



### **Catherine Sharkey**

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## VACCINES AND DRUGS: A BRAVE NEW TORT WORLD

Catherine M. Sharkey\*

The proliferation of vaccine and pharmaceutical drug-related injuries challenges our conception of how the tort system can best meet its compensatory and regulatory aims in the twenty-first century. In 1986, Congress created the National Childhood Vaccine Injury Act of 1986, establishing a no-fault compensation scheme for vaccine-related injuries.<sup>1</sup> In 2011, the U.S. Supreme Court ruled in *Bruesewitz v. Wyeth* that design defect claims against vaccine manufacturers were preempted.<sup>2</sup> This follows closely on the heels of the Court's decision in *Wyeth v. Levine*, finding that failure to warn claims against a drug manufacturer were not preempted.<sup>3</sup>

The symposium contributors—who include two prominent tort and product liability scholars (Mary Davis and Robert Rabin), a policy expert (James Copland), and a seasoned litigator (Malcolm Wheeler)—explore whether it makes sense to have separate legal regimes for vaccines and other pharmaceuticals. They also address issues at the core of tort law in the modern administrative state: the need for no-fault victim compensation and the respective roles of litigation and governmental regulation.

Robert Rabin's remarks, *The Vaccine No-Fault Act: An Overview*, set the scene by outlining the structure of the Vaccine Injury Compensation Program.<sup>4</sup> Established in 1988, the vaccine no-fault fund provides an alternative to tort litigation related to childhood vaccine exposure. Professor Rabin details the stress put on the program by the recent Omnibus Autism Proceeding, which brings to light the proclivity of the administrative scheme to reject awards based on scientific findings.<sup>5</sup> But his overall assessment of the Vaccine Program is tantamount to a positive endorsement for the “expertise model” it embodies, with its reliance on low visibility decision-making, by expert special masters, insulated from various political pressures.

James Copland's essay, *Administrative Compensation for Pharmaceutical- and Vaccine-Related Injuries*, builds on his previous work examining whether and how the Vaccine Injury Compensation Program can serve as a template for a federal administrative regime that marries broader compensa-

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1. National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3756 (codified as amended at 42 U.S.C. § 300aa-1 to -34 (2000)).

2. *Bruesewitz v. Wyeth, LLC*, 131 S. Ct. 1068 (2011).

3. *Wyeth v. Levine*, 555 U.S. 555 (2009).

4. Robert L. Rabin, *Vaccine No-Fault Act: An Overview*, *infra* p. 267.

5. *Id.* at 272-73.

tion with field preemption of tort law claims.<sup>6</sup> Mr. Copland is a tort skeptic; moreover, he is critical of the stringent ex ante Food and Drug Administration (“FDA”) regulatory regime. He argues that the FDA is more likely to commit “Type II” (denying entry to drugs that would prove to have enormous benefits) versus “Type I” (allowing drugs onto the market that cause harms) error.<sup>7</sup> Indeed, according to Mr. Copland, the federal regulatory system, as implemented by the FDA, costs far more lives by delaying and denying new drug entry, and increasing the costs of drug development than it saves by preventing drugs with unknown, harmful side effects from entering the market.<sup>8</sup> Moreover, Mr. Copland argues that the peculiar economic characteristics of the vaccine market—most notably, its supply-side sensitivity to tort litigation—make vaccines a prime candidate for an administrative compensation scheme in lieu of tort.<sup>9</sup>

With her essay, *The Case Against Preemption: Vaccines & Uncertainty*, Mary Davis champions the significance of a continuing role for tort litigation alongside federal regulation of products generally, and vaccines more specifically.<sup>10</sup> Professor Davis outlines some broad trends in U.S. Supreme Court preemption jurisprudence, such as the growing influence of federal agencies and the waning influence of the presumption against preemption.<sup>11</sup> She laments the (perhaps temporary) passing of the presumption, which, to her mind, should operate to preserve longstanding traditional tort laws of responsibility. She adeptly showcases *Bruesewitz* as involving “hyper-textual analysis which does not refer to the presumption against preemption, or to other elements of preemption doctrine for that matter.”<sup>12</sup> Professor Davis closes with a cautionary note that the procedural drawbacks of the administrative compensation program relative to tort litigation must be scrutinized “to defend its effectiveness in carrying out its mandate to

