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# AGAINST CATEGORICAL PREEMPTION: VACCINES AND THE COMPENSATION PIECE OF THE PREEMPTION PUZZLE

*Catherine M. Sharkey\**

## INTRODUCTION

Preemption is the doctrine whereby federal law displaces state law. Preemption doctrine is divided into express preemption, which occurs when Congress includes an explicit preemption provision in a statute, and implied preemption, when there is no such express provision but preemption may nonetheless be inferred from the statutory and regulatory scheme. Implied preemption is further divided into field preemption, when federal law so dominates an area such that there is no room left for state law to operate, and conflict preemption, a narrower form of preemption that occurs when federal law displaces only that state law with which it is at odds or in tension. The degree of conflict spawns further doctrinal categories: impossibility preemption, when an actor could not follow the dictates of state law while complying with federal law, and obstacle preemption, when the state law obstructs or frustrates the purposes of the federal statutory or regulatory scheme.

While these neat doctrinal categories provide a semblance of order, they offer little in terms of a coherent analytical framework for the resolution of preemption disputes. The line separating express and implied preemption, for example, is not so distinct. Even when Congress includes an express preemption provision in a statute, the scope of intended preemption is often ambiguous and textual analysis comes up short; courts then resort to some of the same inferential analyses that unfold under implied preemption.<sup>1</sup> Nor does the existence of an

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1. Conversely, implied impossibility preemption can resemble express preemption analysis. Consider, for example, the U.S. Supreme Court's analysis in *PLIVA, Inc. v. Mensing*, 131 S. Ct.

express preemption provision (or an express savings provision) preclude courts from applying implied preemption principles; in other words, cases involving statutory preemption provisions are often both express and implied preemption cases.

For this reason, when textual analysis fails (or comes up short), a basic framework centered on legal and functional considerations that transcend these doctrinal categories is needed. In tort preemption cases (my focus in this Article), when federal law ousts conflicting state tort law, two fundamental functional premises should hold true: (1) the federal standard of care is more than a minimal standard and (2) the state standard of tort liability has a significant regulatory effect (if not the regulatory purpose) by trading off risks and benefits to inhibit or to encourage risk-taking conduct that interferes with, or substantially alters, a federal regulatory scheme. The regulatory role of state tort law is front and center in this paradigm of preemption.

But what about the compensatory role of tort law? Should there, in fact, be a third premise that the federal regulatory regime must provide a substitute to injured victims for tort-based compensation? Or perhaps a weaker version, such that the absence of federally provided compensation is a thumb on the scale against preemption? Conversely, should the existence of such a federal compensation scheme weigh in favor of preemption?

In the products liability realm, when Congress enacts statutes and federal agencies implement them with regulations, full attention is devoted to the standard-setting or regulatory side of the equation; compensation is typically not addressed.<sup>2</sup> The National Childhood Vaccine Injury Act (Vaccine Act) is a notable exception—it is the rare example whereby Congress provides for a federally administered compensation fund alongside its newly fashioned regulatory stan-

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2567 (2011), the generic-drug preemption case. Justice Thomas, writing for the majority, focused narrowly on the text of the relevant federal regulations (as interpreted by the FDA) and held that it was impossible for generic-drug manufacturers to satisfy the state common law duty to provide additional warnings, consistent with the federal “sameness” dictate that prohibits generic-drug labels from deviating from their brand name counterparts. The Court resolved the case solely on implied *impossibility* preemption and thus did not consider the wider obstacle (or frustration of purposes) preemption. *See id.* at 2581 n.7 (“[T]hat type of pre-emption [obstacle] is not argued here.”). In that regard, the Court’s analysis shares more affinities with express preemption cases—in which the Court’s task is to interpret the language of the explicit preemption provision—than implied obstacle preemption cases that require resort to extra-textual sources, chief among them the agency’s stated objectives, regulatory record, and views on preemption.

2. Some prominent examples include the Motor Vehicle Safety Act, 49 U.S.C. § 30101 (2006), the Recreational Boat Safety Act, 43 U.S.C. § 4301 (2006), and the Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. § 301 (2006).

dards.<sup>3</sup> The vaccine context thus provides an opportunity to explore the relationship between preemption and compensation.

Who better to inspire such ruminations than Robert Rabin? Professor Rabin's own academic career traversed from administrative law into torts. His grounding in both fields is reflected in his equanimous approach to federal preemption, whereby he "join[s] those commentators who seek to forge a path that recognizes the distinct benefits that both regulation and tort have to offer."<sup>4</sup> Professor Rabin has also written extensively on compensation systems, placing the Vaccine Compensation Fund into context as arising out of "a crisis atmosphere" in which "the individual rights perspective of tort yielded to a collective, insurance-based model of compensation."<sup>5</sup>

Justice Antonin Scalia, writing for the majority of the U.S. Supreme Court in *Bruesewitz v. Wyeth*, a vaccine preemption case heard in the October 2010 Term and decided February 22, 2011, provocatively characterized the symbiotic relationship as a "*quid pro quo*": "The vaccine manufacturers fund from their sales an informal, efficient compensation program for vaccine injuries; in exchange they avoid costly tort litigation and the occasional disproportionate jury verdict."<sup>6</sup> But these are Justice Scalia's words, not Congress's. Congress was in fact much more cryptic about any link between the federally provided compensation and state tort law remedies.

*Bruesewitz* illustrates a more general conundrum: when statutory text is ambiguous, precisely where should courts turn to elucidate congressional intent? "[T]he purpose of Congress is," according to the Supreme Court, "the ultimate touchstone in every pre-emption case."<sup>7</sup> *Bruesewitz* follows a long line of cases whereby the Court interjects policy-laden principles cloaked in an analysis of congressional intent. While in previous cases such policy-laden principles have centered upon institutional comparisons of juries versus agencies as decision

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3. The Vaccine Compensation Fund joins a handful of specialty administrative compensation schemes put forth by Congress. See, e.g., Federal Coal Mine Health and Safety Act of 1969, Pub. L. No. 91-173, 83 Stat. 742 (codified as amended at 30 U.S.C. § 801); September 11th Victim Compensation Fund of 2001, Pub. L. No. 107-42, §§ 401-409, 115 Stat. 237, 237-41 (codified as amended at 49 U.S.C. § 40101).

4. Robert L. Rabin, *Territorial Claims in the Domain of Accidental Harm: Conflicting Conceptions of Tort Preemption*, 74 BROOK. L. REV. 987, 1009 (2009) [hereinafter Rabin, *Territorial Claims*].

5. Robert L. Rabin, *The Renaissance of Accident Law Plans Revisited*, 64 MD. L. REV. 699, 708 (2005).

6. *Bruesewitz v. Wyeth LLC*, 131 S. Ct. 1068, 1080 (2011) (footnote omitted).

7. *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996) (internal quotation marks omitted); accord *Wyeth v. Levine*, 555 U.S. 555, 565 (2009).

makers, in *Bruesewitz* the existence of the federally provided compensation scheme is front and center.

In this Article, I provide some alternative frames for analysis. Frame One is conventional statutory interpretation focused on statutory text and legislative history. Although it is an express preemption case (Congress included a preemption provision in the relevant statute), *Bruesewitz* cannot be resolved using statutory text alone, the protestations of the majority notwithstanding.

Whereas the Court turns to *sub rosa* policy analysis at this juncture, I would turn to Frame Two: consideration of the backdrop of tort lawsuits at the time when Congress acted and, relatedly, whether Congress provided a substitute administrative compensation scheme for tort law remedies. This frame is key to resolving disputes that amount to implied *field* preemption—namely, a *categorical* preemption claim that federal law ousts state law regardless of the precise risks considered by the underlying federal regulatory agency. For example, under this definition, the contention that all design-defect claims are preempted by the Vaccine Act is a categorical preemption claim because it does not depend on the regulating federal agencies—such as the Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC)—having considered the specific risks of a particular vaccine, or class of vaccines, in the premarket approval and postmarket ongoing monitoring processes. The absence of a federally provided compensation scheme in an area in which Congress legislates against a backdrop of tort lawsuits should preclude an assertion of a categorical preemption claim. Arguments for field preemption (the doctrinal stand-in for categorical preemption claims) depend on the comprehensiveness of the regulatory scheme. My argument here is that the absence of compensation—particularly against a backdrop in which, prior to enactment of the federal scheme, tort law effectuated both regulatory and compensatory goals—renders the regulatory scheme incomplete. Conversely, the existence of a federal compensation scheme keeps categorical preemption claims on the table.

But the analysis should not end with Frame Two. Even if a categorical preemption argument fails because of the absence of a federal compensation fund, a narrower form of risk-based implied *conflict* preemption—in which the underlying regulatory agency has considered the risks and benefits at issue and resolved them in a way that is at odds or in tension with imposition of the asserted state-law duty—may be justified. And even where a categorical preemption argument is plausible, given the existence of a federal compensatory regime,

there may nonetheless be a stronger underlying risk-based argument worth considering. Here is where Frame Three comes into play.

