Id.* at 1007. A caveat, however, will be relevant to my further discussion. Justice Scalia nowhere in the opinion mentions victim compensation as a complementary goal that Congress might also have in mind, along with risk-benefit considerations, in enacting regulatory legislation. Indeed, he refers to the possible reading of preemption as extending only to state regulatory activity, but not state tort law, as a “perverse distinction.” *Id.* at 1008. But the distinction is only perverse if one totally ignores the fact that state regulatory law offers nothing by way of compensation to accident victims, unlike tort law, which does double-duty in promoting both regulatory and compensation objectives. *See also infra* note 56.

<sup>46</sup> 529 U.S. 861 (2000).

<sup>47</sup> National Traffic and Motor Vehicle Safety Act of 1966, 80 Stat. 718, 15 U.S.C. § 1381 (1988).

<sup>48</sup> *Id.* § 1397(k).

<sup>49</sup> *Id.* § 1392(d) (“Whenever a Federal motor vehicle safety standard established under this subchapter is in effect, no State or political subdivision of a State shall have any authority either to establish, or to continue in effect, with respect to any motor vehicle or item of motor vehicle equipment any safety standard applicable to the same aspect of performance of such vehicle or item of equipment which is not identical to the Federal standard.”). Note that in this preemption clause, it is not a “requirement” that is equated with tort liability, but a “safety standard.” *Geier*, 529 U.S. at 871.

<sup>50</sup> *Geier*, 529 U.S. at 865; *see* Federal Motor Vehicle Safety Standard No. 208; Occupant Crash Protection, 49 C.F.R. § 571.208 (2003).

<sup>51</sup> *See Geier*, 529 U.S. at 877-78.

regulatory scheme? The Court's resolution was to read congressional intent as limiting the saving clause to regulatory directives adopted by the agency that set a floor on safety, rather than those grounded in risk/benefit balancing.<sup>52</sup> With reference to the air-bag regulation, the Court regarded no-air-bag tort claims as directly inconsistent with the optimality of a phased-in scheme of safety enhancement envisioned by the agency.<sup>53</sup>

What is perhaps most interesting, however, about the *Geier* opinion is that the saving clause compelled the Court to take cognizance of a broader set of systemic congressional purposes than one finds in the advocacy of categorical preemption proponents, as well as in later cases like *Riegel*, which focus exclusively on tort as a competing regulatory regime.<sup>54</sup> Contrary to this constrained reading of congressional intent, Justice Breyer remarked that:

[T]he saving clause reflects a congressional determination that occasional nonuniformity is a small price to pay for a system in which juries not only create, but also enforce, safety standards, *while simultaneously providing necessary compensation to victims*. That policy by itself disfavors pre-emption, at least some of the time. But we can find nothing in any natural reading of the two provisions that would favor one set of policies over the other where a jury-imposed safety standard actually conflicts with a federal safety standard.<sup>55</sup>

In my view, there is no reason to think that simply because a saving clause is not present in a regulatory scheme, Congress has necessarily turned a blind eye to this concern for tort as a mechanism of injury compensation—again that is, apart from the situation of “actual conflict” referred to by Justice Breyer.<sup>56</sup>

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<sup>52</sup> *Id.* at 868.

<sup>53</sup> *Id.* at 874. The Court makes reference to “frustration-of-purpos[e]” as a rationale for invoking preemption, *id.* (alteration in original), and this factor is sometimes treated as an independent trigger for the defense. But as I see it, frustration of purpose—in *Geier* and more generally—is simply one variant in expressing the prospect of directly competing risk/benefit analysis that is the crux of the test for satisfying conflict preemption.

<sup>54</sup> For advocacy of this categorical approach, see Epstein, *supra* note 23; Schuck, *supra* note 6.

<sup>55</sup> *Geier*, 529 U.S. at 871 (emphasis added). Justice Breyer's concession regarding congressional sensitivity to the compensation goal can plausibly raise the question of why a saving clause should not be taken as a legislative expression of intent to limit the preemption clause to conflicting state *regulatory* directives. It certainly can be argued that this is a more natural reconciliation of the preemption and saving clauses than that adopted by the Court, which resolved the facial conflict by relegating saved tort claims to regulatory directives meant to establish a floor on safety. Those latter directives would create no conflict with tort claims even without a saving clause.

<sup>56</sup> In response to the *Riegel* decision, Senator Edward Kennedy (D-MA) remarked, “Congress never intended that F.D.A. approval would give blanket immunity to manufacturers from liability for injuries caused by faulty devices,” and Representative Henry Waxman (D-CA) added, “The Supreme Court's decision strips consumers of the rights they've had for decades. . . . This isn't what Congress intended, and we'll pass legislation as quickly as possible to fix this nonsensical situation.” Linda Greenhouse, *Justices Shield Medical Devices From Lawsuits*, N.Y. TIMES, Feb. 21, 2008, at A1 (internal quotation marks omitted). These reactions are not conclusive, of course, on legislative intent, but surely Kennedy and Waxman, leaders in the enactment of the Medical Devices

If a saving clause coupled with a preemption provision poses one set of interpretive conundrums, what of a regulatory scheme that makes no explicit reference at all to tort through a preemption clause? Under some circumstances can a congressional intent to preempt be nonetheless implied? The following Part will address that question with special reference to the context of prescription drug regulation by the FDA.