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6. James R. Copland, *Administrative Compensation for Pharmaceutical- and Vaccine-Related Injuries*, *infra* p. 275. See James R. Copland & Paul Howard, Manhattan Institute for Policy Research, *IN THE WAKE OF WYETH V. LEVINE: MAKING THE CASE FOR FDA PREEMPTION AND ADMINISTRATIVE COMPENSATION* (Mar. 2009), available at <http://www.manhattan-institute.org/pdf/fda01.pdf>.

7. Copland, *supra* note 6, at 279-81.

8. *Id.* at 281 (citing Tomas J. Philipson et al., *How Safe is Too Safe?*, 2 MILKEN REV. 38, 44 (2006) (presenting evidence from empirical study comparing drug applications before and after adoption of accelerated review procedure under Prescription Drug User Fee Act (“PDUFA”), finding that the cost of avoidable deaths for drugs approved under the accelerated process and later withdrawn was 56,000 life-years, compared with 180,000-300,000 life-years saved by drugs approved under the accelerated process)).

9. Copland, *supra* note 6, at 285-287.

10. Mary J. Davis, *The Case Against Preemption: Vaccines & Uncertainty*, *infra* p. 291.

11. *Id.* at 296-303. For an in-depth treatment of the role of federal agencies in the Court’s preemption jurisprudence, see Catherine M. Sharkey, *Products Liability Preemption: An Institutional Approach*, 76 GEO. WASH. L. REV. 449, 471-77 (2008).

12. Davis, *supra* note 10, at 307.

compensate and increase vaccine safety.”<sup>13</sup>

In his remarks, *The Case For Preemption: Why the U.S. Supreme Court and the Administration are Wrong to Curtail Implied Conflict Preemption*, Malcolm Wheeler seeks not only to defend preemption on normative grounds, but also to illustrate how the U.S. Supreme Court’s hand in shaping preemption law is guided by the parties’ legal strategy.<sup>14</sup> Mr. Wheeler compares and contrasts the litigation strategies leading up to the Supreme Court cases in *Geier v. American Honda Motor Co.*<sup>15</sup> (which he litigated and argued) and *Wyeth v. Levine*<sup>16</sup> (which edged out a case Mr. Wheeler was poised to take to the Court).<sup>17</sup> Mr. Wheeler tells the tale from the battlefield, where the strategic decisions regarding where to litigate cases<sup>18</sup> and how to select an appropriate case for Supreme Court review are critical to the development of doctrine in evolving areas of the law. His story invites us to consider the contingency of the Supreme Court’s preemption jurisprudence: might the Court have ruled differently in *Levine* had Mr. Wheeler’s case involving SSRI anti-depressants reached the Court first? In particular, would the Court have been receptive to the argument that, in the SSRI context, the manufacturer should not be held responsible for failing to add warnings that had been considered and rejected by the FDA (not to mention determined to have done more harm than good by the medical-scientific community)?

Taken as a whole, the symposium issue’s focus on the no-fault vaccine fund and preemption disputes in the pharmaceutical and vaccine contexts invites renewed reflection on the perennial health and safety debate that pits the decentralized tort system against a central administrative system. The participants represent a diversity of viewpoints. Professor Rabin takes an evenhanded approach, painting a picture of a compensatory and regulatory framework for vaccines that combines a no-fault administrative fund with some resort to tort law. Professor Davis urges more emphatically that tort litigation is needed for vaccine injuries as a “longstanding complement to more formal regulatory action for responding to uncertainty in risk information.”<sup>19</sup> Mr. Copland argues, quite to the contrary, that, far

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13. *Id.* 315 (citing Brief of Marguerite Willner in Support of Petitioners at 3, *Bruesewitz v. Wyeth*, 131 S. Ct. 1068 (2011) (discussing procedural limitations in Vaccine Court, which does not authorize discovery as of right)).