Frame Three encapsulates the “agency reference model” I have developed in prior work,<sup>8</sup> whose prime target is conflict preemption. The primary question in conflict preemption cases involving ambiguous congressional intent should be whether the federal agency considered the same risks and benefits that are the source of the competing state standard. Substantial deference should also be accorded to the underlying agency’s position on preemption, based on the thoroughness and consistency of its considered views. *Bruesewitz* warrants preemption under this standard, but its holding would be limited to vaccines for diphtheria, tetanus, and pertussis (DTP), the class whose safety profile was investigated by the FDA and CDC, and reviewed by the courts. Moreover, the fact-intensive review of the regulatory record called for under this model is likely to better safeguard health and safety, and accordingly, Frame Three should be preferred to categorical preemption (if permitted under Frame Two) when congressional intent is ambiguous.

## II. FRAME ONE: STATUTORY TEXT AND LEGISLATIVE HISTORY

On its surface, *Bruesewitz* presented a statutory interpretation question, plain and simple, centered on the meaning of the express preemption provision Congress enacted as part of the Vaccine Act:

No vaccine manufacturer shall be liable in a civil action for damages arising from a vaccine-related injury or death associated with the administration of a vaccine . . . if the injury or death resulted from side effects that were unavoidable even though the vaccine was properly prepared and was accompanied by proper directions and warnings.<sup>9</sup>

The *Bruesewitzes* contended that this language required a court’s case-by-case determination of whether a vaccine’s side effects were “unavoidable” in order to sustain a preemption finding.<sup>10</sup> In the *Bruesewitzes*’ view, their daughter Hannah’s predicament following a

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8. See Catherine M. Sharkey, *Federalism Accountability: “Agency-Forcing” Measures*, 58 DUKE L.J. 2125, 2148–49 & n.89 (2009) [hereinafter Sharkey, *Federalism Accountability*]. See generally Catherine M. Sharkey, *Products Liability Preemption: An Institutional Approach*, 76 GEO. WASH. L. REV. 449 (2008) [hereinafter Sharkey, *Products Liability Preemption*].

9. 42 U.S.C. § 300aa-22(b)(1) (2006).

10. Brief for Petitioners at 41, *Bruesewitz*, 131 S. Ct. 1068 (2011) (No. 09-152), 2010 WL 2130598 (“[T]he best reading of § 22(b) . . . is that a vaccine manufacturer is exempt from civil liability only upon a case-specific showing that the vaccine’s side effects were unavoidable, and, even then, only if the vaccine was properly prepared and accompanied by proper directions and warnings.”).

vaccine injection—a month-long series of violent seizures that led to permanent brain damage and developmental delays—was entirely avoidable given a known, safer alternative vaccine design, and thus, their state law design-defect claim should go forward.<sup>11</sup> Hannah, a seemingly healthy infant, suffered violent seizures following her injection with Tri-Immunol, a “whole cell” DTP vaccine manufactured by Wyeth.<sup>12</sup> Her seizures began in April 1992, after she took the third of five recommended doses of Tri-Immunol.<sup>13</sup> Hannah’s dose came from a particularly troublesome lot, which “generated sixty-five reports of adverse reactions with the FDA and [CDC], including thirty-nine emergency room visits, six hospitalizations, and two deaths.”<sup>14</sup> The U.S. Court of Appeals for the Third Circuit found that Hanna would likely require permanent medical care for the rest of her life.<sup>15</sup> The Bruesewitzes claimed that Tri-Immunol was defective and that Wyeth had, at the relevant time, an approved license for Tri-Solgen, an alternative, safer “non-cellular” DTP vaccine.<sup>16</sup>

Wyeth raised a preemption defense to the Bruesewitzes’ design-defect claim. In Wyeth’s view, the Vaccine Act’s preemption provision categorically preempted liability for design defects, while leaving intact liability for manufacturing defects and failure to warn.<sup>17</sup>

Neither party’s interpretation of the statutory text is entirely satisfying. The Bruesewitzes’ interpretation elevated the import of one statutory phrase—“if the injury or death resulted from side effects that were unavoidable”—at the expense of the subsequent phrase (which it rendered superfluous)—“even though the vaccine was properly prepared and was accompanied by proper directions and warnings.”<sup>18</sup> And Wyeth’s interpretation committed the same sin in reverse.

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11. *Id.* at 22.

12. “Whole cell” vaccines such as Tri-Immunol were the first type of vaccine developed to inoculate children against DTP and licensed by the National Health Institute in 1948. *Bruesewitz v. Wyeth Inc.*, 561 F.3d 233, 236 & n.3 (3d Cir. 2009).

13. *See id.* at 237.

14. *Id.* “Hannah’s physician later indicated, as part of this litigation, that she would not have immunized Hannah had she known of the adverse event reports associated with this lot of the vaccine.” *Id.*

15. *Id.* at 236.

16. *Bruesewitz v. Wyeth, Inc.*, 508 F. Supp. 2d 430, 437 (E.D. Pa. 2007); *see also infra* notes 92–98 and accompanying text.

17. Brief for Respondent at 24, *Bruesewitz v. Wyeth, Inc.*, 131 S. Ct. 1068 (2011) (No. 09-152), 2010 WL 2962899 (“The plain text of Section 22(b)(1) categorically preempts design-defect claims.”).

18. *See* Brief for Petitioners, *supra* note 10, at 25–26; *see also Bruesewitz*, 131 S. Ct. at 1078 (“Since a vaccine is not ‘quite incapable of being made safer for [its] intended use’ if manufacturing defects could have been eliminated or better warnings provided, the entire ‘even though’ clause is a useless appendage.” (alteration in original)).

Namely, it emphasized the latter phrase, in effect reading the “unavoidable” clause out of the statute.<sup>19</sup>

Nor does legislative history provide definitive resolution. The Bruesewitzes have support for their position that “Congress designed the Compensation Program to be an ‘appealing alternative’ to, but not a substitute for, the traditional tort system.”<sup>20</sup> They relied on a statement in a 1986 House Energy Committee Report: “Vaccine-injured persons will now have an appealing alternative to the tort system.”<sup>21</sup> The Bruesewitzes read this as Congress’s intention that the Compensation Program “be a carrot, not a stick.”<sup>22</sup> They pointed to further support in a 1987 House Budget Committee Report (which accompanied Congress’s funding legislation for the 1986 Vaccine Act) that includes the emphatic statement:

It is important to note that both at the time of original enactment and in passing this legislation, the Committee acted with the understanding that tort remedies were and are available. . . .

It is not the Committee’s intention to preclude court actions under applicable law. . . . An amendment to establish as part of this compensation system that a manufacturer’s failure to develop safer vaccine was not grounds for liability was rejected by the Committee during its original consideration of the Act.<sup>23</sup>

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19. See Brief for Respondent, *supra* note 17, at 30–31; see also *Bruesewitz*, 131 S. Ct. at 1094 (Sotomayor, J., dissenting) (“There would have been no need for Congress to include the additional 13 words ‘the injury or death resulted from side effects that were unavoidable even though.’”); *Bruesewitz*, 131 S. Ct. at 1094 (Sotomayor, J., dissenting) (“[T]he majority’s interpretation of §22(b)(1) functionally excises 13 words out of the statute, including the key term ‘unavoidable.’”).

20. Brief for Petitioners, *supra* note 10, at 12.

21. H.R. REP. NO. 99-908, pt. 1, at 26 (1986), reprinted in 1986 U.S.C.C.A.N. 6344, 6367; accord Brief for Petitioners, *supra* note 10, at 24.

22. Reply Brief for Petitioners at 17, *Bruesewitz*, 131 S. Ct. 1068, 2010 WL 3334502.

23. H.R. REP. NO. 100-391, pt. 1, at 691 (1987), reprinted in 1987 U.S.C.C.A.N. 2313-1, 2313-65; accord Brief for Petitioners, *supra* note 10, at 15–16. According to the U.S. Court of Appeals for the Third Circuit, “the views of a subsequent Congress form a hazardous basis for inferring the intent of an earlier one.” *Bruesewitz v. Wyeth Inc.*, 561 F.3d 233, 250 (3d Cir. 2009) (quoting *United States v. Price*, 361 U.S. 304, 313 (1960)). The court thus “refuse[d] to view the relevant legislative history as containing ‘dueling’ committee reports.” *Id.*

This issue divided the U.S. Supreme Court. The dissent reasoned that “[b]ecause the tort reforms in the 1986 Act . . . had no operative legal effect unless and until Congress provided funding for the compensation program, the views of the Congress that enacted that funding legislation are a proper and, indeed, authoritative guide to the meaning of § 22(b)(1).” *Bruesewitz*, 131 S. Ct. at 1092–93 (Sotomayor, J., dissenting). But the majority emphatically rejected this proposition: “Post-enactment legislative history (a contradiction in terms) is not a legitimate tool of statutory interpretation. . . . Permitting the legislative history of subsequent funding legislation to alter the meaning of a statute would set a dangerous precedent.” *Id.* at 1081–82 (majority opinion).