### III. IMPLIED PREEMPTION: PRESCRIPTION DRUG REGULATION AND BEYOND

The Supreme Court faced its latest challenge in the preemption arena in *Wyeth v. Levine*,<sup>57</sup> involving the highly-contested question of preemption in the prescription drug area.<sup>58</sup> Critical to the inquiry is that new prescription drugs are certified for marketing by the FDA under a different statutory scheme than the Court reviewed in the *Lohr/Riegel* tandem involving new medical devices—and it is a statutory scheme that has no express preemption provision.<sup>59</sup> Thus, the case raised a question of implied preemption in an especially dynamic area of tort litigation.

In *Levine*, plaintiff's arm had to be partially amputated after gangrene set in following a botched injection of the anti-nausea drug, Phenergan, by a so-called "IV push" procedure (direct injection into a vein) that mistakenly missed the mark and mixed the drug with arterial blood. Plaintiff argued inadequate warning of the risk of amputation associated with the IV push method—the risk that in fact came to fruition. In response, defendant Wyeth pointed to the explicit language

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Amendments ("MDA"), are more privy to congressional deliberations on congressional aims than Justice Scalia, who concluded his armchair speculation with the comment that

it is implausible that the MDA was meant to "grant greater power (to set state standards 'different from, or in addition to' federal standards) to a single state jury than to state officials acting through state administrative or legislative lawmaking processes." That perverse distinction is not required or even suggested by the broad language Congress chose in the MDA, and we will not turn somersaults to create it.

*Riegel v. Medtronic, Inc.*, 128 S. Ct. 999, 1008 (2008) (quoting *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 504 (Breyer, J., concurring in part and concurring in the judgment)) (citation omitted).

That the MDA was intended to grant significant power to a jury is "implausible" only if one reads the desire to compensate victims, via tort liability, entirely out of the purview of Congress. While I support the Court's conclusion in *Riegel*, where the tort suit would revisit the regulatory approval process with no claim of changed circumstances, it is quite another matter to adopt the broader implausibility rationale.

<sup>57</sup> *Wyeth v. Levine*, 129 S. Ct. 1187 (2009).

<sup>58</sup> FDA regulation of prescription drugs is the focus of much of the recent scholarly commentary on preemption. See, e.g., Mary J. Davis, *The Battle Over Implied Preemption: Products Liability and the FDA*, 48 B.C. L. REV. 1089 (2007); Epstein, *supra* note 23; Margaret Gilhooly, *Addressing Potential Drug Risks: The Limits of Testing, Risk Signals, Preemption, and the Drug Reform Legislation*, 59 S.C. L. REV. 347 (2008); Kessler & Vladeck, *supra* note 29; Richard A. Nagareda, *FDA Preemption: When Tort Law Meets the Administrative State*, 1 J. TORT L., art. 4 (2006); Catherine M. Sharkey, *What Riegel Portends for FDA Preemption of State Law Products Liability Claims*, 102 NW. U. L. REV. 415 (2008); Schuck, *supra* note 6.

<sup>59</sup> Federal Food, Drug, and Cosmetic Act, 52 Stat. 1040, as amended, 21 U.S.C. § 301 (2006).

on the label that warned about the risk of amputation, and further noted that it had, in fact, sought to revise the warning to re-word the reference to the risk of amputation, and was instructed by the FDA to retain the existing warning.<sup>60</sup>

The Supreme Court, by a 6-3 margin, upheld the Vermont state court's damage award, premised on a rejection of the preemption defense. The majority opinion, however, does not treat the absence of an express preemption clause as determinative of the outcome. Instead, the majority places great emphasis on the FDA's "changes being effected" (CBE) regulation, which provides that a manufacturer can take the initiative to strengthen a product risk warning without prior agency approval when "safe use of the drug product" would warrant such action.<sup>61</sup> Despite evidence of "at least 20 incidents prior to [Levine's] injury in which a Phenergan injection resulted in gangrene and an amputation,"<sup>62</sup> Wyeth had not sought—nor had the FDA taken any action to preclude—a stronger warning.

Hence, in the majority's view, there was no direct conflict between plaintiff's tort claim and the agency's earlier, now possibly outdated, approval. Indeed, the majority opinion suggests a sharply restrictive test for establishing conflict preemption: "absent clear evidence that the FDA would not have approved a change in Phenergan's label, we will not conclude that it was impossible for Wyeth to comply with both federal and state requirements."<sup>63</sup> There is no hint here of the preemption determination resting on a distinction between express and implied congressional intent; instead, the dominant theme is consistent with the redundancy principle that, as I have expressed it, seems consonant with reconciling tort and regulatory functions.<sup>64</sup>

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<sup>60</sup> The warning on the label read in part:

Due to the close proximity of arteries and veins in the areas most commonly used for intravenous injection, extreme care should be exercised to avoid perivascular extravasation or inadvertent intra-arterial injection. Reports compatible with inadvertent intra-arterial injection of Phenergan Injection, usually in conjunction with other drugs intended for intravenous use, suggest that pain, severe chemical irritation, severe spasm of distal vessels, and resultant gangrene requiring amputation are likely under such circumstances. Intravenous injection was intended in all the cases reported but perivascular extravasation or arterial placement of the needle is now suspect. There is no proven successful management of this condition after it occurs. . . .