14. Malcolm E. Wheeler, *The Case For Preemption: Why the U.S. Supreme Court and the Administration are Wrong to Curtail Implied Conflict Preemption*, *infra* p. 317.

15. *Geier v. Am. Honda Motor Co.*, 529 U.S. 861 (2000).

16. *Wyeth v. Levine*, 555 U.S. 555 (2009).

17. Wheeler, *supra* note 14, at 326-28.

18. Compare, in this regard, the anecdote included in Mr. Copland’s essay regarding the propensity for plaintiffs’ attorneys to engage in “forum shopping” to find favorable jurisdictions in terms of known partisan judges and jury pools. Copland, *supra* note 6, at 282-83. As Mr. Wheeler reminds, defense attorneys are well advised to consider forum when deciding the attractiveness of raising novel defenses.

19. Davis, *supra* note 10, at 316.

from serving as a useful complement to the FDA's regulatory scheme, the extra layer of review provided by the tort system generates a net social welfare loss, by further delaying introduction of beneficial drugs to the market and pricing consumers (and manufacturers) out of the market.<sup>20</sup> Mr. Wheeler bolsters his anti-tort argument with an example where, he argues, tort liability (i.e., a finding of no preemption of tort claims where the FDA had approved an antidepressant drug) led to adverse safety consequences, namely, increases in suicides due to decreases in use of antidepressants.<sup>21</sup>

Finally, the diversity of backgrounds of the participants, from tort and product liability scholars to a policy expert and seasoned litigator, offers rich and varied perspectives on the evolution and future direction of the U.S. Supreme Court's preemption jurisprudence. Professor Davis sees reason for pessimism on the express preemption front, where, as in *Bruesewitz*, the Court appears to be taking a statute-by-statute approach to preemption, guided by hyper-textual analysis, uninformed by background principles of tort and compensation. But Professor Davis is relatively optimistic about the trajectory for implied preemption, arguing that "the Court seems to have settled into a more balanced approach" that values state common-law tort actions.<sup>22</sup> Mr. Copland, by contrast, applauds the *Bruesewitz* outcome and would, ideally, extend its concept of the "quid pro quo" of preempting tort claims in exchange for the provision of no-fault compensation beyond vaccines to include other pharmaceuticals.<sup>23</sup> Mr. Wheeler disagrees sharply with Professor Davis about the merits of the Court's recent constriction of the implied conflict preemption defense, seeing it more cynically as the fruit of a long-wagered campaign, led by Justice John Paul Stevens, to undo the outcome of *Geier*, the Court's seminal implied conflict preemption decision.<sup>24</sup>

This symposium issue does not aspire to reach consensus among the participants, nor deem any contributor the ultimate victor. Instead, it aims to provoke and to challenge pre-existing conceptions of how the tort and

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20. Copland, *supra* note 6, at 280 (citing Tomas J. Philipson & Eric Sun, *Is the Food and Drug Administration Safe and Effective?*, 22 J. ECON. PERSPECTIVES 85 (2008) (presenting evidence that litigation floods in the 1980s for the polio and DPT vaccines raised prices sevenfold and fortyfold, respectively)).

21. Wheeler, *supra* note 14, at 328 (citing R.D. Gibbons et al., *Early Evidence on the Effects of Regulators' Suicidality Warnings on SSRI Prescriptions and Suicide in Children and Adolescents*, 164 AM. J. PSYCHIATRY 1356 (2007) (finding an inverse relationship between the twenty-two percent decrease in SSRI prescriptions in the United States and the Netherlands following FDA's directive for manufacturers to add suicidality warnings and a fourteen percent and forty-nine percent increase in youth suicide rates in the United States and the Netherlands, respectively)).

22. Davis, *supra* note 10, at 306 (noting with approval the Court's decision in *Wyeth v. Levine*, where the Court wielded the presumption against preemption to uphold state tort law claims).

23. Copland, *supra* note 6, at 289-90. See also Copland & Howard, *supra* note 6.

24. Wheeler, *supra* note 14, at 330.

administrative systems should interact in the “brave new tort world” of vaccines and drugs.