The Bruesewitzes attempted to bolster their case by arguing that the limitations of the “Vaccine Court,”<sup>24</sup> in particular the absence of a right to discovery,<sup>25</sup> demonstrate that Congress could not have intended to oust tort law. They claimed that “Congress preserved victims’ right to seek relief through the civil justice system precisely *because* the Vaccine Court process contains limits.”<sup>26</sup> One of their amici chimed in that Congress, “[k]nowing the importance of the tool of discovery to explaining how vaccine injuries occur,” would not have taken it away from injured children by preempting civil tort suits.<sup>27</sup>

But Wyeth provided equally strong support for the opposite view that Congress intended to preempt tort suits alleging design defects (while preserving those alleging manufacturing defects and failure to warn) by giving injured victims an outlet for compensation. Wyeth too quoted from the 1986 House Energy Committee Report, which states that if vaccine-injured persons cannot demonstrate “either that a vaccine was improperly prepared or that it was accompanied by im-

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24. The Vaccine Act created the National Vaccine Injury Compensation Program, an administrative no-fault scheme whereby claimants seeking damages for vaccine-related injuries must first file a petition in the administrative division of the U.S. Court of Federal Claims. 42 U.S.C. § 300aa-11(a) (2006). Special masters preside over these claims in “Vaccine Court” in proceedings that are “less-adversarial, expeditious, and informal” as compared to civil courts. *Id.* § 300aa-12(d)(2)(A).

25. Rule 7(a) of the Vaccine Rules of the United States Court of Federal Claims reads: “There is no discovery as a matter of right. The informal and cooperative exchange of information is the ordinary and preferred practice.” U.S. Court of Federal Claims App. B, Rule 7(A), at 123, *available at* [http://www.usfc.uscourts.gov/sites/default/files/court\\_info/Vaccinerules\\_20100111\\_v4.pdf](http://www.usfc.uscourts.gov/sites/default/files/court_info/Vaccinerules_20100111_v4.pdf) [hereinafter Vaccine Rules]. The 1986 House Energy Committee Report elaborates:

In order to expedite the proceedings, the power of the Special Master is intended to replace the usual rules of discovery in civil actions in Federal courts. Because the only issues relevant to the compensation proceeding are whether the petitioner suffered a compensable injury and, if so, the extent of compensable damages, there should be no need for a wider inquiry, which might be appropriate in a civil action raising other issues.

H.R. REP. NO. 99-908, pt.1, at 16.

26. Brief for Petitioners, *supra* note 10, at 57 (emphasis added). The Bruesewitzes complain that special masters “normally do not permit [discovery].” *Id.* But in the Bruesewitzes’ own case in Vaccine Court, the special master noted that she allowed the “extensive discovery that petitioners wanted.” *Bruesewitz v. Sec’y of the Dep’t of Health & Human Servs.*, No. 95-0266V, slip op. at 26 (Fed. Cl. Dec. 20, 2002) 2002 WL 31965744. The judge allowed almost everything the parties requested, including testimony from doctors and subpoenas to obtain hospital records. *See id.* at 2–3. The Vaccine Act grants special masters broad discretion, authorizing them to “require the testimony of any person and the production of any documents as may be reasonable and necessary.” 42 U.S.C. § 300aa-12(d)(3)(B)(iii). The definition of what is “reasonable and necessary” is subject to debate; not surprisingly, there appears to be variation in the vaccine cases with respect to the amount of discovery allowed. *See, e.g., DeLoatch v. Sec’y of Health & Hum. Servs.*, No. 09-171V, slip op. at 3 (Fed. Cl. July 28, 2010) (“[S]pecial masters have refrained from ordering discovery in a variety of contexts.”).

27. Brief of Vaccine Injured Petitioners Bar Association et al. as Amici Curiae in Support of Petitioners at 20, *Bruesewitz*, 131 S. Ct. 1068, 2010 WL 2208240.

proper directions or inadequate warnings [they] should pursue recompense in the compensation system, *not the tort system*.”<sup>28</sup> Wyeth further claimed that the very existence of the compensation program was evidence of Congress’s intent to funnel all design-defect claims to the Vaccine Court.<sup>29</sup>

The Solicitor General weighed in on Wyeth’s side, touting the “close fit” between the Vaccine Act’s “preemptive reach and its compensatory promise.”<sup>30</sup> In the government’s view, “Congress saw the Compensation Program as the critical counterpart to Section 22(b)(1)’s withdrawal of certain tort remedies.”<sup>31</sup> And, according to the Solicitor General (with no pretense here of ascribing the view to Congress), “[t]he Compensation Program is a ‘no fault’ scheme analogous to other ‘no fault’ schemes that supplant tort law.”<sup>32</sup>

Here, congressional intent is in the eye of the beholder, made all the more possible given Congress’s contradictory impulses, as reflected in ambiguous statutory text and internally inconsistent legislative history.

Notwithstanding the ambiguity of the statutory text and legislative history, the majority, led by Justice Scalia, engages in a textualist *tour de force*, replete with an exegesis of “concessive subordinate clauses,”<sup>33</sup> to find congressional clarity. But Justice Stephen Breyer’s concession—that “the textual question considered alone is a close one”<sup>34</sup>—is closer to the truth. Moreover, the majority opinion doth

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28. Brief for Respondent, *supra* note 17, at 47 (alteration in original) (emphasis added) (quoting H.R. REP. NO. 99-908, pt. 1, at 26).

29. *Id.* at 29 (“Petitioners’ argument [that design-defect claims survive] is . . . belied by the structure of the Vaccine Act, which establishes a comprehensive federal scheme . . .”).

30. Brief for the United States as Amicus Curiae Supporting Respondents at 28, *Bruesewitz*, 131 S. Ct. 1068, 2010 WL 3017753 [hereinafter U.S. Amicus Brief].

31. *Id.* at 25–26.

32. *Id.* at 34. The Solicitor General, moreover, pressed the inherent advantages of an administrative compensation program over tort law: it is faster; petitioners recover legal fees regardless of whether they prevail; exchanges are informal, cooperative, and flexible; and “[t]he Compensation Program never requires proof of who manufactured the vaccine, which can be a stumbling block in the tort system.” *Id.* at 26–27. With respect to attorneys’ fees, special masters have discretion to award them so long as “the petition was brought *in good faith* and there was a *reasonable basis* for the claim which the petition was brought.” 42 U.S.C. § 300aa-15(e)(1) (2006) (emphases added); see also Vaccine Rules, *supra* note 25, Rule 13, at 131 (“Attorneys’ Fees & Costs”).

33. See *Bruesewitz*, 131 S. Ct. at 1078 (arguing that § 22(b)(1)’s concessive subordinate clause—“even though”—creates opposition between the prerequisites of proper preparation and proper labeling and the word “unavoidable,” and that the petitioners’ assertion that proper preparation and proper labeling are two prerequisites independent of unavoidability would only be defensible if the statute used “a coordinating conjunction like ‘and,’ not a subordinating junction like ‘even though’”).

34. *Id.* at 1082 (Breyer, J., concurring).

protest too much. If textual clarity could actually be found, then there would be no need for most of the additional analytical points in the opinion.<sup>35</sup>

### III. POLICY MASQUERADING AS CONGRESSIONAL INTENT

Congressional intent is the touchstone of the U.S. Supreme Court's preemption jurisprudence. So long as it is within its Commerce Clause authority, Congress can act to displace state law, and, if it does so expressly (and clearly), the preemption inquiry is over. Several scholars, Professor Rabin among them, have argued that policy analysis has no place in this essentially constitutional decision.<sup>36</sup> Moreover, they argue that *Congress* (not courts and not federal agencies) must decide whether to preempt state law. Professor Rabin seems confident that Congress can—and should—clearly express its intent to preempt state tort law and then delineate the precise scope of such preemption.

As an institutional matter, I have much less faith in Congress. *Bruesewitz* is a case in point, demonstrating that even in the rare instance when Congress focuses on the issue of compensation along with preemption, the result is a far cry from clarity. Moreover, the formalist response, represented by fidelity to the “presumption against preemption” and invocation of “clear statement” rules—where Congress has been anything less than crystal clear, do not preempt<sup>37</sup>—does not strike me as normatively desirable, given the context-specific inquiry that is called for in resolving a preemption dispute. Because the devil is in the details of the statutory and regulatory scheme, we ought not decide these cases on general presumptions. Moreover, Congress, in the rare instance in which it is clear, is apt (as has historically been the case) to give an ideologically

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35. In that regard, the opinion is reminiscent of *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008), also authored by Justice Scalia, which declares that the pro-preemption outcome is dictated by plain statutory language, but then wanders far beyond mere statutory interpretation. See generally Catherine M. Sharkey, *What Riegel Portends for FDA Preemption of State Law Products Liability Claims*, 103 Nw. U. L. REV. 437 (2009).

36. According to Rabin, regulatory compliance is about the competency of courts vis-à-vis regulators, whereas preemption is only about whether Congress intended to displace state tort law. See Rabin, *Territorial Claims*, *supra* note 4, at 990. Given that the preemption doctrine is rooted in the Supremacy Clause of the Constitution, Rabin argues that courts should not engage in the explicit weighing of competing policy interests that is called for under regulatory compliance. See Robert L. Rabin, Keynote Paper, *Reassessing Regulatory Compliance*, 88 GEO. L.J. 2049, 2058 (2000) [hereinafter Rabin, *Reassessing Regulatory Compliance*].