*Wyeth*, 129 S. Ct. at 1192 n.1. Wyeth's proposed revision was read by the Court as a formatting change rather than a heightened warning of risk. *See id.* at 1192 n.5.

<sup>61</sup> 21 C.F.R. §§ 314.70(c)(6)(iii)(A), (C) (2008).

<sup>62</sup> *Wyeth*, 129 S. Ct. at 1197.

<sup>63</sup> *Id.* at 1198.

<sup>64</sup> *See supra* text accompanying notes 39-40. An alternative pathway for determining that the regulatory directive reflects meaningful consideration of the risk/benefit analysis that would be undertaken in the tort claim is spelled out in the "agency reference model" proposed by Professor Sharkey, *supra* note 30; for more detailed discussion, see her follow-up article, Sharkey, *supra* note 58. As a prelude to determining the agency directive/tort preemption issue, Sharkey would require that:

Moreover, the “implied” preemption characterization of new drug approvals is not quite as straightforward as commentators suggest. In fact, the FDCA has an *express* saving clause that provides: “Nothing in the amendments . . . shall be construed as invalidating any provision of State law which would be valid in the absence of such amendments unless there is a direct and positive conflict between such amendments and such provisions of State law.”<sup>65</sup>

Whether one views this provision as a saving clause, or instead as a narrow preemption clause, depends on the spin that is put on “unless there is direct and positive conflict between such amendments and such provision of state law.”<sup>66</sup> Whichever characterization is adopted, the key correlative question is whether the “provision of state law” language is read, like “requirements” in earlier-discussed cases, as including state tort awards. Since the *Wyeth* majority found no direct conflict between the agency action on Phenergan and a failure to warn claim, there was no occasion to address this issue.

This narrow reading of conflict preemption, in turn, puts to rest the broader position taken by the FDA (and defendant in *Wyeth*) that agency approval of a new prescription drug categorically displaces later tort relief for an injury victim.<sup>67</sup> This is a salutary development. I see no

courts should look to agencies to supply the empirical data necessary to determine whether a uniform federal regulatory policy should exist—as agencies are in the best position to gather and evaluate data—and to make informed choices regarding the welfare of the American public.

Sharkey, *supra* note 30, at 452-53.

There is appeal to this judicial “hard-look” position and it certainly would be beneficial if agencies would follow Sharkey’s lead on their own initiative. But I have three reservations about the courts imposing the requirement as a judicial initiative as Sharkey proposes. First, there is no plausible reason to read this stipulation into congressional intent as an intrinsic feature of the preemption inquiry. Second, the inquiry seems in part to miss the mark. While it would make a great deal of sense to have the agencies submit findings to support their risk/benefit analysis because that goes directly to the issue of comparative institutional competence, which is the central determinant (and rationale) for conflict preemption, I fail to see what expertise the agency has to supply in predicting the value of uniformity, which is not an element of the agency protocol for regulatory approval. Finally, I am concerned that imposing this requirement on the agencies would be an invitation to *ex post* rationalization (i.e., building a paper record after the fact).

Having expressed these reservations, I would emphasize that Sharkey’s proposal is in part meant to focus the preemption inquiry precisely in the right direction, as I see it. *See* Sharkey, *supra* note 58, at 423 (“[W]hen it comes to making an implied conflict preemption determination, it is critical to discern whether the FDA has weighed in on the precise risk the state action likewise seeks to regulate.”).

<sup>65</sup> Drug Amendments of 1962, Pub. L. No. 87-781, § 202, 76 Stat. 780, 793 (1962).

<sup>66</sup> *Id.*

<sup>67</sup> During the Bush administration, the FDA, along with other regulatory agencies, took this position, venturing beyond contained conflict preemption in a series of regulatory preambles. *See generally* Catherine M. Sharkey, *Preemption by Preamble: Federal Agencies and the Federalization of Tort Law*, 56 DEPAUL L. REV. 227 (2007). The FDA preamble declares that: “FDA believes that under existing preemption principles, FDA approval of labeling under the act . . . preempts conflicting or contrary State law.” Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. 3922, at 3922 (Jan. 24, 2006). For discussion, particularly focused on the FDA, see Sharkey, *supra* note 30, at 504-05, 511-13. *See also* Kessler & Vladeck, *supra* note 29.

reason to think that Congress, in enacting regulatory schemes like the provision for premarketing review of new prescription drugs, entirely lost sight of tort as the sole medium for providing victim compensation when injury occurs after an agency certifies a new product for marketing. As a consequence, I would read conflict preemption narrowly, confining it, as previously indicated, to cases in which plaintiff's claim is based on agency action grounded in the same evidence-based risk/benefit inquiry as the tort process would entail.<sup>68</sup>

Under this narrowly-framed preemption defense, what are the principal types of tort claims that survive? Most importantly, claims should survive that are based on substantial new evidence of risk arising after a product design has been approved if the agency has failed to weigh in on the new findings in a determinate manner at the time of product use by the injury victim. I read the *Wyeth* majority opinion as consistent with this position: the majority appears to embrace the

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The *Wyeth* majority gave short shrift to the FDA preamble, which had been inserted into an agency rule without public notice-and-comment, referring to it as "an agency's mere assertion that state law is an obstacle to achieving its statutory objectives." *Wyeth*, 129 S. Ct. at 1201.

<sup>68</sup> Like Sugarman, *supra* note 29, Kessler and Vladeck argue that the compensation goal should in effect read preemption out of new drug approval cases:

[T]he moment the FDA approves a new drug is the one moment the agency is in the best position to be the exclusive arbiter of a drug's safety and effectiveness. On that day, the FDA has had access to and has devoted considerable resources to reviewing carefully all of the extant health and safety data relating to the drug. On that day, and that day only, we agree that the FDA's determinations about labeling ought not be subject to re-examination by courts or juries in failure-to-warn cases.

Kessler & Vladeck, *supra* note 29, at 465. They attach great weight to the 2007 Amendments to the FDCA, Pub. L. No. 110-85, 121 Stat. 823 (2007). Kessler & Vladeck, *supra* note 29, at 467-69. Those provisions give the FDA greater authority to monitor post-approval risks associated with a drug, and to require labeling changes and safety studies by manufacturers. *See id.* at nn.23-25 (citing provisions of the FDCA). At the same time, however, Kessler and Vladeck assert that the Amendments codify "existing requirements that obligate drug manufacturers to provide up-to-date safety information to physicians and patients and authorize manufacturers to do so without first securing the FDA's approval. The codification of this obligation undercuts the key pro-preemption argument the FDA and manufacturers make—namely, that the FDA alone decides the content of drug labels." *Id.* at 468-69, (discussing FDAAA tit. IX, § 901(a), 505(o)(4)(I), 121 Stat. 823, 925-26 (2007)).

Contrary to Kessler and Vladeck, Schuck reads the enhanced post-monitoring authority in the 2007 Amendments to support his case for categorical preemption of tort claims (apart from misrepresentations to the agency). *See* Schuck, *supra* note 6, at 83. It is a matter of whether one sees the glass as half-full or half-empty.

In contrast to both readings, I regard the Amendments as consistent with my position in the text. On the one hand, the manufacturer's obligation to propose labeling revisions in light of access to new risk information seems germane to allowing a tort claim only so long as the FDA has failed to act on the information. On the other hand, the FDA's bolstered authority to monitor and require labeling changes similarly generates a conflict situation only when the agency has taken post-approval action in view of the allegedly changed circumstances. Prior to the 2007 Amendments, post-approval monitoring by the agency was sharply criticized in Institute of Medicine of the National Academies, *The Future of Drug Safety: Promoting and Protecting the Health of the Public* (2007), available at <http://books.nap.edu/openbook/0309103035/gifmid/R1.gif>, and U.S. Government Accountability Office, *Drug Safety: Improvement Needed in FDA's Postmarket Decision-Making and Oversight Process* (2006), available at <http://www.gao.gov/new.items/d06402.pdf>.

proposition that new risk information, not addressed in determinative fashion by the agency, provides the foundation for a state tort claim.<sup>69</sup>

This category of surviving claims is a logical consequence of containing the comparative institutional competence argument for regulatory preemption within its own domain. If the tort claim rests on an assertion that substantial post-approval new evidence of risk has come to light, and has neither been incorporated into a revised warning, nor rejected by the agency as insubstantial, the foundational risk/benefit analysis on which agency certification was based is inapposite. Hence, the tort claim is not an effort to revisit and supersede the regulatory approval process.<sup>70</sup>

A second critical category of surviving claims should be those grounded in misrepresentations made to the agency in the certification or post-approval process. Once again, this limitation on the scope of preemption follows from a purposive analysis of congressional intent. The agency's certification process is not duplicated by a tort claim based on risk/benefit information that should have been provided to the agency but was not.<sup>71</sup> On this score, I subscribe to Peter Schuck's proposal that the "disclosure deficit," as he calls it, lifting the preemption bar, should not be limited to instances of fraud.<sup>72</sup> Like fraudulent misrepresentations to the agency, instances of innocent or negligent misrepresentation (including knowing failure to provide material data) undermine the foundation for preempting tort based on narrowly-conceived conflict grounds.<sup>73</sup>

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<sup>69</sup> See *Wyeth*, 129 S. Ct. 1187 at 1197. In fact, as I read the dissenting opinion, there is no disagreement on this proposition. Rather, the dissent contests that there was new risk information that compromised the adequacy of the existing label. See *Wyeth*, 129 S. Ct. at 1122-25 (Alito, J., dissenting).

In *Riegel*, Justice Ginsburg had noted, "The Court's holding does not reach an important issue outside the bounds of this case: the preemptive effect of § 360k(a) where evidence of a medical device's defect comes to light only *after* the device receives premarket approval." *Reigel v. Medtronic, Inc.*, 128 S. Ct. 999, 1013 n.1 (2008) (Ginsburg, J., dissenting).