37. The presumption against preemption holds “that the historic police powers of the States were not to be superseded by [federal law] unless that was the clear and manifest purpose of Congress.” *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947).

inflected thumbs-up or thumbs-down to tort lawsuits across the board.<sup>38</sup>

In practice, when courts have considered preemption questions, congressional intent has provided a hook for consideration of the basic policy issue whether tort serves a regulatory or compensatory purpose. In its preemption decisions, the Supreme Court has tended to consider either the regulatory role of tort law (when it decides to preempt) or the compensatory role of tort law (when it refuses to preempt).<sup>39</sup> *Bruesewitz* follows a long line of Supreme Court opinions that interject policy-laden reasoning under the guise of congressional intent. In *Riegel v. Medtronic, Inc.*, Justice Scalia, on behalf of the majority, opined that “the solicitude for those injured by FDA-approved devices . . . was overcome in Congress’s estimation by solicitude for those who would suffer without new medical devices if juries were allowed to apply the tort law of 50 States to all innovations.”<sup>40</sup> Taking the opposite tack in *Sprietsma v. Mercury Marine*, the majority implored, “It would have been perfectly rational for Congress not to pre-empt common-law claims, which—unlike most administrative and legislative regulations—necessarily perform an important remedial role in compensating accident victims.”<sup>41</sup>

In *Bruesewitz*, the Court is not faced with any Faustian dilemma. For here, at least according to the majority, both the regulatory and compensatory functions of common law design-defect claims are promoted by the Vaccine Act, which achieves both the effects of “(1) prompting the development of improved designs, and (2) providing compensation for inflicted injuries.”<sup>42</sup>

Justice Scalia makes a further bold claim that Congress intended a direct *quid pro quo*—in exchange for funding the compensation scheme and submitting to federal guidance, vaccine manufacturers were granted immunity from the unpredictable nature of tort liability.<sup>43</sup> Justice Scalia makes little effort to disguise his—as opposed to

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38. See Sharkey, *Federalism Accountability*, *supra* note 8, at 2149 (“Legislative pronouncements on preemption (or nonpreemption) are sledgehammers where sharp scalpels are more appropriate.”); *id.* at 2148 & n.89 (“When Congress does weigh in on the debate in a more resolute fashion, it is likely to decide preemption on an all-or-nothing basis.”).

39. For elaboration, see Sharkey, *Products Liability Preemption*, *supra* note 8, at 459–71.

40. *Riegel*, 552 U.S. at 326. *But see id.* at 331 (Stevens, J., concurring in part and concurring in the judgment) (rejecting Justice Scalia’s reasoning as “a policy argument advanced by the Court, not by Congress”); *id.* at 333 (Ginsburg, J., dissenting) (“Congress, in my view, did not intend . . . to effect a radical curtailment of state common-law suits seeking compensation for injuries caused by defectively designed or labeled medical devices.”).

41. *Sprietsma v. Mercury Marine*, 537 U.S. 51, 64 (2002).

42. *Bruesewitz v. Wyeth LLC*, 131 S. Ct. 1068, 1079 (2011).

43. *Id.* at 1080.

Congress's—basic distaste for tort law and juries. In a passage reminiscent of the one quoted above from *Riegel*, Justice Scalia claims that Congress expressed a preference, “a sensible choice to leave complex epidemiological judgments about vaccine design to the FDA and the National Vaccine Program rather than juries.”<sup>44</sup> He also describes design-defect claims as “the most speculative and difficult” kinds of products liability cases.<sup>45</sup> (Apart from the more fundamental issue regarding policy-inflected analysis sneaking in under the guise of congressional intent, tort scholars might well question whether design-defect claims deserve this opprobrium any more than, say, failure-to-warn claims.) Under the veil of congressional intent, Justice Scalia makes a policy-laden claim that preemption had to be part of any compromise to entice vaccine manufacturers back into the marketplace.

Where statutory language is ambiguous, courts do have an alternative to policy analysis disguised as congressional intent, which leads me onward to consider alternative frames of analysis.

#### IV. FRAME TWO: TORT BACKDROP AND COMPENSATION

A significant part of Professor Rabin's general unease with both the state regulatory compliance and federal preemption defenses rests on the ground that their effect would be to leave some victims uncompensated.<sup>46</sup> Professor Rabin is insistent that the Janus-faced nature of tort must be acknowledged and appreciated. Specifically, “[u]nless [a regulation] operates in tandem with a legislative compensation scheme, regulation promotes only deterrence. Tort, whatever its shortcomings, does double-duty: it is an engine of compensation as well as deterrence.”<sup>47</sup> The same point was made by Justice Harry Blackmun, in dissent, in *Cipollone v. Liggett Group*, a 1992 watershed federal preemption case: “[T]ort law has an entirely separate function—compensating victims—that sets it apart from direct forms of

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44. *Id.* The dissent rebukes the majority:

The majority's decision today disturbs that careful balance based on a bare policy preference . . . . To be sure, reasonable minds can disagree about the wisdom of having juries weigh the relative costs and benefits of a particular vaccine design. But whatever the merits of the majority's policy preference, the decision to bar all design defect claims against vaccine manufacturers is one that Congress must make, not this Court.

*Id.* at 1100 (Sotomayor, J., dissenting).

45. *Id.* at 1080 (majority opinion).

46. Robert L. Rabin, *Poking Holes in the Fabric of Tort: A Comment*, 56 DEPAUL L. REV. 293, 300–01 (2007).

47. *Id.* at 301.

regulation.”<sup>48</sup> As section A explores below, the Court’s commitment to upholding the compensatory role of tort law has been erratic.

Beyond the mere acknowledgement of the dual roles of tort, it is difficult to specify the precise relationship between compensation and preemption. As detailed below in section B, under my proposed Frame Two, the absence of a federal compensation scheme would take arguments for field preemption—defined as categorical preemption of some class of cases irrespective of the particular circumstances of the regulated risk—off the table. Compensation thus is inextricably linked to categorical preemption arguments; however, it is (as we shall see with Frame Three) not a dispositive factor for risk-based conflict preemption claims.

### A. *The U.S. Supreme Court’s Contradictory Impulses*

In case after case, the Supreme Court has seemed to show little hesitation about the aftershock of its pro-preemption determinations—namely, that injured victims would go uncompensated.<sup>49</sup> One must search the dissents of the Court’s forceful preemption cases for hints of the lurking issue. In *Cipollone*, Justice Blackmun, in dissent, heralded this brave new world: “The Court *in the past* has hesitated to find pre-emption where federal law provides no comparable remedy.”<sup>50</sup> One can follow this thread of indifference to leaving injured victims remediless up to the present preemption cases. Justice Ruth Bader Ginsburg, the lone dissenter in *Riegel*, lamented that Congress would not “without comment, remove all means of judicial recourse” for injured victims.<sup>51</sup>

But the Court has been anything but consistent on this point. Indeed, an alternative thread highlighting the significance of the absence of federally provided compensation weaves its way through the cases,

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48. *Cipollone v. Liggett Grp., Inc.*, 505 U.S. 504, 537 (1992) (Blackmun, J., concurring in part, concurring in judgment in part, and dissenting in part) (citing *Ferebee v. Chevron Chem. Co.*, 736 F.2d 1529, 1540 (D.C. Cir. 1984)).

49. See, e.g., *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008) (holding that the plaintiff’s state law design-defect case was expressly preempted under the Medical Device Amendments to the Federal FDCA); *Buckman Co. v. Plaintiffs’ Legal Comm.*, 531 U.S. 341 (2001) (holding that the plaintiff’s state law fraud-on-the-FDA claim was impliedly preempted under the FDCA); *Geier v. Am. Honda Motor Co., Inc.*, 529 U.S. 861 (2000) (holding that the plaintiff’s state law design-defect claim was impliedly preempted under the Motor Vehicle Safety Act of 1966 and its implementing regulations).

50. *Cipollone*, 505 U.S. at 541 (Blackmun, J., concurring in part, concurring in judgment in part, and dissenting in part) (emphasis added).

51. *Riegel*, 552 U.S. at 337 (Ginsburg, J., dissenting) (quoting *Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238, 251 (1984)).

leading up to the Court's recent emphatic statement, this time by a majority of the Court in *Wyeth v. Levine*:

Congress did not provide a federal remedy for consumers harmed by unsafe or ineffective drugs in the 1938 [Food, Drug, and Cosmetic Act] or in any subsequent amendment. Evidently, it determined that widely available state rights of action provided appropriate relief for injured consumers. It may also have recognized that state-law remedies further consumer protection by motivating manufacturers to produce safe and effective drugs and to give adequate warnings.<sup>52</sup>

The concern raised by Justice Ginsburg in *dissent* in *Riegel* is the same as that raised by the *majority* in *Levine*. In *Levine*, the absence of a federal compensation scheme grounds the majority's understanding of congressional intent and points against preemption; whereas in *Riegel*, it is inconsequential to the Court's determination of preemption. This demonstrates the endless malleability of the concept of congressional intent to fit a prevailing view of the acceptability of upending tort compensation altogether so long as regulatory goals are met.

#### B. *Linking Compensation to Categorical Preemption*

The Court's treatment of tort as compensation in its preemption decisions has been erratic to date. How should compensation be added into the analysis?