Commentators who advocate broad, "categorical" preemption, as Schuck calls it, see Schuck, *supra* note 6, at 102, would make no allowance for new risk information emerging after regulatory approval. His view rejects victim compensation as a complementary consideration, characterizing tort exclusively as a contrasting regulatory regime, see *id.* at 78, 93, a characterization that in my view is indifferent to congressional intent as the foundation for preemption analysis. See also Epstein, *supra* note 23 (advocating blanket preemption for FDA drug approvals based on the comprehensive regulatory scheme established by Congress).

<sup>70</sup> This, of course, says nothing about the merits of the tort claim. At trial, a court might find the studies methodologically flawed or unpersuasive for any of a variety of reasons. Or the plaintiff might fail to establish a cause-in-fact relationship between her injury and the product.

<sup>71</sup> In this regard, it is critical to note that FDA certifications, like those of other health and safety regulatory agencies, are based on data supplied by the applicant. See Kessler & Vladeck, *supra* note 29, at 491.

<sup>72</sup> Schuck, *supra* note 6, at 102-05.

<sup>73</sup> I would also support a threshold requirement that the pleading be with particularity, as advocated by Schuck, *supra* note 6, at 105-07; see FED. R. CIV. P. 9(b).

Let me trace, in somewhat more detail, the contours of these two important categories of tort cases that should survive preemption defense claims grounded in purportedly superseding agency directives.

A. *New Evidence*

Two experienced participant/observers, one the former commissioner of the FDA, put the case for limiting the preclusive effect of agency directives in perspective:

At the time of approval, the FDA's knowledge-base may be close to perfect, but it is also highly limited because, at that point, the drug has been tested on a relatively small population of patients. Once the drug enters the marketplace, risks that are relatively rare, that manifest themselves only after an extended period of time, or that affect vulnerable subpopulations, begin to emerge. These are often not risks foreseen by the drug's manufacturer or the FDA and, for that reason, are not addressed on the label.<sup>74</sup>

Two recent, highly publicized controversies are illustrative of the post-approval issues raised by new evidence of risk that need to be resolved in aligning the domains of regulation and tort. Initially, I will discuss the scenario in the mass tort litigation arising out of claims that antidepressant drugs have triggered suicidal reactions.<sup>75</sup> Then, I will turn to the claims of cardiac disease stemming from ingestion of the anti-arthritis drug Vioxx.

*Colacicco v. Apotex, Inc.*,<sup>76</sup> involved two consolidated wrongful death claims by survivors of adults who committed suicide, allegedly as a consequence of taking antidepressants. Colacicco committed suicide after beginning a prescribed regimen of ingesting the antidepressant Paxil; DeAngelis, the other decedent, had ingested Zoloft in the days before his suicide. Both drugs belong to the class of antidepressants known as selective serotonin reuptake inhibitors (SSRIs), which have triggered major scientific controversy in recent years over whether they promote suicidal tendencies.<sup>77</sup>

Paxil bore a warning label deflecting any causal association: “[t]he possibility of a suicide attempt is inherent in major depressive disorder and may persist until significant remission occurs.”<sup>78</sup> Zoloft bore a similar warning label, deviating only in referring to “depression” rather

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<sup>74</sup> Kessler & Vladeck, *supra* note 29, at 466.

<sup>75</sup> For detailed discussion, see Nagareda, *supra* note 58, at 25-36.

<sup>76</sup> 521 F.3d 253 (3d Cir. 2008), *vacated and remanded*, No. 08-437, 2009 WL 578682 (U.S. Mar. 9, 2009).

<sup>77</sup> Related controversies involve causal effects in children and adolescents, although that was not an issue in *Colacicco*. For discussion of the scientific controversy, see Nagareda, *supra* note 58, at 26 n.106; Nicholas Bakalar, *Suicide Findings Question Link to Antidepressants*, N.Y. TIMES, July 10, 2007 at F7; U.S. Food and Drug Administration, *Antidepressant Use in Children, Adolescents, and Adults*, <http://www.fda.gov/cder/drug/antidepressants/default.htm> (last visited Feb. 13, 2009).

<sup>78</sup> *Colacicco*, 521 F.3d at 256.

than “major depressive disorder.”<sup>79</sup> The linch-pin for both the tort claims and the preemption defense was the fact that neither label indicated any causal relationship between ingestion of the drug and suicidal behavior.

In response to the plaintiffs’ claims of failure to adequately warn, the *Colacicco* majority opinion supported granting summary judgment in favor of defendants by documenting that for more than a decade before the suicidal incidents occurred, the FDA had consistently monitored the controversy about the relationship between SSRIs and adult suicide: denying citizen petitions for labeling change, extending the existing warning to new disorders, and relying on advisory committee recommendations.<sup>80</sup> The court concluded that there was an ongoing dialectic, in which the FDA had unwaveringly taken the position that the defendants’ warning labels were adequate.<sup>81</sup>

Most critically, in my view, to assessing the significance of this holding is the court’s insistence that conflict preemption determinations are case-specific, and its concomitant careful delineation of what was *not* being decided:

[W]e need not decide whether preemption would be appropriate under different facts—such as where the FDA had not rejected the substance of the warning sought or where the FDA only stated its position after a lawsuit had been initiated—or under the broader theories of preemption argued by the parties. Thus, we do not decide whether the FDA’s mere approval of drug labeling is sufficient to preempt state law claims alleging that the labeling failed to warn of a given danger, [or] whether FDA approval of drug labeling constitutes minimum standards in the absence of the FDA’s express rejection of a specific warning . . . .<sup>82</sup>

It is these factual scenarios, put aside for another day by the court, that are critical to defining in further detail the limits of conflict preemption. In my view, the court has in fact articulated precisely where the boundaries should be drawn, with each of the prospective scenarios falling outside the scope of preemption. If the FDA had not rejected the substance of the proposed warning, had only stated its position after the onset of the litigation, or had relied on its mere approval of the label, preemption would be unwarranted, as I see it, because the tort claim would be raising evidentiary issues on which the FDA had not taken a determinative position.<sup>83</sup>

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<sup>79</sup> *Id.* at 257.

<sup>80</sup> *Id.* at 269-70.

<sup>81</sup> *Id.* at 271.

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

<sup>83</sup> The *Colacicco* opinion, in fact, tips its hand on the “mere approval” question when it explicitly distinguishes “between the agency’s legal position in its amicus brief and its factual representations”:

The FDA’s summary of its scientific determinations must be distinguished from the agency’s construction of a statute, as the review of scientific information is strictly within its expertise. The FDA asserted facts [in this case] in support of its legal position, and we take notice of its statement of those facts, rather than its legal position.

By contrast, the Vioxx litigation is illuminating.<sup>84</sup> In the early 1990s, Merck began to develop plans for marketing Vioxx, a non-steroidal anti-inflammatory drug (NSAID), as research indicated that it suppressed the pain and inflammation of arthritis sufferers, without causing the side-effects of gastrointestinal perforations and bleeding often associated with the competing over-the-counter products already on the market.<sup>85</sup>

From the outset, Merck scientists expressed unease about possible adverse cardiac consequences of the product. But in September

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*Id.* at 270 n.15.

This question has been widely discussed in the context of the FDA preamble on preemption, see Sharkey, *supra* note 58, at 421-24, with the focal point being whether the agency's assertion of plenary power to preempt under the FDCA should be given *Chevron* deference or more limited *Skidmore* deference. See *Chevron U.S.A. Inc. v. Natural Res. Def. Council, Inc.*, 468 U.S. 837 (1984); *Skidmore v. Swift & Co.*, 323 U.S. 134 (1944). I see no reason why the agency's views on congressional intent should be afforded any weight at all; the FDA has no comparative expertise advantage over the judiciary when it comes to statutory construction. The *Wyeth* majority reached a similar conclusion. See *Wyeth v. Levine*, 129 S. Ct. 1187, 1200-01 (2009).

<sup>84</sup> For detailed discussion of the history of Vioxx development and regulation, see *McDarby v. Merck & Co.*, 949 A.2d 223 (NJ Super. Ct. App. Div. 2008); Alex Berenson, et al., *Despite Warnings, Drug Giant Took Long Path to Vioxx Recall*, N.Y. TIMES, Nov. 14, 2004, § 1. The following brief discussion of the Vioxx litigation is based on these sources.

<sup>85</sup> A good description of the perceived health benefits of Vioxx is offered in *In re Vioxx Products Liability Litigation*, 401 F. Supp. 2d 565, 570-71 (E.D. La. 2005):

Vioxx (known generically as rofecoxib) belongs to a general class of pain relievers known as non-steroidal anti-inflammatory drugs ("NSAIDs"). This class of drugs contains well-known medications sold either over the counter—such as Advil (ibuprofen) and Aleve (naproxen)—or by prescription—such as Daypro (oxaprozin) and Voltaren (diclofenac). NSAIDs work by inhibiting cyclooxygenase (COX), an enzyme that stimulates synthesis of prostaglandins, which are chemicals produced in the body that promote certain effects.

Traditional NSAIDs have been a longstanding treatment option for patients needing relief from chronic or acute inflammation and pain associated with osteoarthritis, [sic] rheumatoid arthritis, and other musculoskeletal conditions. This relief, however, comes with significant adverse side effects. Specifically, traditional NSAIDs greatly increase the risk of gastrointestinal perforations, ulcers, and bleeds ("PUBs"). This risk is increased when high doses are ingested, which is often necessary to remedy chronic or acute inflammation and pain. Scientists estimated that traditional NSAID-induced PUBs caused a significant number of deaths and hospitalizations each year in the United States.

In the early 1990s, scientists discovered that the COX enzyme had two forms—COX-1 and COX-2—each of which appeared to have several distinct functions. Scientists believed that COX-1 affected the synthesis or production of prostaglandins responsible for protection of the stomach lining, whereas COX-2 mediated the synthesis or production of prostaglandins responsible for pain and inflammation. This belief led scientists to hypothesize that "selective" NSAIDs designed to inhibit COX-2, but not COX-1, could offer the same pain relief as traditional NSAIDs with the reduced risk of fatal or debilitating PUBs. In addition, scientists believed that such drugs might be able to prove beneficial for the prevention or treatment of other conditions, such as Alzheimer's disease and certain cancers, where evidence suggested that inflammation may play a causative role.

*Id.*

1999, when the FDA approved Vioxx for marketing, there was no conclusive evidence in that regard. Soon thereafter, however, unsettling data emerged. In March, 2000, a Merck study of 8,000 rheumatoid arthritis sufferers, the Vigor study, compared the efficacy of Vioxx with that of a competing traditional NSAID product, Naproxen. Vioxx was found to be more efficacious than its competitor in reducing the gastrointestinal side-effects, but patients using it suffered five times as many heart attacks.

More studies followed and the concerns in the scientific community mounted, but Merck maintained that the data were inconclusive: with regard to the Vigor study, for example, Merck argued that it was the cardiac-protective characteristics of Naproxen rather than heightened risks of Vioxx that explained the disparity in cardiac events. In the end, however, Merck voluntarily pulled the product off the market when Approve, an ongoing 2004 trial of the efficacy of Vioxx in preventing colon polyps, indicated alarming rates of heart problems in Vioxx users.

During the four-year post-approval process, Merck reported its findings (and conclusions) to the FDA; independent scientists weighed in, often critically; and controversy raged within the agency itself. In particular, an in-house FDA scientist contended that his assessment of the Vioxx data, which indicated that Vioxx dramatically increased the risk of heart disease, was consistently suppressed by his superiors at the FDA. Most critically, however, throughout this period of agency monitoring, the FDA never arrived at a firm conclusion on cardiac risks associated with the product. The agency neither dismissed the growing evidence, nor on the other hand did it suggest that Merck change its label.<sup>86</sup>

As tort suits came to be filed in steadily growing numbers—exploding in volume after the product was removed from the market amidst great fanfare—the FDA remained agnostic in its stance on the cardiac risks posed by Vioxx.<sup>87</sup> And concomitantly, the preemption defense played no substantial role in stemming the tide of lawsuits.<sup>88</sup>

Nor should it have, in my view. Whether the scientific data, in fact, supported liability in tort has been hotly contested.<sup>89</sup> Legitimate questions exist as to whether there was *substantial* new evidence of risk post-approval, both on the threshold issue of generic risk, and in

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<sup>86</sup> See *supra* note 84.

<sup>87</sup> As of November 2004, 1000 plaintiff groups had filed 375 personal injury lawsuits against Merck, but after Vioxx's withdrawal from the market, attorneys expected a significant increase in filings. See Alex Berenson, et al., *supra* note 84.

<sup>88</sup> See, e.g., *McDarby v. Merck & Co.*, 949 A.2d 223, 251 (2008) (rejecting the defense).

<sup>89</sup> Of the 18 cases tried to judgment prior to the national settlement, Merck won 13 and plaintiffs won 5, although some judgments for plaintiffs were later reversed on appeal. See Samuel Issacharoff, *Private Claims, Aggregate Rights*, 2008 SUP. CT. REV. (forthcoming), available at [http://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=1289505#](http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1289505#).

individual tort suits brought by users with a spectrum of confounding cardiac risk factors, as well as a wide range of temporal dose-response circumstances. But these questions of risk analysis that might serve as barriers to reanalysis in tort were not issues on which the FDA had taken a stand. And consequently, the Vioxx litigation provides a nice counterpoint to the earlier-discussed SSRI tort suits, illuminating the boundaries of regulatory preemption by sharpening the definition of new evidence, and keeping the defense narrow in scope.<sup>90</sup>

### B. *Misrepresentations*

In *Altria Group, Inc. v. Good*,<sup>91</sup> the Supreme Court came full-circle back to its initial venture in marking the territorial restrictions on tort law, the preemption clause in the cigarette labeling act. Reaffirming its earlier plurality opinion in *Cipollone*, the Court held that a claim of fraud—based in *Altria* on advertising “light” cigarettes as delivering reduced tar and nicotine—was not preempted by the labeling act’s preclusion of “requirements” related to smoking and health beyond those expressly delineated in the statute.<sup>92</sup>

In a sharp dissent, Justice Thomas, writing for four members of the Court, twice noted the “theoretical [in]elegance” of carving out a divide between preempted claims of inadequate warning and non-preempted claims of fraud.<sup>93</sup> But the asserted inelegance of the distinction is entirely beside the point. There is no theoretical elegance to statutes such as the federal auto safety act, discussed earlier,<sup>94</sup> that requires tortured reconciliation of a preemption and saving clause, or the September 11th Victim Compensation Fund of 2001,<sup>95</sup> a benefits scheme combining internally contradictory tort-centric and social welfare provisions.<sup>96</sup> The interpretive task is to provide a defensible reading to congressional intent, not to evaluate theoretical elegance.<sup>97</sup>

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<sup>90</sup> See Alicia Mundy, *FDA May Revise Warning for Antismoking Drug*, WALL ST. J., Oct. 23, 2008, at D3 for discussion of road accidents associated with the antismoking drug Chantix, another recent example of tort litigation against the backdrop of regulatory inconclusiveness.

<sup>91</sup> 129 S. Ct. 538 (2008).

<sup>92</sup> *Id.* at 549.

<sup>93</sup> *Id.* at 553, 560 (Thomas, J., dissenting).