Professor Rabin argues that when Congress acts, it legislates against a background norm of preserving tort as a system of compensation.<sup>53</sup> Congress weighs the potential downside of second-guessing federal standards against the upside of compensation for individuals in considering whether to displace common law suits.<sup>54</sup> Rabin's framework, then, has much in common with the classic formalist presumption against preemption.<sup>55</sup> Rabin's framework would likewise operate as a default canon of statutory interpretation whereby the absence of a federally provided remedy tips the balance against a preemption determination.

I think this goes too far. Moreover, such a default canon would be a double-edged sword that could work just as forcefully in the direction

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52. *Wyeth v. Levine*, 555 U.S. 555, 574 (2009) (footnote omitted).

53. See Rabin, *Territorial Claims*, *supra* note 4, at 1001.

54. See *id.*

55. Kenneth Starr and Erwin Chemerinsky take up this classic position as amici curiae in *Bruesewitz*. See Brief of Amici Curiae Kenneth W. Starr and Erwin Chemerinsky in Support of Petitioners at 3, *Bruesewitz v. Wyeth, Inc.*, 131 S. Ct. 1068 (2011) (No. 09-152), 2010 WL 2224727 (arguing for the need to find Congress's "clear and manifest preemptive purpose").

of preemption. In other words, the provision of a compensation scheme—such as the Vaccine Compensation Fund—would fuel a presumption *in favor* of preemption. Indeed, there are strong signals that this was at work in Justice Scalia's *Bruesewitz* opinion.

But the absence of federally provided compensation should defeat a subclass of preemption arguments—those framed as field preemption or categorical preemption arguments. Field preemption arguments depend upon the comprehensiveness of the statutory and regulatory scheme. As an initial matter, the Supreme Court has exercised caution in the realm of implied field preemption: “[W]e will seldom infer, solely from the comprehensiveness of federal regulations, an intent to pre-empt in its entirety a field related to health and safety.”<sup>56</sup>

Aviation is the prototypical example of a realm conducive to implied field preemption arguments.<sup>57</sup> The Federal Aviation Administration (FAA) has implemented a detailed and far-ranging system of rules regulating all aspects of flight safety, from pilot certification and preflight duties to flight responsibilities and flight rules.<sup>58</sup> In *City of Burbank v. Lockheed Air Terminal*, the Supreme Court held that the “pervasive nature” of federal regulation of aircraft noise left no room for state regulation,<sup>59</sup> which was thereby displaced by the federal Noise Control Act.<sup>60</sup> In support of its implied field preemption deter-

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56. *Hillsborough Cnty., Fla. v. Automated Med. Labs., Inc.*, 471 U.S. 707, 718 (1985). In *Hillsborough*, the Court rejected the argument that the comprehensiveness of the FDA's blood-plasma regulations was sufficient to preempt state and local regulations touching the same issue. At the time the FDA issued its regulations, it made clear that they were “not intended to usurp the powers of State or local authorities to regulate plasmapheresis procedures in their localities.” *Id.* at 714 (quoting 38 Fed. Reg. 19,365 (July 20, 1973)). Despite the fact that the FDA had subsequently extended the scope of its regulations, absent clear preemptive intent from Congress (or the FDA), the implied field preemption plea could not overcome what the Court described as an “uphill battle.” *Id.*

57. In 1958, Congress enacted the Federal Aviation Act, which created the Federal Aviation Administration (FAA). Pub. L. No. 85-726, § 301(a), 72 Stat. 731 (codified as amended at 49 U.S.C. §§ 40101). The Act does not contain an express preemption clause and contains a savings clause for state law remedies. 49 U.S.C. § 40120(c).

There is also express preemption under the Airline Deregulation Act (ADA), which Congress enacted in 1978. The ADA contains an express preemption provision that prohibits the state from enacting “a law, regulation, or other provision . . . related to a price, route, or service of an air carrier that may provide air transportation.” Pub. L. No. 103-272, 108 Stat. 1143 (codified at 49 U.S.C. § 41713(b)(1)).

58. The Federal Aviation Act delegates to the FAA “the power to frame rules for the safe and efficient use of the nation's airspace.” *Air Line Pilots Ass'n Int'l v. Quesada*, 276 F.2d 892, 894 (2d Cir. 1960).

59. *City of Burbank v. Lockheed Air Terminal, Inc.*, 411 U.S. 624, 633 (1973).

60. To supplement the Federal Aviation Act, Congress enacted the Noise Control Act of 1972, which requires the FAA, after consultation with the Environmental Protection Agency (EPA), to promulgate regulations regarding aircraft noise that are necessary to protect the public health and welfare. Pub. L. No. 92-574, 86 Stat. 1234 (codified as amended at 42 U.S.C. § 4901).



mination, the Court highlighted the “intricate system of federal commands” governing aviation.<sup>61</sup> Courts are divided on how far beyond *Burbank*’s preemption of aircraft noise regulation to extend the berth of implied field preemption under the federal aviation statutes.<sup>62</sup> But it is telling that some have embraced the view that, given the breadth and depth of the federal regulatory scheme, there is no room for state law to operate. By contrast, courts have universally rejected implied field preemption arguments in other highly regulated fields, such as drug and medical device regulation.<sup>63</sup> To my mind, the rigor of the federal regulatory review is certainly relevant to the preemption debate, but it does not, standing alone, justify categorical displacement of state tort law.

In deciding whether or not the federal regulations crowd out state law, it is worth considering both the compensatory and regulatory roles of tort law. Current doctrine offers some support by analogy. First, the existence and reach of federal remedial provisions are relevant to the determination whether a federal statute displaces *federal* common law. In *County of Oneida, New York v. Oneida Indian Nation of New York State*, the U.S. Supreme Court contrasted the Nonintercourse Act, which “did not establish a comprehensive remedial plan for dealing with violations of Indian property rights,” with the Federal Water Pollution Control Act, which had specific remedial provisions.<sup>64</sup> The Court held that the former did not displace federal

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61. *City of Burbank*, 411 U.S. at 633. The Court elaborated:

Federal control is intensive and exclusive. Planes do not wander about in the sky like vagrant clouds. They move only by federal permission, subject to federal inspection, in the hands of federally certified personnel and under an intricate system of federal commands. The moment a ship taxis onto a runway it is caught up in an elaborate and detailed system of controls.

*Id.* (quoting *Nw. Airlines, Inc. v. Minnesota*, 322 U.S. 292, 303 (1944) (Jackson, J., concurring)).

62. Compare *Cleveland v. Piper Aircraft Corp.*, 985 F.2d 1438, 1447 (10th Cir. 1993) (holding that Congress did not intend to occupy the field of airplane safety and that there was no conflict between the plaintiff’s products liability claim and FAA regulations), with *Abdullah v. Am. Airlines, Inc.*, 181 F.3d 363, 369 (3d Cir. 1999) (finding implied field preemption given that the FAA Administrator had “implemented a comprehensive system of rules and regulations, which promotes flight safety by regulating pilot certification, pilot pre-flight duties, pilot flight responsibilities, and flight rules” (footnotes omitted)), and *French v. Pan Am Express, Inc.*, 869 F.2d 1, 4 (1st Cir. 1989) (describing the federal aviation regulatory scheme as an “intricate web of statutory provisions [that] affords no room for the imposition of state-law criteria vis-a-vis pilot suitability”).

63. See generally Richard A. Epstein, *The Case for Field Preemption of State Laws in Drug Cases*, 103 Nw. U. L. REV. 463 (2009) (making an academic’s last stand argument for implied field preemption in drug cases).

64. *Cnty. of Oneida, N.Y. v. Oneida Indian Nation of N.Y. State*, 470 U.S. 226, 237 (1985).

common law, whereas the latter did.<sup>65</sup> And in *American Electric Power Co. v. Connecticut*, the Court, citing *County of Oneida* for the proposition that the “reach of remedial provisions is important to determination whether statute displaces federal common law,” held that the Clean Air Act and the Environmental Protection Agency actions it authorizes displace federal common law nuisance actions seeking abatement of carbon dioxide emissions that contribute to global warming.<sup>66</sup>

Second, when *state* common law is threatened, the Supreme Court has alluded to the backdrop of tort litigation to buttress the presumption against preemption. Justice John Paul Stevens was most explicit in *Bates v. Dow Agrosiences LLC*: “The long history of tort litigation against manufacturers of poisonous substances adds force to the presumption against pre-emption, for Congress surely would have expressed its intention more clearly if it had meant to deprive injured parties of a long available form of compensation.”<sup>67</sup>

I would consider the relevance of remedial and enforcement options for assessing the *comprehensiveness* of a regulatory scheme that is required in order to categorically preempt state tort law. Against a backdrop in which tort law effectuated both regulatory and compensatory goals, the removal of state tort law without providing some kind of substitute compensatory mechanism renders the scheme incomplete.

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65. *Id.* at 239 (citing *City of Milwaukee v. Illinois (Milwaukee II)*, 451 U.S. 304, 313–15 (1981)).