<sup>94</sup> See discussion of *Geier*, *supra* Part II.

<sup>95</sup> Pub. L. No. 107-42, § 401, 115 Stat. 237 (2001).

<sup>96</sup> For discussion of its main provisions, see Robert L. Rabin, *The Quest for Fairness in Compensating Victims of September 11*, 49 CLEV. ST. L. REV. 573, 576-77 (2001).

<sup>97</sup> Justice Thomas asserts in that regard that “[t]he text of the statute must control.” *Altria*, 129 S. Ct. at 558 (Thomas, J., dissenting). But that is an entirely illusory view; the foundational reading of “requirements” in *Cipollone* to include tort suits cannot be found from textual reading of the preemption clause. It is based on an interpretive gloss—and a highly contested one at the time. See *supra* text accompanying notes 20-22. Indeed, in my view, the generally accepted dichotomy between express and implied preemption is an oversimplification if it is taken to mean anything more than the difference between statutes that contain a preemption clause and those that do not. Defining the scope of an “express” preemption clause is always an interpretive matter (i.e., an exercise in implication).

In an important sense, the majority view in *Altria* provides a salient consideration in defining the scope of regulatory preemption provisions. The central thrust of *Altria* is to treat tort claims based on fraudulent misrepresentations as theoretically distinct from proscribed claims that would directly challenge the sufficiency of congressionally-determined upper limits on warning language.<sup>98</sup> Fraud is inherently an exercise in paying lip-service respect to the legislative labeling directives. Rather than challenging the adequacy of the required warning, the misrepresentation claim in *Altria* is premised on defendant creating a false sense of security that the legislative directive has been satisfied.<sup>99</sup>

Similarly, in the context of regulatory directives, there is no reason to conclude that Congress would anticipate sweeping exemption from tort liability where the claim of industry misconduct is based on a polluting of the agency process rather than a challenge to its substantive determinations. For this reason, I would read *Buckman* narrowly, containing its reach to stand-alone fraud on the agency claims, as in the case itself—where the Court concluded that a private right of action would be inconsistent with the FDA’s self-policing authority.<sup>100</sup>

#### IV. CONCLUDING THOUGHTS

In the preceding section, the focal point of my discussion was predominantly the intersection of FDA regulation and the tort system. It is a natural tack to pursue, both because it is highly topical (and much-discussed by the commentators) at this point in time and due to the FDA’s intrinsic importance as a singularly comprehensive regulatory

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In his *Wyeth* concurrence, Justice Thomas agrees with the holding that plaintiff’s tort claim is not preempted “[b]ecause implied preemption doctrines . . . wander far from the statutory text [and hence] are inconsistent with the Constitution.” *Wyeth v. Levine*, 129 S. Ct. 1187, 1205 (2009) (Thomas, J., concurring).

<sup>98</sup> *Altria*, 129 S. Ct. at 551 (majority opinion).

<sup>99</sup> Fraud claims are to preempted inadequate warning claims somewhat as manufacturing defect claims are to design defect claims: they are deviations from the legislative or regulatory norm rather than challenges to its adequacy.

<sup>100</sup> See *Buckman v. Plaintiffs’ Legal Comm.*, 531 U.S. 341, 344 (2001) (consultant to a manufacturer of orthopedic bone screws was alleged to have supplied false information to the FDA in the product approval process). For detailed discussion of the issue, see Catherine M. Sharkey, *The Fraud Caveat to Agency Preemption*, 102 NW. U. L. REV. 841 (2008). Sharkey would impose a primary jurisdiction-type requirement as a prelude to a private tort suit: “Once the FDA has made a finding of such fraud . . . private litigants should be able to wield such findings offensively to pursue damages against manufacturers in their state law tort litigation and, where necessary, to disarm regulatory immunity or preemption.” *Id.* at 844.

I would not impose any such restriction on state tort law. If the FDA has, in fact, exercised “primary jurisdiction” then I would, as a matter of course, concur that a tort suit can make use of the agency finding. But I would also allow a tort suit on grounds of fraud (or other material misrepresentation) where the agency has made no such finding. Where the agency approval is materially based on false information, a tort suit is not in conflict with the agency finding under my constrained definition of conflict; that is, the agency directive was not grounded in the same evidence-based risk/benefit inquiry as the tort claim because the evidence before the agency was polluted. It follows, of course, that if the FDA has investigated and *rejected* the fraud or misrepresentation allegations, then it would be appropriate to preempt the tort claim.

authority that nonetheless cannot possibly achieve perfection in preventing unanticipated injuries.

But my intent in this Article has been to be more all-encompassing. In the course of my discussion, I have alluded to a wide array of regulatory schemes that generate a broad spectrum of agency directives creating tensions with accident law—tensions that have crystallized into preemption claims with increasing frequency in recent years. Whatever the political leaning of the executive branch, there is no reason to think that sharply disparate views on the appropriate scope of preemption claims will disappear from the policy arena. In proposing a framework for addressing these tensions, based on focused examination of whether the agency directive is grounded in the same evidence-based risk/benefit inquiry as the tort process would entail, I join those commentators who seek to forge a path that recognizes the distinct benefits that both regulation and tort have to offer.