66. *Am. Elec. Power Co. v. Connecticut*, 131 S. Ct. 2527, 2538 (2011). The Court elaborated:

The Act provides multiple avenues for enforcement. EPA may delegate implementation and enforcement authority to the States, but the agency retains the power to inspect and monitor regulated sources, to impose administrative penalties for noncompliance, and to commence civil actions against polluters in federal court. . . . And the Act provides for private enforcement. If States (or EPA) fail to enforce emissions limits against regulated sources, the Act permits ‘any person’ to bring a civil enforcement action in federal court.

*Id.* (citations omitted).

67. *Bates v. Dow Agrosiences LLC*, 544 U.S. 431, 432–33 (2005). The petitioners in *Bates* urged that “[f]or six decades prior to [enactment of the federal regulatory scheme], farmers routinely brought state-law actions against manufacturers for damages to their crops caused by pesticides.” Brief for Petitioners at 16, *Bates*, 544 U.S. 431, 2004 WL 2075750. They cited cases dating back to the beginning of the twentieth century. *Id.* at 4 n.3.

Several other courts have relied on *Bates* for the same proposition. See, e.g., *Riegel v. Medtronic, Inc.*, 451 F.3d 104, 128 (2d Cir. 2006) (“[W]here the states have a long tradition of providing a tort remedy to protect their citizens, the presumption against preemption is particularly strong.”), *aff’d*, 552 U.S. 312 (2008); *Levine v. Wyeth*, 944 A.2d 179, 184 (Vt. 2006) (stating that the presumption against preemption “has ‘add[ed] force’ when there has been a ‘long history of tort litigation’ in the area of state common law at issue” (alteration in original)), *aff’d*, 555 U.S. 555 (2009).

Congress enacted the Vaccine Act in 1986 against a distinct backdrop of tort lawsuits. Indeed, Congress was motivated to act in large part by the escalating lawsuits filed against vaccine manufacturers.

The number of product-liability cases filed against manufacturers increased substantially in the early 1980s. Manufacturers of DTP were sued once each year in 1978 and 1979, four times in 1980, and three times in 1981. In 1982 there were 17 lawsuits against DTP manufacturers; that number rose to 219 in 1985 and 255 in 1986.<sup>68</sup>

Tort law was doing double-duty, regulating vaccine safety while simultaneously providing compensation to injured victims.<sup>69</sup>

Against this backdrop of tort lawsuits—or, more accurately, in response to it—Congress not only created a new regulatory framework for vaccines but also set up the federal Vaccine Fund. Given the existence of a federal compensation scheme, field (or categorical) preemption claims are not taken off the table. But nor should that be the end of the story; here is where Frame Three comes into play.

#### V. FRAME THREE: AGENCY REFERENCE MODEL

In numerous contexts, I have proposed an “agency reference model,”<sup>70</sup> which compares the risk–benefit (or risk–risk) assessment by the federal agency with that required by the jury under the relevant state law tort standard. It depends on the existence of “a specialized agency with domain-specific authority over the risk-creating conduct at the core of the tort claim.”<sup>71</sup> The *Bruesewitz* result—if not the Supreme Court’s textualist reasoning—comports with the agency reference model. First, the stringent pre- and post-approval regulatory review of vaccines by several federal agencies seems to have influenced the Justices’ opinions in the case. Second, a searching probe of the regulatory record of the DTP vaccine at issue (which the Justices

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68. RICHARD ARNOULD & LARRY DEBROCK, *The Application of Economic Theory to the Market*, in SUPPLYING VACCINES: AN ECONOMIC ANALYSIS OF CRITICAL ISSUES 101, 118 (Mark V. Pauly et al. eds., 1996) (citation omitted). After passage of the Vaccine Act, tort lawsuits dropped significantly in number. “[T]he number of cases declined from 255 cases in 1986 to 144 in 1988, 47 in 1989, 19 in 1990, and 18 in 1991.” *Id.*

69. The *Bruesewitz* district court took note of the *Bates* Court’s reliance upon the history of tort litigation, but held that such history is not, by itself, enough: “*Bates* merely underscores the need to pay close attention to the scope of the [federal statute’s] preemption clause and assists the court in framing the questions to be addressed.” *Bruesewitz v. Wyeth, Inc.*, 508 F. Supp. 2d 430, 444 (E.D. Pa. 2007) (quoting *Mills v. Giant of Md., LLC*, 441 F. Supp. 2d 104, 107 (D.D.C. 2006)), *aff’d*, 561 F.3d 233 (3d Cir. 2009), *aff’d*, 131 S. Ct. 1068 (2011).

70. See Sharkey, *Federalism Accountability*, *supra* note 8, at 2153; Sharkey, *Products Liability Preemption*, *supra* note 8, at 477–502.

71. Rabin, *Reassessing Regulatory Compliance*, *supra* note 36, at 2052.

did not undertake but which is called for under the agency reference model) supports a finding of preemption.

A. *An Alternative Reading of Bruesewitz*

Recasting *Bruesewitz* in terms of the agency reference model, we begin by examining the structure of the underlying regulatory review process. More so than for any product or drug, the government is heavily involved in the development of vaccines and in the testing of their safety and efficacy.<sup>72</sup> Several federal agencies are involved in the process that leads to the government's recommendations for routine vaccine administration to children. The FDA must approve the vaccine for "safety and effectiveness" and grant a license to a specific manufacturer.<sup>73</sup> The Department of Health and Human Services (HHS) and CDC, however, have primary responsibility for the administration of vaccines that are included in the Vaccine Injury Table (Table). Congress has delegated authority to the Secretary of HHS to manage the Table based on CDC's recommendations and reports of side effects.<sup>74</sup> The Secretary's determinations are, moreover, subject to several layers of congressionally directed oversight. The Secretary cannot act without first consulting with the Advisory Commission on Childhood Vaccines (ACCV), a body established by Congress to advise the Secretary on implementation of the National Vaccine Injury Compensation Program, including recommending changes to the Table.<sup>75</sup> The ACCV is a diverse body, composed of nine members appointed by the Secretary—including three health professionals, three members from the general public (at least two of whom are legal representatives of children who have suffered vaccine-related injury or death), and three attorneys (including one who represents plaintiffs and one who represents manufacturers in vaccine-injury litigation)—plus (as nonvoting ex officio members) the Director of the National Institutes of Health, the Assistant Secretary for Health, the Director of CDC, and the Commissioner of the FDA.<sup>76</sup>

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72. See Transcript of Oral Argument at 45–46, *Bruesewitz*, 131 S. Ct. 1068 ("The government sets the agenda for what are our targets for development.")

73. See 42 U.S.C. § 262 (2006); see also 21 C.F.R. § 601.2(d) (2011); 21 C.F.R. § 601.12(a)(2).

74. See 42 U.S.C. § 300aa-14(e)(2) ("When . . . [CDC] recommends a vaccine to the Secretary [of HHS] for routine administration to children, the Secretary shall, within 2 years of such recommendation, amend the Vaccine Injury Table . . .").

75. See *id.* § 300aa-14(d) ("[T]he Secretary [of HHS] may not propose a regulation . . . unless the Secretary has first provided to the Commission a copy of the proposed regulation or revision, requested recommendations and comments by the Commission, and afforded the Commission at least 90 days to make such recommendations.")

76. *Id.* § 300aa-19(a).

As the Solicitor General represented before the Court, “the categories of vaccines on the Table reflect the concurrent judgments of expert scientists at CDC and of Congress.”<sup>77</sup> Before any vaccine is included on the Table, scientists at CDC—and the government emphasizes it is scientists, not lawyers—must make a “reasoned judgment” that the vaccine should be “recommended for routine administration” to children.<sup>78</sup> CDC works closely with pharmaceutical manufacturers as well as the medical and scientific community in a collaborative process leading up to its recommendations.<sup>79</sup> In its consideration of the risks and benefits of vaccines, CDC analyzes not only FDA-approved vaccines and proposed vaccines, but also the background scientific literature as a whole.<sup>80</sup> CDC’s conclusions are published in its official journal, *Morbidity and Mortality Weekly Report*.<sup>81</sup>

While the Secretary’s decision-making process for Table revisions has been criticized for lack of transparency,<sup>82</sup> according to the government, “the Secretary’s management of the Table has been challenged only rarely, and never successfully.”<sup>83</sup>

Government involvement and oversight, moreover, extends beyond initial approval and Table listing to the equally (if not more) significant realm of post-approval monitoring. HHS administers the Vaccine Adverse Event Reporting System (VAERS), used by manufacturers and health care providers to report and monitor adverse events caused by a vaccine on the Table.<sup>84</sup> CDC administers the Vaccine Safety Datalink (VSD), which allows CDC to coordinate with manufacturers to investigate the side effects of recommended vaccines and to keep a watchful ongoing eye on the safety of vaccines.<sup>85</sup>

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77. See U.S. Amicus Brief, *supra* note 30, at 28.

78. *Id.* at 3; Transcript of Oral Argument, *supra* note 72, at 46.

79. See Transcript of Oral Argument, *supra* note 72, at 45 (“[T]he vaccines that are on the original table in this statute were taken from CDC’s recommendations that reflect CDC’s expert scientific judgment, based on the input from the medical and scientific community, of what vaccines do we have that are the ones we should use to protect the public health?”).

80. See *id.* at 50–52.

81. *Id.* at 49.

82. See, e.g., Brief of Amicus Curiae Marguerite Willner in Support of Petitioners at 24, *Bruesewitz*, 131 S. Ct. 1068, 2010 WL 2224729 (criticizing the fact that “seizures have been removed from the Table, although that the pertussis vaccine can cause seizures is uncontested (and warned in the manufacturer’s package insert)”; *id.* at 24 n.14 (“Hannah Bruesewitz’s injuries likely would have been considered on-Table but for the 1995 administrative revisions [which removed seizures].”).

83. U.S. Amicus Brief, *supra* note 30, at 29.

84. *Id.* at 21.

85. See *id.* at 22. The government provided as an illustrative example its experience with Rotashield, a vaccine that protects children from rotavirus. *Id.* at 23. In March 1999, CDC recommended routine administration of Rotashield. *Id.* At that time, clinical trials showed no statistically significant adverse effects. *Id.* at 23–24. Subsequently, however, data reported to

Consistent with the thrust of the agency reference model—and contrary to formalist, textualist models of statutory interpretation that are especially prevalent in the express preemption realm—the rigorous system of approval and post-approval monitoring of vaccines influenced both the *Bruesewitz* majority opinion and Justice Breyer’s separate concurrence. Writing for the majority, Justice Scalia points to the postapproval monitoring by federal agencies (as well as the existence of the compensation scheme) as suggesting that Congress’s statutory silence regarding design defects should be read as evincing its intent that, unlike manufacturing-defect or failure-to-warn claims, design-defect claims should not be a basis for tort liability: “These provisions for federal agency improvement of vaccine design, and for federally prescribed compensation, once again suggest that § 300aa-22(b)(1)’s silence regarding design-defect liability was not inadvertent.”<sup>86</sup>

Justice Breyer—consistent with his track record as the staunchest purveyor of something akin to the agency reference model<sup>87</sup>—places more emphatic weight on the views of HHS. For Justice Breyer, in the face of ambiguous statutory language and murky evidence of congressional intent, the “rigorous administrative safety review” of vaccines and HHS’s thorough understanding of vaccine production and safety sufficed to read the Vaccine Act as preempting state tort design-defect claims.<sup>88</sup>

Even the dissent frames its disagreement within the paradigm of the agency reference model. Justice Sonia Sotomayor, writing for the dissent, chides the majority for “leav[ing] a regulatory vacuum in which no one ensures that vaccine manufacturers adequately take account of scientific and technological advancements when designing or distributing their products.”<sup>89</sup> Specifically, “neither the Act nor any other provision of federal law places a legal *duty* on vaccine manufacturers to

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VAERS showed some adverse events linked to the administration of Rotashield. *Id.* As a result, CDC conducted a subsequent investigation of the vaccine’s safety through VSD. *Id.* CDC’s investigation discovered an increased risk of bowel obstruction in infants and led to the suspension of Rotashield’s administration and to the ultimate withdrawal of Rotashield from the market. *Id.* at 24.

86. *Bruesewitz*, 131 S. Ct. at 1080.

87. See, e.g., *Williamson v. Mazda Motor of Am., Inc.*, 131 S. Ct. 1131, 1135 (2011); *Wyeth v. Levine*, 555 U.S. 555, 582 (2009) (Breyer, J., concurring); *Geier v. Am. Honda Motor Co.*, 529 U.S. 861, 868 (2000); see also Catherine M. Sharkey, *The Politics of Preemption: NHTSA, State Tort Law & Automobile Safety*, TORTSPROF BLOG (Oct. 4, 2010), <http://lawprofessors.typepad.com/tortsp/2010/10/guest-blogger-cathy-sharkey-on-the-politics-of-preemption-nhtsa-state-tort-law-automobile-safety.html> (noting Justice Breyer’s propensity to defer to agency determinations of whether state tort law impedes federal purpose).

88. *Bruesewitz*, 131 S. Ct. at 1085 (Breyer, J., concurring).

89. *Id.* at 1086 (Sotomayor, J., dissenting).

improve the design of their vaccines to account for scientific and technological advances.”<sup>90</sup>

### B. Probing the Regulatory Record

The disagreement between the majority and dissent highlights the fact-intensive nature of the inquiry called forth by the agency reference model. The most demanding formulation of the relevant standard asks: Did the relevant federal agency weigh the precise risk–benefit (or risk–risk) tradeoffs that constitute the state law design-defect standard? The *Bruesewitz* majority, and especially Justice Breyer’s concurrence, answers with a resounding yes, whereas the dissent is skeptical. Alas, the agency regulatory record is a bit murky, at least in part because, notwithstanding its apparent influence on Supreme Court decision making, cases are not (yet) consistently litigated with the agency reference model in mind.<sup>91</sup>

Here is what can be gleaned from the existing regulatory record. There was a push in the 1950s and 1960s to develop alternative DTP vaccines in light of evidence of serious side effects (including seizures) from the injection of whole cell vaccines. An alternative “fractionated” vaccine, Tri-Solgen, was available in the U.S. market and was

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90. *Id.* at 1097.

91. This is beginning to change. *Dobbs v. Wyeth Pharmaceuticals*, 530 F. Supp. 2d 1275 (W.D. Okla. 2008), provides an instructive example. In that case, the district court granted a summary judgment motion on preemption:

The record establishes that the express type of warning which Plaintiff claims Defendant should have included in its Effexor label had been considered and rejected by the FDA as not supported by credible evidence at the time Mr. Dobbs used Effexor. Where the FDA has evaluated scientific evidence regarding an alleged risk associated with a drug, has considered whether that evidence warrants a labeling warning, and has expressly rejected the need for such warning as not supported by credible evidence, a state law determination that such a warning is required creates a conflict for the manufacturer as between federal and state law, and imposes inconsistent federal and state obligations.

*Id.* at 1289–90 (footnote omitted). After *Levine* announced a “clear evidence” rule for the standard of proof necessary to support a claim of conflict preemption based on FDA labeling regulations, 555 U.S. 555, 571 (2009), the U.S. Court of Appeals for the Tenth Circuit vacated and remanded the district court’s order, 606 F.3d 1269 (10th Cir. 2010). The district court then granted a renewed motion for summary judgment on preemption, distinguishing the regulatory record in the case from that in *Levine*:

[T]he record reflects the FDA’s ongoing study and analyses regarding the propriety of enhancing SSRI warnings to include the association between SSRIs and suicidality. That history is in contrast to the facts in *Levine*, in which the Court noted that the trial court found the record reflected that, during the time period relevant to the claims asserted, neither the manufacturer or the FDA “gave more than passing attention” to the issue of the proper method for intravenous administration of Phenargen.

*Dobbs v. Wyeth Pharms.*, No. CIV 04 1762, 2011 WL 2746321, at \*10 (W.D. Okla. June 13, 2011) (quoting *Levine*, 555 U.S. at 572), *appeal docketed*, No. 12-6077 (10th Cir. filed Mar. 22, 2012).

heavily used throughout the early 1970s.<sup>92</sup> In 1975, Eli Lilly sold the license for Tri-Solgen to Wyeth.<sup>93</sup> Because Eli Lilly's FDA certification was not transferrable to Wyeth, Wyeth had to reapply for FDA certification.<sup>94</sup> Wyeth submitted a modified version of Tri-Solgen to the FDA, which the FDA rejected, "citing the need for further design improvements, concerns about two adverse reactions in trials of the modified Lilly design, and the lack of conclusive evidence that the modified Lilly design was more effective than Wyeth's whole cell DTP [vaccine]."<sup>95</sup> Wyeth made no attempt to resubmit an application for its modified version of Tri-Solgen or its original Eli Lilly formulation.<sup>96</sup> As a result, Tri-Solgen was discontinued altogether in 1977,<sup>97</sup> though Eli Lilly remained licensed by the FDA to sell Tri-Solgen until the manufacturer requested that the FDA revoke the license in 1985.<sup>98</sup>

Starting in the mid-1980s, the FDA and CDC began studying whether whole cell vaccines should be phased out in favor of "fractionated" vaccines (such as Tri-Solgen) or newer "acellular" vaccines (such as Acel-Imune).<sup>99</sup> In a 1985 proposed rule, the FDA recommended additional field testing of any fractionated pertussis vaccines and stated that "[r]esearch to develop a new generation of acellular pertussis vaccines is in a dynamic state; thus it is difficult to predict

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92. See *Toner v. Lederle Labs.*, 779 F.2d 1429, 1431 (9th Cir. 1986) ("During the 1950's, the Eli Lilly Company developed a fractionated cell pertussis vaccine called Tri-Solgen that was prepared by treating whole killed pertussis cells with salt. Early studies indicated that this method of preparation resulted in a less toxic vaccine, and following its approval by the FDA in 1967, Tri-Solgen occupied a substantial share of the market.").

93. *Ackley v. Wyeth Labs., Inc.*, 919 F.2d 397, 398 (6th Cir. 1990).

94. *Id.*

95. *Id.* at 398–99; see also *Toner*, 779 F.2d at 1431 ("[A] review panel within the Bureau of Biologics of the FDA refused to certify Tri-Solgen as 'safe and effective' although it did so certify the whole cell vaccines."). *Toner* was a pre-Vaccine Act products liability case in which the plaintiffs asserted basically the same design-defect claim as the Bruesewitzes—namely, that Wyeth should have manufactured Tri-Solgen, not Tri-Immunol. See *id.* The district court rejected the plaintiffs' claim, holding that Tri-Solgen was not an alternate design, given that its FDA license had been revoked. See *id.*

96. See *White v. Wyeth Labs., Inc.*, 533 N.E.2d 748, 756 (Ohio 1988) (Douglas, J., concurring in part and dissenting in part) ("The FDA suggested changes Wyeth would have to make in this vaccine in order for the FDA to approve it. However, Wyeth made no further attempts to license the vaccine.").

97. See *Selected Discontinued U.S. Vaccines*, CDC, [http://www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/b/discontinued\\_vaccines.pdf](http://www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/b/discontinued_vaccines.pdf) (last visited Nov. 2011).

98. *Ackley*, 919 F.2d at 402; accord *Biological Products; Bacterial Vaccines and Toxoids; Implementation of Efficacy Review*, 69 Fed. Reg. 255, 257 (Jan. 5, 2004) (codified at 21 C.F.R. pts. 201, 610) ("On December 2, 1985, FDA revoked the [Eli Lilly] license for Diphtheria and Tetanus Toxoids and Pertussis Vaccine Adsorbed at the request of the manufacturer.").

99. See *Biological Products; Bacterial Vaccines and Toxoids; Implementation of Efficacy Review*, 50 Fed. Reg. 51002, 51112 (Dec. 13, 1985) (codified at 21 C.F.R. pt. 610) (discussing beginning development, clinical testing, and evaluation of new "acellular pertussis vaccines").



what tests would be necessary to demonstrate the effectiveness of a newly developed acellular pertussis vaccine.”<sup>100</sup> Acel-Imune was recommended for routine administration as the fourth and fifth DTP booster shots in 1992;<sup>101</sup> the recommendation was in force when Hannah Bruesewitz was vaccinated. In 1994, the U.S. Institute of Science concluded that Tri-Immunol could cause brain damage, and HHS published this finding in the Federal Register.<sup>102</sup> The FDA approved Acel-Imune for all five DTP vaccination doses in 1996.<sup>103</sup> In 1997, CDC recommended Acel-Imune for all DTP vaccinations.<sup>104</sup> In 1998, Wyeth voluntarily removed Tri-Immunol from the market.<sup>105</sup>

Significantly, during the *Bruesewitz* oral argument, the Solicitor General represented to the Court that the

Federal Government made a choice and said we . . . don’t want manufacturers and our scientists pursuing the . . . Tri-Solgen approach and trying to improve that. We don’t understand that vaccine very well. We know the ultimate target needs to be the development of an acellular vaccine, and so that’s the research path . . . to go on.<sup>106</sup>

Neither the briefs nor oral argument in *Bruesewitz*, however, focus on the relevant evidence from the agency record. Nor do the parties elaborate upon the FDA revocation of the license for Tri-Solgen.<sup>107</sup> Nor do any of CDC’s reports mention Tri-Solgen or the use of fractionated or acellular vaccines in the 1960s and 1970s.<sup>108</sup> Whereas the 1985 FDA rule discusses the need for further testing of fractionated vaccines (such as Tri-Solgen) to prove their efficacy and references the “dynamic” state of research on acellular varieties, it does not go so far

100. *Id.*

101. See Notice to Readers, *Recommended Childhood Immunization Schedule—United States, 1997*, 46 MORBIDITY & MORTALITY WKLY. REP., Jan. 17, 1997, at 35, 38, available at <ftp://ftp.cdc.gov/pub/Publications/mmwr/wk/mm4602.pdf>.

102. National Vaccine Injury Compensation Program: Revision to Vaccine Injury Table, 59 Fed. Reg. 13,916, 13,918 (Mar. 24, 1994) (codified at 42 C.F.R. pt. 100).

103. Notice to Readers, *FDA Approval of a Second Acellular Pertussis Vaccine for Use Among Infants and Young Children*, 46 MORBIDITY & MORTALITY WKLY. REP., Feb. 7, 1997, at 110, 110 (1997), available at <ftp://ftp.cdc.gov/pub/Publications/mmwr/wk/mm4605.pdf>; see also *Bruesewitz v. Wyeth Inc.*, 561 F.3d 233, 236–37 (3d Cir. 2009).

104. See Notice to Readers, *supra* note 101, at 38.

105. *Bruesewitz*, 561 F.3d at 237.

106. Transcript of Oral Argument, *supra* note 72, at 46.

107. See *supra* notes 95–98 for an explanation of how Tri-Solgen’s license was revoked.

108. My research assistant, Matthew Shahabian, conducted searches of the Federal Register and a Google search of the public .gov top-level domain (Google search for site: \*.gov) for “Tri-Solgen” or “Solgen.” Searches for “acellular” or “fractionated” DTP vaccines did not return any information from CDC prior to its 1990s investigation and recommendations. This regulatory record may be more complete in a nondigitized form, but that record is not available online nor discussed in the briefing for the *Bruesewitz* case.

as to establish a clear choice of acellular vaccines (such as Acel-Imune).<sup>109</sup>

Nonetheless, assuming that the regulatory record—if it were fully presented to the Court as would be necessary under the agency reference model—backs the Solicitor General’s statement that the relevant federal agencies specifically rejected Tri-Solgen, this would clearly conflict with a state law design-defect claim premised on Tri-Solgen as the viable alternative that would have “avoided” the side effects of the Tri-Immunol vaccine administered to Hannah Bruesewitz. According to the agency reference model (pursuant in fact to its most demanding standard; namely, that the relevant agency specifically reject the alternative design at the heart of the plaintiff’s state tort law claim), preemption should follow.

## VI. CONCLUSION: PUTTING THE FRAMES TOGETHER

*Bruesewitz* lays bare the flaws in the U.S. Supreme Court’s preemption jurisprudence. Though ostensibly an express preemption case that turned on the plain meaning of statutory language, the Court moved beyond statutory text and legislative history (what I have termed “Frame One”) into the realm of policy-based arguments masquerading as evidence of congressional intent. I have offered two further analytic frames to replace the Court’s exhortations of congressional intent as the touchstone of preemption analysis. Frame Two considers the relevance of the existence of remedial provisions within the federal regulatory scheme, alongside the pre-existing tort law litigation backdrop. Rather than assigning dispositive weight to this factor, or allowing it to tip the balance of the scale one way or another via a default presumption against (or in favor of) preemption, I propose that compensation be linked to categorical preemption claims. Specifically, remedial provisions should be a necessary component of a federal regulatory scheme deemed so comprehensive as to leave no room for state tort law. The absence of a federal compensa-

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109. In fact, although the FDA Panel expressed concern over the extent of rigorous efficacy testing on Tri-Solgen, it recommended (by a split vote of three to two) that Tri-Solgen be placed in “Category I for primary immunization,” finding that it was “safe, effective, and not misbranded.” Biological Products; Bacterial Vaccines and Toxoids; Implementation of Efficacy Review, 50 Fed. Reg. 51,002, 51,002, 51,052 (Dec. 13, 1985) (codified at 21 C.F.R. pt. 610). This recommendation, interestingly, was the result of an administrative mistake, as the Panel was not aware that the FDA had revoked Eli Lilly’s license just two weeks earlier at the manufacturer’s request. Biological Products; Bacterial Vaccines and Toxoids; Implementation of Efficacy Review, 69 Fed. Reg. 255, 257 (Jan. 5, 2004) (codified at 21 C.F.R. pts. 201, 610) (“On December 2, 1985, FDA revoked the license for Diphtheria and Tetanus Toxoids and Pertussis Vaccine Adsorbed at the request of the manufacturer. FDA inadvertently omitted this information in the December 1985 proposal.”).

tion scheme would take arguments for categorical preemption off the table. But the mere presence of such a scheme should not end the inquiry—at least where congressional ambiguity persists. Frame Three superimposes the agency reference model, which zeroes in on narrower conflict preemption questions, interrogating whether the regulating federal agency addressed the same risk that is the basis for the state law tort claim.

Putting the frames together, *Bruesewitz* would likely reach the same outcome, albeit on far narrower grounds. The majority decision reads much like a field preemption case and upholds categorical preemption of all design-defect claims, regardless of the regulatory record of the underlying agencies. In reaching its decision, the majority highlights the comprehensiveness of the statutory scheme.<sup>110</sup> Under my Frame Two, the existence of the federal administrative compensation scheme is relevant to the determination of comprehensiveness, such that categorical preemption claims are not foreclosed. However, Frame Three provides a more solid foundation for a preemption determination, especially in the realm of health and safety. In *Bruesewitz*, preemption would be limited to the class of vaccines whose safety profile was investigated by the FDA, HHS, and CDC via a regulatory record that would be scrutinized by the courts. More generally, the agency reference model takes an implicit stand against categorical preemption claims.

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110. *Bruesewitz*, 131 S. Ct. at 1079 (stating that the Act “micromanages” manufacturers and that the Act and vaccine regulations in general “pervasively regulate the manufacturing process”).